

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

**Edesa Biotech, Inc.**

CIK: **1540159** | IRS No.: **000000000** | State of Incorporation: **A1** | Fiscal Year End: **0930**  
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SIC: **2834** Pharmaceutical preparations

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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): August 30, 2019

Edesa Biotech, Inc.  
(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada  
(State or Other Jurisdiction of Incorporation)

001-37619  
(Commission File Number)

N/A  
(IRS Employer Identification No.)

100 Spy Court  
Markham, Ontario, Canada L3R 5H6  
(Address of Principal Executive Offices)

(905) 475-1234  
Registrant's telephone number, including area code

N/A  
(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 (see General Instruction A.2. below):

- 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))

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.

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Shares	EDSA	The Nasdaq Capital Market

## Explanatory Note

On June 10, 2019, Edesa Biotech, Inc., formerly known as “Stellar Biotechnologies, Inc.” (the “Company”), filed a Current Report on Form 8-K with the Securities and Exchange Commission reporting, among other items, that on June 7, 2019, the Company completed its business combination with Edesa Biotech Research, Inc., formerly known as Edesa Biotech Inc. (“Edesa”).

This Current Report on Form 8-K is being filed with the Securities and Exchange Commission to report certain contracts entered into by Edesa prior to its business combination with the Company.

### Item 8.01 Other Items

#### *Lease Agreement*

On January 1, 2017, Edesa entered into a lease agreement with 1968160 Ontario Inc. (the “Lease Agreement”) pursuant to which Edesa leased approximately 2,800 square feet of office space located at 100 Spy Court, Markham, Ontario Canada (the “Premises”). 1968160 Ontario Inc. at the time of entry into the agreement was an affiliate of Edesa. The Premises now serves as the corporate headquarters of the Company. The rent per month is \$8,320 (Cdn), with the rent payment increasing by \$1 per square foot every two years. Subject to certain exceptions, the rent includes Edesa’s proportionate share of the costs of maintaining and repairing common areas and common facilities of the building and Edesa’s utilities, security janitorial services and share of insurance and property taxes for the building. The lease is scheduled to terminate on December 31, 2022, subject to Edesa having a right to renew the lease for an additional period of two years. Edesa also has the right to terminate the lease at any time upon one month’s notice to the landlord.

The foregoing description of the Lease Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the Lease Agreement, which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

#### *License Agreement with Yissum*

On June 29, 2016, Edesa entered into an exclusive license agreement with Yissum Research Development Company, the technology transfer company of the Hebrew University of Jerusalem Ltd. (“Yissum”), which agreement was subsequently amended on each of April 3, 2017 and May 7, 2017. Pursuant to the license agreement as amended, Edesa obtained exclusive rights throughout the world to certain know-how, patents and data relating to a pharmaceutical product. Edesa will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications (the “Field”). Unless earlier terminated, the term of the license agreement will expire on a country by country basis on the later of (i) the date of expiry of the last valid licensed patent in such country; (ii) the date of expiry of any period of exclusivity granted to a product by a regulatory authority in such country or (iii) the date that is fifteen (15) years after the first commercial sale of a product in such country.

Pursuant to the license agreement, Edesa is exclusively responsible, at its expense, for the development of the product in the Field, including conducting clinical trials and seeking regulatory approval for the product, and once regulatory approval has been obtained, for the commercialization of the product. Edesa is required to use its commercially reasonable efforts to develop and commercialize the product in the Field in accordance with the terms of a development plan established by the parties. Subject to certain conditions, Edesa is permitted to engage third parties to perform its activities or obligations under the agreement.

In exchange for the exclusive rights to develop and commercialize the product in the Field, Edesa is committed to payments of various amounts to Yissum upon meeting certain milestones outlined in the license agreement up to an aggregate amount of \$18.6 million. In addition, upon divestiture of substantially all of the assets of Edesa, Edesa is obligated to pay Yissum a percentage of the valuation of the licensed technology sold as determined by an external objective expert.

Edesa also has a commitment to pay Yissum a royalty based on net sales of the product in countries where Edesa, or an affiliate, directly commercializes the product and a percentage of sublicensing revenue received by Edesa and its affiliates in the countries where the company does not directly commercialize the product.

The license agreement provides that Yissum shall remain the exclusive owner of the licensed technology and that Edesa is responsible for preparing, filing, prosecuting and maintaining the patents on the licensed technology in Yissum’s name. Notwithstanding the foregoing, Edesa will be the exclusive owner of all patents and other intellectual property that is made by or on behalf of Edesa after the date of the agreement, including all improvements to the licensed technology.

If Edesa defaults or fails to perform any of the terms, covenants, provisions or its obligations under the license agreement, Yissum has the option to terminate the license agreement, subject to providing Edesa an opportunity to cure such default. Edesa has the right to terminate the agreement if it determines that the development and commercialization of the product is no longer commercially viable.



Subject to certain exceptions, Edesa has undertaken to indemnify Yissum against any liability, including product liability, damage, loss or expense derived from the use, development, manufacture, marketing, sale or sublicensing of the licensed product and technology.

The foregoing description of the agreement with Yissum contained herein does not purport to be complete and is qualified in its entirety by reference to the agreement, as amended, which is attached hereto as Exhibits 10.2, 10.3 and 10.4 and incorporated herein by reference.

#### ***License Agreement with Cipher***

On June 15, 2016, Edesa entered into an exclusive license agreement with Cipher Pharmaceuticals Inc., an Ontario corporation (“Cipher”). Pursuant to the license agreement, Edesa obtained exclusive rights throughout the world to certain know-how, patents and data relating to a pharmaceutical product. Edesa will use the exclusive rights to develop the product for therapeutic, prophylactic and diagnostic uses in human and veterinary anorectal applications (the “Cipher Field”). Unless earlier terminated, the term of the license agreement will expire on the date that is twenty (20) years after the first commercial sale of the product, subject to automatic renewal for successive one (1) year periods.

Pursuant to the license agreement, Edesa is exclusively responsible, at its expense, for the development of the product in the Cipher Field, including conducting clinical trials and seeking regulatory approval for the product, and once regulatory approval has been obtained, for the commercialization of the product. Edesa is required to use its diligent efforts to develop and commercialize the product in the Cipher Field in accordance with the terms of the agreement and with a goal to maximize profits from net sales of the product in the Cipher Field. Subject to certain conditions, Edesa is permitted to engage third parties to perform its activities or obligations under the agreement.

In exchange for the exclusive rights to develop and commercialize the product in the Field, Edesa is committed to payments of various amounts to Cipher upon meeting certain milestones outlined in the license agreement up to an aggregate amount of \$18.5 million.

Edesa also has a commitment to pay Cipher a royalty based on net sales of the product in countries where Edesa, or an affiliate, directly commercializes the product and a percentage of sublicensing revenue received by Edesa and its affiliates in the countries where the company does not directly commercialize the product.

The license agreement provides that Cipher shall remain the exclusive owner of the licensed technology. Notwithstanding the foregoing, Edesa will be the exclusive owner of all patents and other intellectual property that is made by or on behalf of Edesa after the date of the agreement, including all improvements to the licensed technology.

If Edesa defaults or fails to perform any of the terms, covenants, provisions or its obligations under the license agreement, Cipher has the option to terminate the license agreement, subject to providing Edesa an opportunity to cure such default. Edesa has the right to terminate the agreement without cause upon sixty (60) days prior written notice to Cipher.

Subject to certain exceptions, Edesa has undertaken to indemnify Cipher against any liability, including product liability, damage, loss or expense derived from the use, development, manufacture, marketing, sale or sublicensing of the licensed product and technology.

The foregoing description of the agreement with Cipher contained herein does not purport to be complete and is qualified in its entirety by reference to the agreement, which is attached hereto as Exhibit 10.5 and incorporated herein by reference.

#### ***License and Development Agreement with Pendopharm***

On August 27, 2017, Edesa entered into an exclusive license and development agreement with Pendopharm, a division of Pharmascience Inc. (“Pendopharm”). Pursuant to the license and development agreement, Edesa granted to Pendopharm an exclusive license throughout Canada to certain know-how, patents and data for the sole purpose of obtaining regulatory approval for certain pharmaceutical products to allow Pendopharm to distribute, market and sell the licensed products for human therapeutic use in the conditions of hemorrhoids and anal fissures.

On a licensed product by licensed product basis, Edesa is required to use reasonable commercial efforts to develop the licensed products in the indications of hemorrhoids and anal fissures for the purposes of obtaining regulatory approval with the United States Food and Drug Administration (“FDA”) and provide to Pendopharm, on a licensed product by licensed product basis, the data package submitted to the FDA. Upon receipt of the data package, Pendopharm will elect whether it desires to seek regulatory approval in Canada of the applicable product. If Pendopharm elects not to seek regulatory approval of the applicable product, the applicable product will be removed

from the license rights granted to Pendopharm and will revert to Edesa. If Pendopharm elects to seek regulatory approval in Canada for the sale and marketing of the applicable product, Pendopharm will be responsible for obtaining regulatory approval for the applicable licensed product in Canada.

In exchange for the exclusive rights to market, import, distribute, and sell the pharmaceutical products, Pendopharm is required to pay Edesa a royalty in respect of aggregate annual net sales for each pharmaceutical product sold in Canada.

Unless earlier terminated, the term of the license and development agreement will expire, on a licensed product by licensed product basis, on the later to occur of (i) the date that is thirteen (13) years after the first commercial sale of the licensed product in Canada; (ii) the date of expiry of the last valid licensed patent in Canada relating to the licensed product; or (iii) the date of expiry of any period of exclusivity granted to the licensed product by a regulatory authority in Canada. The license and development agreement shall also terminate upon the termination of the license agreement with Yisum or the license agreement with Cipher, each described above. Pendopharm also has the right to terminate the license and development agreement for any reason upon one hundred twenty (120) days notice to Edesa.

The license and development agreement provides that Edesa shall remain the exclusive owner of the licensed technology and any improvements to the licensed technology made by Edesa or Edesa jointly with Pendopharm.

The foregoing description of the license and development agreement with Pendopharm contained herein does not purport to be complete and is qualified in its entirety by reference to the agreement, which is attached hereto as Exhibit 10.6 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
<a href="#">10.1</a>	Lease, dated as of January 1, 2017, by and between the Registrant and 1968160 Ontario Inc.
<a href="#">10.2+</a>	Exclusive License Agreement, dated as of June 29, 2016, by and between the Registrant and Yisum Research Development Company.
<a href="#">10.3</a>	First Amendment to Exclusive License Agreement, dated April 3, 2017, by and between the Registrant and Yisum Research Development Company.
<a href="#">10.4</a>	Second Amendment to Exclusive License Agreement, dated May 7, 2017, by and between the Registrant and Yisum Research Development Company.
<a href="#">10.5+</a>	Exclusive License Agreement, dated as of June 15, 2016, by and between the Registrant and Cipher Pharmaceuticals Inc.
<a href="#">10.6+</a>	License and Development Agreement, dated as of August 27, 2017, by and between the Registrant and Pendopharm, a division of Pharmascience Inc.

+ Portions of this exhibit have been omitted pursuant to Rule 601(b)(10)(iv) of Regulation S-K.

**SIGNATURE**

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.

**EDESA BIOTECH INC.**

Date: August 30, 2019

By: /s/ Michael Brooks \_\_\_\_\_

Name: Michael Brooks

Title: President



**LEASE  
(COMMERCIAL)**

Made as of the 1st day of January, 2017 (the "**Lease Commencement Date**")

*BETWEEN*

**1968160 ONTARIO INC.**, a Corporation incorporated pursuant to the laws of the Province of Ontario,

(the "**Landlord**")

and-

**EDESA BIOTECH INC.**, a Corporation incorporated pursuant to the laws of the Province of Ontario,

(the "**Tenant**")

In consideration of the rents, covenants and obligations stipulated herein the Landlord and the Tenant have agreed to enter into a lease of certain offices in the building (the "**Building**") located at 100 Spy Court, Markham, ON, consisting of approximately 2,800 square feet as more particularly shown on Schedule "A"

(the "**Premises**"), subject to the terms and conditions contained herein.

*I. GRANT OF LEASE*

The Landlord leases the Premises to the Tenant:

- (a) at the Rent set forth in Section 2;
- (b) for the Term set forth in Section 3; and
- (c) subject to the conditions and in accordance with the covenants, obligations and agreements herein.

*2. RENT*

- (1) Rent means the amounts payable by the Tenant to the Landlord pursuant to this Section.
- (2) The Tenant covenants to pay to the Landlord, during the term of this Lease, a fixed annual gross rent plus HST as follows:
  - (a) Eight Thousand Three Hundred Twenty Dollars (\$8,320.00) per month, payable by the Tenant in equal monthly installments, plus harmonized sales taxes on the 1<sup>st</sup> day of each and every month, commencing on the first day of the month following the Lease Commencement Date. For the period between the Lease Commencement Date and the first day of the month following the Lease Commencement Date, the Tenant shall pay a pro-rated amount of such annual gross rent, on the Lease Commencement Date
- (3) Rent payment increase by \$1/sqft every two years, see Schedule B for payment schedule.
- (4) For greater certainty, the fixed annual gross rent described above shall include the Tenant's proportionate share of the costs of maintaining and repairing common areas and common facilities of the Building, unless required due to the acts or omissions of the Tenant, the Tenant's utilities in the Building, Tenant's security, Tenant's janitorial services and the Tenant's share of insurance and property taxes for the Building. Such annual gross rent shall not include those costs associated with the Tenant's obligations of repair of the Premises as described

in this Lease or the Tenant's insurance obligations as set out in this Lease, or any cost incurred by the Landlord that is caused as a result of the Tenant's acts or omissions.

- (5) Intentionally deleted.
- (6) The Tenant shall have non-exclusive access and use of any common areas located in the Building including the kitchen, washrooms, lobby areas, parking areas, staff rooms, waiting rooms and other common areas of the Building, in common with other tenants of the Building at no additional cost to the Tenant, except as set out above. Cleaning staff engaged by the Tenant shall have access to the Premises at all reasonable times. Employees of the Tenant shall have full access to the staff room serving the Premises. Each of the Landlord and the Tenant acknowledge that a portion of the racking will be used by Edesa Biotech to store its pharmaceutical products.
- (7) All payments to be made by the Tenant pursuant to this Lease shall be delivered to the Landlord at the Landlord's address for service and notice as set out herein or to such other place as the Landlord may from time to time direct in writing.
- (8) All Rent in arrears and all sums paid by the Landlord for expenses incurred which should have been paid by the Tenant shall bear interest from the date payment was due, or made, or expense incurred until paid at a rate per annum equal to the prime commercial lending rate of the Landlord's bank.
- (9) The Tenant acknowledges and agrees that the payments of Rent provided for in this Lease shall be made without any deductions for any reason whatsoever unless expressly allowed by the terms of this Lease or agreed to by the Landlord in writing; and no partial payment by the Tenant which is accepted by the Landlord shall be considered as other than a partial payment on account of rent owing and shall not prejudice the Landlord's right to recover any rent owing.

3. *TERM AND POSSESSION*

- (1) The Tenant shall have possession of the Premises commencing on the Lease Commencement Date and ending on December 31, 2022, with a two year option. (the "**Term**").
- (2) Subject to the Landlord's rights under this Lease, and as long as the Tenant is not in default, the Landlord covenants that the Tenant shall have quiet enjoyment of the Premises during the Term of this Lease without any interruption or disturbance from the Landlord or any other person or persons lawfully claiming through the Landlord.
- (3) Notwithstanding any of the foregoing, the Tenant shall have the right, upon not less than one (1) month's prior written notice to the Landlord, to terminate the Term, following which the parties shall have no further obligations to each other, save and except for the Tenant's obligations described in Article 7 of this Lease.

4. *ASSIGNMENT*

- (1) The Tenant shall not assign this Lease or sublet the whole or any part of the Premises, unless it first obtains the consent of the Landlord in writing, which consent shall not unreasonably be withheld or delayed, and the Tenant hereby waives its right to the benefit of any present or future Act of the Legislature of Ontario which would allow the Tenant to assign this Lease or sublet the Premises without the Landlord's consent.

- (2) The consent of the Landlord to any assignment or subletting shall not operate as a waiver of the necessity for consent to any subsequent assignment or subletting.
- (3) Any consent granted by the Landlord shall be conditional upon the assignee, sublessee or occupant executing a written agreement directly with the Landlord agreeing to be bound by all the terms of this Lease as if the assignee, sublessee or occupant had originally executed this Lease as Tenant.
- (4) Any consent given by the Landlord to any assignment or other disposition of the Tenant's interest in this Lease or in the Premises shall not relieve the Tenant from its obligations under this Lease, including the obligation to pay rent as provided for herein.
- (5) Intentionally deleted.

5. *USE*

- (1) During the Term of this Lease the Premises shall not be used for any purpose other than a pharmaceutical/distribution office, without the express consent of the Landlord given in writing.
- (2) The Tenant shall not do or permit to be done at the Premises anything which may:
  - (a) constitute a nuisance;
  - (b) cause damage to the Premises;
  - (c) cause injury or annoyance to occupants of neighbouring premises;
  - (d) make void or voidable any insurance upon the Premises; or
  - (e) constitute a breach of any by-law, statute, order or regulation of any municipal, provincial or other competent authority relating to the Premises.
- (3) The Tenant shall conduct all of its operations on the Premises in strict compliance with all environmental laws and regulations and shall conduct such operations in accordance with prudent business practices aimed at preventing any adverse effects, as the same are defined under the *Environmental Protection Act*. Without limiting the generality of the foregoing, the Tenant shall obtain all required permits issued by environmental agencies or divisions with respect to its operations of the Premises.
- (4) The Tenant and the Premises shall adhere to and shall be responsible for any infractions of labour laws, municipal laws, and fire codes, and any other laws pertaining to the Building or the Premises.

6. *REPAIR AND MAINTENANCE*

- (1) The Tenant covenants that during the term of this Lease and any renewal thereof the Tenant shall repair any damage caused to the Premises by the Tenant, its employees, servants, agents and invitees.
- (2) The Tenant shall be responsible for all routine maintenance and repairs to the Premises.
- (3) The Tenant shall be responsible for repairs and proportional part of maintenance of the structural components of the roof, outside walls and foundations of the Building or any mechanical, electrical, plumbing or HVAC systems.

- (4) The Tenant shall permit the Landlord or a person authorized by the Landlord to enter the Premises to examine the condition thereof and view the state of repair at reasonable times.
  - (a) If upon such examination repairs are found to be necessary, written notice of the repairs required shall be given to the Tenant by or on behalf of the Landlord and the Tenant shall make the necessary repairs within the time specified in the notice.
  - (b) If the Tenant refuses or neglects to keep the Premises in good repair the Landlord may, but shall not be obliged to, make any necessary repairs, and shall be permitted to enter the Premises, by itself or its servants or agents, for the purpose of effecting the repairs without being liable to the Tenant for any loss, damage or inconvenience to the Tenant in connection with the Landlord's entry and repairs, and if the Landlord makes repairs the Tenant shall pay the cost of them immediately as rent in addition to the fixed annual gross rent.
- (5) Upon the expiry of the Term or other determination of this Lease the Tenant agrees to leave the Premises in a clean broom-swept condition.
- (6) The Tenant shall immediately give written notice to the Landlord of any substantial damage that occurs to the Premises from any cause,

7. *ALTERATIONS AND ADDITIONS*

- (1) If the Tenant, during the Term of this Lease or any renewal of it, desires to make any alterations or additions to the Premises, including but not limited to: erecting partitions, attaching equipment, and installing necessary furnishings or additional equipment of the Tenant's business, the Tenant may do so at its own expense, at any time and from time to time, if the following conditions are met:
  - (a) before undertaking any alteration or addition the Tenant shall submit to the Landlord a plan showing the proposed alterations or additions and items included in the plan which are regarded by the Tenant as "Tenant's Trade Fixtures" shall be designated as such on the plan, and the Tenant shall not proceed to make any alteration or addition unless the Landlord has approved the plan (including, without limitation, the right of the Landlord to designate certain such alterations or additions as "Non-Standard Leasehold Improvements") and agreed to the designation of the Tenant's Trade Fixtures, and the Landlord shall not unreasonably or arbitrarily withhold its approval; and
  - (b) any and all alterations or additions to the Premises made by the Tenant must comply with all applicable building code standards and by-laws of the municipality in which the Premises are located.
- (2) The Tenant shall be responsible for and pay the cost of any alterations, additions, installations or improvements that any governing authority, municipal, provincial or otherwise, may require to be made in, on or to the Premises.
- (3) All alterations and additions to the Premises made by or on behalf of the Tenant, other than the Tenant's Trade Fixtures and the Non-Standard Leasehold Improvements, shall immediately become the property of the Landlord without compensation to the Tenant. For greater certainty, the Tenant shall only be entitled to remove those trade fixtures and equipment which the Landlord and the Tenant have agreed to designate as the "Tenant's Trade Fixtures". All other trade fixtures and equipment shall remain the property of the Landlord.

- (4) The Tenant agrees, at its own expense and by whatever means may be necessary, immediately to obtain the release or discharge of any encumbrance that may be registered against the Landlord's property in connection with any additions or alterations to the Premises made by the Tenant or in connection with any other activity of the Tenant.
- (5) The Tenant shall remove the Tenant's Trade Fixtures and Non-Standard Leasehold Improvements at the end of the Term or other termination of this Lease and the Tenant covenants that it will make good and repair or replace as necessary any damage caused to the Premises by the removal of the Tenant's Trade Fixtures and Non-Standard Leasehold Improvements.
- (6) Other than as provided in paragraph 7(5) above, the Tenant shall not, during the Term of this Lease or anytime thereafter remove from the Premises any alterations, additions, Trade Fixtures or other goods and chattels of the Tenant except in the following circumstances:
  - (a) the removal of the Tenant's Trade Fixture is in the ordinary course of business;
  - (b) the Tenant's Trade Fixture has become unnecessary for the Tenant's business or is being replaced by a new or similar Trade Fixture; or
  - (c) the Landlord has consented in writing to the removal;

but in any case the Tenant shall make good any damage caused to the Premises by the installation or removal of any Trade Fixtures, equipment, partitions, furnishings and any other objects whatsoever brought onto the Premises by the Tenant;

- (7) The Tenant shall not bring onto the Premises or any part of the Premises any machinery, equipment or any other thing that might in the opinion of the Landlord, by reason of its weight, size or use, damage the Premises or overload the floor of the Premises, and if the Premises are damaged or overloaded as a result thereof, the Tenant shall restore the Premises immediately or pay to the Landlord the cost of restoring the Premises.
- (8) The Tenant shall not allow any construction lien to arise or be registered against the Premises, the leasehold interest of the Tenant, or the Building.
- (9)
  - (a) The Tenant shall be permitted to place signage in the reception area of the Leased Premises to identify the Tenant's reception staff and to identify services offered by the Tenant to patients. Costs of all such signage shall be borne by the Tenant.
  - (b) The Tenant shall be permitted to place signage near Brock Road, subject to compliance with applicable municipal by-laws and approval by the Landlord, such approval not to be unreasonably or arbitrarily withheld. Costs of all such signage shall be borne by the Tenant.

#### 8. *PROPERTY TAXES*

The Tenant shall pay all personal property taxes with respect to the Tenant's personal property on the Premises that is not covered in the fixed annual gross rent.

#### 9. *INSURANCE*

- (1) The Landlord shall obtain and maintain insurance against any risk of physical loss or damage to property respecting the Premises on a replacement cost basis, naming the Landlord as an insured and the Tenant as an additional insured.
- (2) The Tenant shall obtain and maintain at the Tenant's sole cost and expense all risk public liability and property damage insurance, including personal injury, in respect of the Premises and the operations therein, to the extent of not less than \$5,000,000, inclusive of all injuries and/or death to persons and damage to property

of others arising from any one occurrence. The Tenant shall provide the Landlord with a copy of the above policies or certificates of insurance, as applicable, upon request.

- (3) The Tenant covenants to keep the Landlord indemnified against all claims and demands whatsoever by any person, whether in respect of damage to person or property, arising out of or occasioned by the maintenance, use or occupancy of the Premises or the subletting or assignment of same or any part thereof. And the Tenant further covenants to indemnify the Landlord with respect to any encumbrance on or damage to the Premises occasioned by or arising from the act, default, or negligence of the Tenant, its officers, agents, servants, employees, contractors, customers, invitees or licensees and the Tenant agrees that the foregoing indemnity shall survive the termination of this Lease notwithstanding any provisions of this Lease to the contrary.

#### *10. UTILITIES*

Tenant shall pay all charges for gas, electricity, telephone and other services and utilities used by the Tenant in the Premises during the term of the Lease unless otherwise expressly agreed in writing by the Landlord. Tenant acknowledges that the Premises are designed to provide standard office use electrical facilities and standard office lighting. Tenant shall not use any equipment or devices that utilize excessive electrical energy or which may, in the Landlord's reasonable opinion, overload the wiring.

#### *11. DAMAGE TO THE PREMISES*

- (1) If the Premises or the building in which the Premises are located, are damaged or destroyed, in whole or in part, by fire or other peril, then the following provisions shall apply:
  - (a) if the damage or destruction renders the Premises unfit for occupancy and impossible to repair or rebuild using reasonable diligence within 120 clear days from the happening of such damage or destruction, then the Term hereby granted shall cease from the date the damage or destruction occurred, and the Tenant shall immediately surrender the remainder of the Term and give possession of the Premises to the Landlord, and the rent from the time of the surrender shall abate;
  - (b) if the Premises can with reasonable diligence be repaired and rendered fit for occupancy within one hundred and twenty (120) days from the happening of the damage or destruction, but the damage renders the Premises wholly unfit for occupancy, then the rent hereby reserved shall not accrue after the day that such damage occurred, or while the process of repair is going on, and the Landlord shall repair the Premises with all reasonable speed, and the Tenant's obligation to pay rent shall resume immediately after the necessary repairs have been, completed;
  - (c) if the Premises can be repaired within one hundred and twenty (120) days as aforesaid, but the damage is such that the Premises are capable of being partially used, then until such damage has been repaired, the Tenant shall continue in possession and the rent shall abate proportionately.
- (2) Any question as to the degree of damage or destruction or the period of time required to repair or rebuild shall be determined by an architect retained by the Landlord.
- (3) Apart from the provisions of Section 11 (1)(a) there shall be no abatement from or reduction of the rent payable by the Tenant, nor shall the Tenant be entitled to claim against the Landlord for any damages, general or special, caused by fire, water, sprinkler systems, partial or temporary failure or stoppage of services or utilities which the Landlord is obliged to provide according to this Lease, from any cause whatsoever.



## 12. ACTS OF DEFAULT AND LANDLORD'S REMEDIES

- (1) An Act of Default has occurred when:
  - (a) the Tenant has failed to pay rent when due, regardless of whether demand for payment has been made or not;
  - (b) The Tenant has breached its covenants or failed to perform any of its obligations under this Lease; and
    - (i) the Landlord has given notice specifying the nature of the default and the steps required to correct it; and
    - (ii) the Tenant has failed to correct the default as required by the notice;
  - (c) the Tenant has:
    - (i) become bankrupt or insolvent or made an assignment for the benefit of the Creditors;
    - (ii) had its property seized or attached in satisfaction of a judgment;
    - (iii) had a receiver appointed;
    - (iv) committed any act or neglected to do anything with the result that a Construction Lien or other encumbrance is registered against the Landlord's property;
    - (v) without the consent of the Landlord, made or entered into an agreement to make a sale of its assets to which the *Bulk Sales Act* applies; or
    - (vi) taken action if the Tenant is a corporation, with a view to winding up, dissolution or liquidation.
  - (d) any insurance policy is cancelled or not renewed by reason of the use or occupation of the Premises, or by reason of non-payment of premiums;
  - (e) the Premises are used by any other person or persons, or for any other purpose than as provided for in this Lease without the written consent of the Landlord.
- (2) When an Act of Default on the part of the Tenant has occurred:
  - (a) the current month's rent and the next three (3) months' rent shall become due and payable immediately; and
  - (b) the Landlord shall have the right to terminate this Lease and to reenter the Premises and deal with them as he may choose.
- (3) If, because an Act of Default has occurred, the Landlord exercises its right to terminate this Lease and re-enter the Premises prior to the end of the Term, the Tenant shall nevertheless be liable for payment of rent and all other amounts payable by the Tenant in accordance with the provisions of this Lease until the Landlord has re-let the Premises or otherwise dealt with the Premises in such manner that the cessation of payments by the Tenant will not result in loss to the Landlord, and the Tenant agrees to be liable to the Landlord, until the end of the Term of this Lease for payment of any difference between the amount of rent hereby agreed to be paid for the Term hereby granted and the rent any new tenant pays to the Landlord.

- (4) The Tenant covenants that notwithstanding any present or future Act of the Legislature of the Province of Ontario, the personal property of the Tenant during the term of this Lease shall not be exempt from levy by distress for rent in arrears.
- (a) The Tenant acknowledges that it is upon the express understanding that there should be no such exemption that this Lease is entered into, and by executing this Lease:
- (i) the Tenant waives the benefit of any such legislative provisions which might otherwise be available to the Tenant in the absence of this agreement; and
- (ii) the Tenant agrees that the Landlord may plead this covenant as an estoppel against the Tenant if an action is brought to test the Landlord's right to levy distress against the Tenant's property.
- (b) The Landlord shall remit to the Tenant any surplus over the rent in arrears over the amount received by the Landlord from any levy by distress, less any costs reasonably incurred by the Landlord in connection therewith and any amount which the Landlord is required by law to remit to any governmental authority from such proceeds.
- (5) If, when an Act of Default has occurred, the Landlord chooses not to terminate the Lease and re-enter the Premises, the Landlord shall have the right to take any and all necessary steps to rectify any or all Acts of Default of the Tenant and to charge the costs of such rectification to the Tenant and to recover the costs as rent.
- (6) If, when an Act of Default has occurred, the Landlord chooses to waive its right to exercise the remedies available to it under this Lease or at law the waiver shall not constitute condonation of the Act of Default, nor shall the waiver be pleaded as an estoppel against the Landlord to prevent its exercising its remedies with respect to a subsequent Act of Default. No covenant, term, or condition of this Lease shall be deemed to have been waived by the Landlord unless the waiver is in writing and signed by the Landlord.

13. *TERMINATION UPON NOTICE AND AT END OF TERM*

- (1) If the Premises are expropriated or condemned by any competent authority the Landlord shall have the right to terminate this Lease by giving ninety (90) clear days' notice in writing to the Tenant.
- (2) The Tenant agrees to permit the Landlord, during the last six (6) months of the Term of this Lease, to display "For Rent" or "For Sale" signs or both at the Premises and to show the Premises to prospective new tenants or purchasers and to permit anyone having written authority of the Landlord to view the Premises at reasonable hours without disruption to the business of the Tenant and having regard to patient confidentiality.
- (3) If the Tenant remains in possession of the Premises after termination of this Lease as aforesaid and if the Landlord then accepts rent for the Premises from the Tenant, it is agreed that such overholding by the Tenant and acceptance of rent by the Landlord shall create a monthly tenancy only but the tenancy shall remain subject to all the terms and conditions of this Lease except those regarding the Term.

14. *SUBORDINATION AND POSTPONEMENT*

- (1) This Lease and all the rights of the Tenant under this Lease are subject and subordinate to any and all charges against the land, buildings or improvements of which the Premises form part, whether the charge is in the nature of a mortgage, trust deed, lien or any other form of charge arising from the financing or re-financing, including extensions or renewals, from time to time in existence against the building.
- (2) Upon request, if a lender delivers a non-disturbance agreement in favour of the Tenant, the Tenant will subordinate this Agreement and all rights hereunder in such form as the Landlord requires to any and all mortgages, or other instruments of financing, refinancing or collateral financing as mentioned above.

15. **INTENTIONALLY DELETED**

16. *WAIVER*

Failure by either party to require performance of any term, covenant or condition herein contained shall not be deemed to be a waiver of such term, covenant or condition or of any subsequent breach of the same or of any other term, covenant or condition herein contained. The subsequent acceptance or payment of rent, hereunder by the Landlord shall not be deemed to be a waiver of any preceding breach by the other of any term, covenant or condition of this Lease, other than the failure of the Tenant to pay the particular rent so accepted, regardless of the Landlord's knowledge of such preceding breach at the time of acceptance of such rent. No covenant, term or condition of this Lease shall be deemed to have been waived by the Landlord or Tenant, unless such waiver be in writing by the Landlord or Tenant.

17. *ACCORD AND SATISFACTION*

No payment by the Tenant or receipt by the Landlord of a lesser amount than the monthly rent herein stipulated shall be deemed to be other than on account of the earliest stipulated rent, nor shall any endorsement or statement or any cheque or any letter accompanying any cheque or notation on any cheque or payment as rent be deemed an accord and satisfaction, and the Landlord may accept such cheque or payment without prejudice to the Landlord's right to recover the balance of such rent or pursue any other remedy in this Lease provided.

18. *ENTIRE AGREEMENT*

This Lease and the schedules if any, attached hereto and forming a part hereof, set forth all the covenants, promises, agreements, conditions and understandings between the Landlord and the Tenant concerning the Premises and there are no covenants, promises, agreements, conditions or representations, either oral or written, between them other than are herein and in the said schedules, if any, set forth. Except as herein otherwise provided, no subsequent alteration, amendment, change or addition to this Lease shall be binding upon the Landlord or the Tenant unless reduced to writing and signed by them.

19. *NO SET-OFF*

Subject to the other provisions of this Lease all rent required to be paid by the Tenant hereunder shall be paid without any deduction, abatement or set-off whatsoever.

20. *NOTICE*

- (1) Any notice required or permitted to be given by one party to the other pursuant to the terms of this Lease may be given

To the Landlord at: 330 Hwy #7 East, Suite 510, Richmond Hill, ON L4B 3P8  
To the Tenant at the Premises.

- (2) The above addresses may be changed at any time by giving ten (10) days written notice.
- (3) Any notice or document so given shall be deemed to have been received on the third (3rd) business day following the date of mailing, if sent by registered mail or certified mail, but shall be deemed to have been

received on the next business day if transmitted by facsimile transmission. Any party may from time to time by notice given as provided above, change its address for the purpose of this section.

21. *COUNTERPARTS OF THIS AGREEMENT*

This Agreement may be executed in counterparts, each of which so executed shall be deemed to be an original, and such counterparts together shall constitute one and the same instrument.

22. *DISTRESS*

The Tenant waives and renounces the benefit of any present or future statute taking away or limiting the Landlord's right of distress and the Tenant covenants and agrees that notwithstanding any such statute none of the goods and chattels of the Tenant on the Leased Premises at any time during the Term shall be exempt from levy by distress for rent in arrears.

23. *ENVIRONMENTAL ISSUES AND CONTAMINANTS*

The Tenant shall not do or permit anything to be done on, around or in relation to the Premises, or bring or keep anything thereon which may in any way increase or cause environmental contamination, adverse environmental effects, or which may be in contravention with *The Environmental Protection Act*, R.S.O. 1990, c.E.19 as amended, or any other federal, provincial or municipal legislation, regulation, ordinances or rules regarding environmental protection which are currently existing or which are enacted during the currency of this Lease. The Tenant shall not cause, and shall not permit to be caused, the escape, discharge, leaching, disposal, maintenance and/or the storage of any contaminants, pollutants, radioactive material, PCB, or other hazardous material on, around, or in relation to the Premises. The Tenant shall be solely and totally responsible for the clean-up and repair of any environmental damage, or adverse effects arising as a result of the breach of the covenants herein contained. The Tenant hereby agrees to indemnify, defend and save the Landlord and any mortgagee harmless from any and all liability, claims, damage, expense, causes of action, suits or judgments arising from the Tenant's breach of this covenant, and all payments arising pursuant to this or the preceding paragraph shall be deemed to be rent in addition to the fixed annual gross rent and recoverable as such. The indemnity referred to herein shall include, but not be limited to, claims made by third parties arising out of common law. The Tenant herein covenants to provide immediate notice to the Landlord of any breach of the covenants contained herein. The Tenant acknowledges that the Landlord, or its agents, shall be permitted to enter onto the Leased Premises at any time to inspect the Leased Premises, if it has reason to believe that the Tenant has breached its covenant contained herein this Section. The Landlord shall also be entitled to take corrective action regarding any breach of the Tenant's covenants contained herein, at the Tenant's expense.

24. *REGISTRATION*

The Tenant shall not at any time register notice of or a copy of this Lease on title to the property of which the premises form part without consent of the Landlord.

25. *INTERPRETATION*

- (1) The words importing the singular number only shall include the plural, and vice versa, and words importing the masculine gender shall include the feminine gender, and words importing persons shall include firms and corporations and vice versa.
- (2) Unless the context otherwise requires, the word "Landlord" and the word "Tenant" wherever used herein shall be construed to include the executors, administrators, successors and assigns of the Landlord and Tenant, respectively.
- (3) When there are two or more Tenants bound by the same covenants herein contained, their obligations shall be joint and several.

*[signatures on next page]*

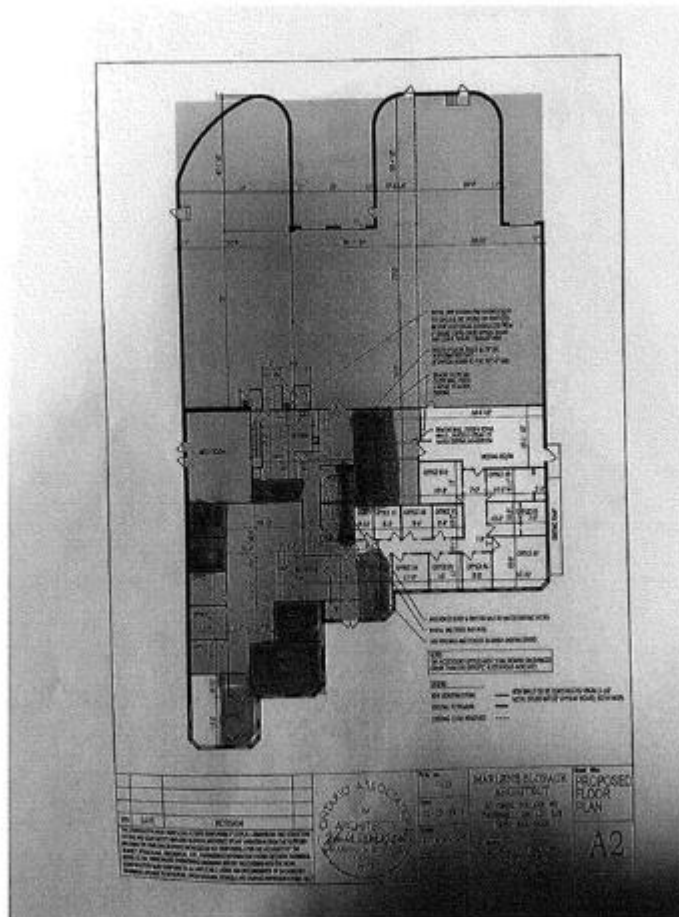
IN WITNESS WHEREOF the Landlord and the Tenant have signed and sealed this Lease as of the day and year first above written.

**SIGNED, SEALED AND DELIVERED**

in the presence of

)  
) **1968160 ONTARIO INC.**  
)  
)  
) /s/ Nidhi Nijhawan  
) By: Nidhi Nijhawan  
) Its: President  
) I have authority to bind the Corporation.  
)  
)  
) **EDESA BIOTECH INC.**  
)  
)  
) /s/ Dr. Par Nijhawan  
) By: Dr. Par Nijhawan  
) Its: Chief Medical Officer  
) I have authority to bind the Corporation.

Schedule "A"  
DRAWING OF PREMISES



Schedule "B" Rent Payment Schedule

<b>Start Date</b>	<b>End Date</b>	<b>Monthly Rent</b>
<i>Jan-17</i>	<i>Dec-18</i>	\$8,320.00 +HST
<i>Jan-19</i>	<i>Dec-20</i>	\$8,553.33 +HST
<i>Jan-21</i>	<i>Dec-22</i>	\$8,786.67 +HST
<i>Jan-23</i>	<i>Dec-24</i>	\$9,020 +HST



**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

**Execution Version: 29/06/16**

**EXCLUSIVE LICENSE AGREEMENT**

**by and between**

**YISSUM RESEARCH DEVELOPMENT COMPANY OF THE HEBREW UNIVERSITY OF JERUSALEM LTD**

**and**

**EDESA BIOTECH INC.**

**June 29, 2016**

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## EXCLUSIVE LICENSE AGREEMENT

This Agreement ("**Agreement**"), effective as of June 29, 2016 ("**Effective Date**"), is entered into by and between Yissum Research Development Company of the Hebrew University of Jerusalem, an Israeli corporation with its principal office at Hi-Tech Park, Edmond J. Safra Campus, Givat-Ram, Jerusalem P.O. Box 39135, Jerusalem 91390 Israel ("**YISSUM**"), and Edesa Biotech Inc., an Ontario corporation with its principal office at I 00 Spy Court, Markham, Ontario, L3R 5H6 ("**EDESA**"). YISSUM and EDESA may be referred to herein individually as a "**Party**" or collectively as the "**Parties**". Reference to a Party shall be deemed to include that Party's Affiliates.

### RECITALS:

- A. YISSUM owns the rights to certain know-how, patents and data relating to MRX-6 (a topical formulation of a Hyaluronic Acid (HA) conjugated with dipalmitoyl PHOSPHATIDYL-ethanolamine (DPPE) (the "**Product**") developed by Professor Saul Yedgar (the "**Researcher**"), of the Hebrew University of Jerusalem (the "**University**") and Akari Therapeutics (f/k/a Celsus Therapeutics), the previous licensee of the Licensed Technology (as defined below).
- B. EDESA is a pharmaceutical company having expertise in the discovery, development, manufacturing and commercialization of innovative human pharmaceutical products.
- C. EDESA and YISSUM desire to enter into an agreement under which EDESA will obtain exclusive rights to develop the Product for therapeutic, prophylactic and diagnostic uses in topical dermal applications and anorectal applications (but excluding ophthalmological uses)(collectively, the "**Field**").

Concurrently with the execution of this Agreement, EDESA is executing a consulting agreement with the Researcher, under which the Researcher shall provide certain consulting services to EDESA. In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

- 1.1 "Adverse Event"** shall mean any undesirable medical occurrence in a patient or clinical investigation subject administered the Product that must be reported to the relevant regulatory authority and which does not necessarily have to have a causal relationship with the Product.
- 1.2 "ADRC"** has the meaning set forth in Section 13.14.
- 1.3 "Affiliate"** means with respect to a Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.3, "**control**" shall mean: (a) in the case of a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity; and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.

**1.4"Arbitration Panel Finalization"** has the meaning set forth in Section 13.14.

**1.5"Calendar Quarter"** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

**1.6"Calendar Year"** means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.

**1.7"Claimant"** has the meaning set forth in Section 13.14.

**1.8"Clinical Material(s)"** means the Product formulated in accordance with the Specifications and applicable Canadian, United States and/or foreign laws, rules and regulations: (a) for preclinical activities; and (h) for administration to subjects in Clinical Trials.

**1.9"Clinical Trial(s)"** means clinical trials in each with respect to the Product in the Field.

**1.10"Commercialization" or "Commercialize"** means activities undertaken after obtaining Regulatory Approval relating specifically to the launch, promotion, marketing, sales force recruitment, pricing determination, sale, use and distribution of a pharmaceutical product and post-launch medical activities, including: (a) manufacturing and distribution for commercial sale, (b) strategic marketing, sales force detailing, advertising, and market and product support; (c) medical education and liaison; (d) all customer support and product distribution, invoicing and sales activities; (e) all post-Regulatory Approval regulatory activities, including those necessary to maintain Regulatory Approvals; (f) target product profile, pricing, formulary and reimbursement related activities including pricing and reimbursement approvals; and (g) organizing formulary access and drug distribution.

**1.11"Confidential Information"** has the meaning set forth in Section 8.1.

**1.12"Confirmatory Efficacy Study"** means a second human Clinical Trial to confirm with statistical significance the efficacy and safety of the Product in the Field.

**1.13"Control," "Controls" or "Controlled by"** means (except as used in Section 1.3), with respect to any item or right under the Licensed Technology, the ability of a Party (whether through ownership or license, other than pursuant to this Agreement) to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

**1.14"Debarred"** has the meaning set forth in Section **Error! Reference source not found..**

**1.15"demand for arbitration"** has the meaning set forth in Section 13.14.

**1.16"Develop" or "Development" or "Developing"** means research, discovery, process development, manufacturing for preclinical and clinical uses, preparation for drug reimbursement, preparation and initiation of medical education and liaison activities and preclinical and clinical drug or biological development activities, including test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, Regulatory Approval and registration, in each case, of a Product for use in the Field.

**1.17"EDESA Indemnitee(s)"** has the meaning ascribed to it in Section 10.2.

**1.18"EDESA Data"** means any proprietary scientific, technical, clinical or regulatory information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, filings, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data that are related to the Product (or a composition containing the Product or the manufacturing or use of the Product).

**1.19"EMA"** means the European Medicines Evaluation Agency or any successor agency thereto.

**1.20"FDA"** means the United States Food and Drug Administration or any successor agency thereto.

**1.21"Field"** has the meaning ascribed to it in the recitals.

**1.22"First Commercial Sale"** means, with respect to the Product in the Field, the first sale to a Third Party for end use or consumption of the Product in the Field in a country in the Territory after Regulatory Approval of the Product in the Field has been granted by the Regulatory Authority of such country.

**1.23"ICH"** means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**1.24"IFRS"** means International Financial Regulatory Standards as the same may be in effect from time to time.

**1.25"IND"** means an Investigational New Drug application in the United States, a Clinical Trial Application in Canada, or a foreign equivalent application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

**1.26"Indemnifying Party"** has the meaning ascribed to it in Section **Error! Reference source not found..**

**1.27"indemnitee"** has the meaning ascribed to it in Section **Error! Reference source not found..**

**1.28"Indication"** means any separate and distinct disease (or stage of disease), disorder or medical condition in humans or non-human animals which a Product is intended to treat, prevent, diagnose, monitor or ameliorate and which, for a Product candidate, is intended to be reflected in the labeling for such Product as an approved indication, and which, for an approved Product, is reflected in the labeling for such Product.

**1.29"Information"** means any and all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information and data related to the Product, in any tangible or intangible form.

**1.30"Knowledge"** shall mean actual knowledge of any of the current officers of the Party gained in the regular course of the relevant Party's business.

**1.31"Licensed Technology"** means (a) all Patents; (b) any regulatory approvals relating to the Product; (c) any proprietary scientific, technical, clinical or regulatory information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, filings, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data and (d) any proprietary biological, chemical or physical materials; all Controlled by YISSUM or the Researcher as of the Effective Date or at any time during the Term, including any active pharmaceutical ingredient related to the product in the case of each of (a), (b), (c) and (d) that are: (i) related to the Product (or a composition containing the Product or the manufacturing or use of the Product); and (ii) necessary or useful for EDESA to exercise the rights licensed to it under this Agreement or to perform its obligations under this Agreement.

**1.32"NDA" or "New Drug Application"** means an application submitted to FDA pursuant to 21 U.S.C. § 505(6) or a Canadian or foreign equivalent application or submission to a Regulatory Authority which contains complete details of the manufacture and testing of a new drug, for purposes of obtaining Regulatory Approval for such new drug in the applicable jurisdiction, for a particular Indication, and also includes a Biologics License Application.

**1.33"Net Sales"** means the gross amount invoiced and billed by EDESA or its Affiliates to unrelated Third Parties (excluding any Sublicense) for the Product in the Territory, less:

(a) Trade, quantity and cash discounts actually allowed or paid;

- (b) Commissions, discounts, refunds, rebates (including wholesaler fees), chargebacks, retroactive price adjustments, and any other allowances actually allowed or paid which effectively reduce the net selling price;
- (c) Actual Product returns and allowances;
- (d) Any sales, use, excise, value added taxes or similar taxes measured by the billing amount, when included in billing;
- (e) Any freight, postage, shipping, and insurance charges related to delivery of the Product from an applicable warehouse, all to the extent included in the third party invoices; and
- (f) custom, import and export duties actually paid.

Any refund or reimbursement of any of the foregoing amounts previously deducted from Net Sales shall be appropriately credited to Net Sales, or adjusted through allowances, upon receipt thereof.

For greater certainty "Net Sales" shall not include sales or transfers between members of the group comprised of EDESA, Sublicensees, and their Affiliates.

For greater certainty, provision of Product for the purpose of conducting Clinical Trials in order to obtain Regulatory Approvals shall not be deemed to be a sale.

Such amounts shall be determined from the books and records of EDESA or its Affiliates or Sublicensees, as applicable, maintained in accordance with IFRS, consistently applied, except where IFRS is not the standard, in which case whatever the accounting standard is in effect will be applied. EDESA further agrees that in determining such amounts, it will use EDESA's then current standard procedures and methodology, including EDESA's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars, consistently applied.

**1.34 "Patent(s)"** means: (a) all patents and patent applications in any country or supranational jurisdiction; and (b) any provisionals, substitutions, divisions, continuations, continuations **in part, reissues, renewals, registrations, confirmations, reexaminations, extensions**, supplementary protection certificates and the like, of any such patents or patent applications Controlled by YISS UM or the Researcher where the Researcher is listed as an inventor, as of the Effective Date or at any time during the Term that are related to the Product (or a composition containing the Product or the manufacturing or use of the Product) and necessary or useful for EDESA to exercise the rights licensed to it under this Agreement or to perform its obligations under this Agreement, including, without limitation, the Patents listed in Appendix B.

**1.35 "Phase III Clinical Study"** means a human clinical study to confirm with statistical significance the efficacy and safety of the Product in the Field performed to obtain Regulatory Approval for the Product.



**1.36"Product"** has the meaning ascribed to it in the recitals.

**1.37"Regulatory Approval(s)"** means all approvals or authorizations by Regulatory Authorities necessary to market and sell the Product in the Field in the Territory.

**1.38"Regulatory Authority"** means any applicable government regulatory authority involved in granting approvals for the conduct of Clinical Trials or for an NDA in the Territory, including in the United States, the FDA, and in Canada, Health Canada.

**1.39"Respondent"** has the meaning set forth in Section 13.14.

**1.40"Royalties"** has the meaning set forth in Section 6.2.

**1.41"Specifications"** means the specifications for the Product as provided by Yissum as part of the Licensed Technology.

**1.42"Sublicensee"** means a Third Party that is granted a sublicense under the licenses granted to a Party under this Agreement.

**1.43"Sublicensing Fees"** has the meaning set forth in Section 6.2.

**1.44"Sublicensing Revenue"** means the net amount of all revenues, royalties, receipts, and monies, including upfront payments, milestone payments, and license fees, earned or received by EDESA and its Affiliate(s) from Sublicensee(s) with respect to the Product.

**1.45"Term"** has the meaning set forth in Section 12.1.

**1.46"Territory"** means the entire world.

**1.47"Third Party"** means an entity other than: (a) EDESA and its Affiliates; and (b) YISSUM and its Affiliates.

**1.48"United States"** means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

**1.49"YISSUM indemnitee(s)"** has the meaning ascribed to it in Section 10.1.

## ARTICLE 2 SCOPE

### 2.1 Scope.

Pursuant to and subject to the terms of this Agreement: (a) EDESA will be exclusively responsible for the Development of the Product in the Territory in the Field with the goal of obtaining Regulatory Approval for the Product, and, once Regulatory Approval has been obtained, for the Commercialization of the Product; and (b) EDESA will have exclusive rights to Develop and Commercialize the Product as further set forth in Section 3.1, in exchange for royalty and other payments to be made to YISSUM as described in Article 6.

## ARTICLE 3 PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

### 3.1 Overview.

From and after the Effective Date, EDESA shall have full responsibility and authority, at its sole cost and expense, for the Development and Commercialization of the Product in the Field in the Territory, including (a) the conduct of all Clinical Trials and (b) seeking Regulatory Approvals for the Product. Upon EDESA 's request, YISSUM will promptly execute such letters as may be required in order to effect transfer to EDESA of any IND, for filing with the relevant Regulatory Authorities.

### 3.2 Conduct of Development and Commercialization.

EDESA shall use commercially reasonable efforts to Develop and Commercialize the Product in the Field in the Territory in accordance with the Development Plan, as defined in Section 3.3. For purposes of this Agreement, "commercially reasonable efforts" means such efforts as would be employed by EDESA for a product at a similar development stage, having similar market potential and having similar commercial and scientific advantages and disadvantages based on conditions then prevailing. EDESA shall report to YISSUM through the Development Plan as to the status of Development and Commercialization of the Product in the Field.

### 3.3 Development Plan

EDESA will be responsible for the Development of the Product in accordance with the plan (the "**Development Plan**") set forth in Appendix A, including the development targets (the "**Development Targets**") referenced therein. EDESA shall periodically prepare an update to the Development Plan and deliver same to YISSUM within sixty (60) days of the end of every 6- month period following the execution of this Agreement, for the first two years of this Agreement and, thereafter, within sixty (60) days following each twelve (12) month anniversary of the execution of this Agreement. The parties acknowledge and agree the Development Targets will initially be based on the Parties best estimation of what can be accomplished and will be adjusted by mutual agreement in light of EDESA 's actual Development experience. After the submission of each Development Plan update, the Parties will meet (in person or through other means) and work in good faith to amend and adjust the Development Plan and Development Targets as needed.

### 3.4 Sponsored Research.

EDESA shall sponsor research by or under the direction of the Researcher in connection with the development of the Licensed Technology and the Products as needed. EDESA shall consider in good faith (but is not obligated to approve) requests from the Researcher to sponsor research to be conducted by or under the direction of Researcher to develop the Licensed Technology.

### 3.5 Rights to Sublicense.

EDESA shall have the right to engage Third Parties (each a "**Sublicensee**") to perform any of its activities or obligations hereunder, provided that EDESA shall be responsible for ensuring

that, prior to any such engagement, any Sublicensees are subject to a agreement (a "**Sublicense Agreement**") containing terms and conditions: (i) specifying that such written agreements terminate upon termination of this Agreement; (ii) consistent with the relevant terms and conditions of this Agreement protecting the rights of YISSUM under this Agreement including imposing obligations of confidentiality on each such Sublicensee; (iii) that vest ownership of any and all inventions developed by such Sublicensee relating lo Products in the course of performing activities under such sublicense in EDESA; and (iv) that do not impose any payment obligations or liability on YISSUM without the prior written consent of YJSSUM. EDESA shall require each Sublicensee to provide it with regular written royalty reports that include at least the detail that EDESA is required to provide to YJSSUM pursuant to this Agreement. Upon request, EDESA shall provide such reports to YISSUM. EDESA shall provide YISSUM with an executed copy of each Sublicense Agreement within thirty (30) days of its execution.

## ARTICLE 4 MANUFACTURE AND SUPPLY

### 4.1 Responsibility for Manufacturing and Supply.

(a) EDESA will be responsible, at its own cost, for the manufacture of Product and Clinical Materials. Promptly following the execution of this Agreement, YISSUM shall deliver to EDESA copies of all Information in its possession or Control, including manufacturing know how, and any and all original processes, records, directly related to the manufacture and supply of the Product and Clinical Materials in accordance with the applicable Specifications.

(b) Upon the request of EDESA, YISSUM shall promptly ship to EDESA any unexpired active pharmaceutical ingredient for the Product in its possession or Control.

## ARTICLE 5 REGULATORY

### 5.1 Regulatory Obligations.

EDESA shall be responsible, at its own cost, for, and shall have the sole right to control, all regulatory activities and strategy associated with JNDs, NDAs and all other submissions for Regulatory Approvals, all Regulatory Approvals, and the maintenance of such submissions and Regulatory Approvals, as well as seeking approval for reimbursement or pricing of a Product in the Territory, in each case with respect to the Product in the Field, including communicating and preparing and filing all reports including all INDs and NDAs with the applicable Regulatory Authorities. YISSUM shall reasonably cooperate with EDESA as requested, in preparing and filing all such reports, and YISSUM shall provide EDESA with all available information, including regulatory, technical and clinical data concerning the Product to enable EDESA to prepare and file such reports. EDESA shall pay all governmental fees associated with obtaining and maintaining any and all Regulatory Approvals including any establishment license fees of EDESA or Third Parties which must be paid with respect to facilities used in the manufacture of the Product by or on behalf of EDESA.

## 5.2 Safety Reporting.

EDESA shall be responsible for all regulatory activities relating to the Product in the Field including: (i) management and monitoring of safety and Adverse Event/experience information for; (ii) regulatory reporting; (iii) managing the global safety data base for the Product; and (iv) reviewing and approving of safety information for inclusion in the Product label in the Territory, including the costs and expenses thereof.

## 5.3 Recalls.

EDESA shall be responsible for any recall decision and the conduct of any recall in respect of the Product in the Field, including the costs and expenses thereof.

## 5.4 Pricing and Reimbursement.

EDESA shall be solely responsible for setting the price for the Product in the Field and may do so without discussion or consultation with YISSUM.

# ARTICLE 6 PAYMENTS

## 6.1 Milestone Payments.

EDESA shall immediately notify YISSUM of the achievement of any of the following development and commercial milestones, all for the Product in the Field, and EDESA shall pay to YISSUM the milestone payments listed below which shall be due and payable within thirty (30) days after the event for which the payment is due (or, for milestones based on Net Sales, within thirty (30) days after the end of the Calendar Year with respect to which such milestone is triggered):

Upon Execution of this Agreement	[ ]
Upon the 6-month Anniversary of the Execution of this Agreement	[ ]
Upon the dosing of the 1st patient into a Confirmatory Efficacy Study for the first Indication for which Regulatory Approval will be sought.	[ ]
Upon receipt of the first Regulatory Approval for the Product from the FDA	[ ]
Upon the First Commercial Sale of the Product in the United States	[ ]
First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in countries where EDESA or an Affiliate directly Commercializes the Product	[ ]

First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in countries where EDESA or an Affiliate directly Commercializes the Product [ ]

First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in countries where EDESA or an Affiliate directly Commercializes the Product [ ]

Upon divestiture of substantially all of the assets of the EDESA, during the process of evaluating the assets of the EDESA, EDESA shall pay YISSUM: [ ]% of the valuation of the Licensed Technology by an external objective expert, if the transaction is closed within 5 years from the date of the execution of this Agreement

[ ]% of the valuation of the Licensed Technology by an external objective expert, if the transaction is closed after 5 years from the date of the execution of this Agreement

For clarity, the aggregate Net Sales that are taken into account in order to calculate the achievement of a specific sales threshold milestone for a Calendar Year cannot also be taken into account in order to calculate the achievement of additional sales threshold milestone(s) in that same calendar year.

## 6.2 Product Royalties.

EDESA shall pay to YISSUM a royalty of [ ]% of Net Sales ("**Royalties**") of the Product in the countries in the Territory where it or an Affiliate directly Commercializes the Product. EDESA shall pay to YISSUM an amount equal to [ ]% of Sublicensing Revenue received by EDESA and its Affiliates ("**Sublicensing Fees**") in the countries in the Territory where it does not directly Commercialize the Product.

## 6.3 Reports; Payment of Royalty.

Following the earlier of (a) the First Commercial Sale of the Product and (b) execution of a Sublicense Agreement with a Sublicensee, EDESA shall furnish to YISSUM written reports for each fiscal quarter and each fiscal year; each such report showing in relation to the reporting period, as applicable: (i) the Net Sales of the Product in the Territory and the royalties payable under this Agreement in respect thereof; and (ii) Sublicensing Revenues received and the Sublicensing Fees payable under this Agreement in respect thereof. Reports in respect of a fiscal quarter shall be due on the thirtieth (30th) day following the close of such fiscal quarter and annual reports shall be due on the sixtieth (60th) day following the close of such fiscal year. Royalties and Sublicensing Fees shown to have accrued by each report shall be due and payable on the date such

report is due. EDESA shall keep complete and accurate records in sufficient detail to enable the Royalties and Sublicensing Fees payable hereunder to be determined.

#### **6.4 Audits.**

- (a) EDESA will keep and maintain (and to the extent applicable, will cause its Affiliates, and their respective Sublicensees, distributors, assignees and transferees to keep and maintain) proper and complete records and books of account in such form and detail as is necessary for the determination of the amounts payable by EDESA (on behalf of itself and its Affiliates and their respective Sublicensees, distributors, assignees and transferees) to YISSUM under this Agreement and for the purposes of this Agreement.
- (b) Upon the written request of YISSUM and not more than once in each Calendar Year, EDESA shall permit an independent certified public accounting firm of nationally recognized standing in the United States (that has been retained on an hourly or flat fee basis and receives no contingency fee or other bounty or bonus fee) selected by YISSUM, at YISSUM's expense, to have access during normal business hours to such of the records of EDESA as may be reasonably necessary solely to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty six (36) months prior to the date of such request. This right to audit shall remain in effect throughout the life of this Agreement and for a period of three (3) years after the termination of this Agreement.
- (c) YISSUM shall share the accounting firm's final written report with EDESA within thirty (30) days of its receipt by YISSUM. If such accounting firm identifies a discrepancy by EDESA made during such period, EDESA shall pay YISSUM the amount of the discrepancy within thirty (30) days of the date YISSUM delivers to EDESA such accounting firm's written report so concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by YISSUM unless the underpayment exceeded ten percent (10%) of the amount owed by EDESA to YISSUM for such Calendar Year, in which case, EDESA shall pay to YISSUM the reasonable fees charged by such accounting firm which fees shall not exceed \$25,000. EDESA shall pay interest on the amounts owed to YISSUM, and said interest shall be calculated as being 2% greater than the U.S. commercial prime rate as published by the Wall Street Journal on the date of the first discrepancy identified in the audit, and shall accrue from the date payments should have been made.
- (d) EDESA shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to make reports to EDESA, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by YISSUM's independent accountant to the same extent required of EDESA under this Agreement.
- (e) YISSUM shall treat all financial information subject to review in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with EDESA, its Affiliates or Sublicensees, as applicable obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

## **6.5 Payment Exchange Rate.**

All payments to be made by one Party to the other under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to a bank account designated in writing by the Party receiving the payment. In the case of sales outside the United States, royalty payments by EDESA to YISSUM shall be converted to United States Dollars in accordance with the following: the rate of currency conversion shall be calculated using a simple average of mid-month and month-end rates as provided by the spot rate as published by The Wall Street Journal, New York City Edition for such accounting period.

## **6.6 Tax Withholding.**

The Parties will withhold taxes with respect to payments under this Agreement under applicable law.

## **6.7 Late Payments.**

EDESA shall pay interest to YISSUM on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to one percent (1%) per month, calculated on the number of days such payments are paid after the date such payments are due and compounded monthly.

# **ARTICLE 7 LICENSES; EXCLUSIVITY**

## **7.1 Exclusive License and Right to Sublicense.**

Subject to the terms and conditions of this Agreement, YISSUM hereby grants EDESA and its Affiliates an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses in accordance with Section 3.5 above, to use the Licensed Technology for the Development and Commercialization of the Product in the Field in the Territory.

## **7.2 No Implied Licenses.**

Except as explicitly set forth in this Agreement, neither Party nor its Affiliates grants any license, express or implied, under its intellectual property rights to the other Party. Without limiting the foregoing, this Agreement and the licenses and rights granted herein do not and shall not be construed to confer any rights upon either Party or its Affiliates by implication, estoppel, or otherwise as to any of the other Party's or its Affiliates' intellectual property, except as otherwise expressly set forth herein.

## **7.3 Retained Rights**



Notwithstanding the provisions of Section 7.1, above, YISSUM, on behalf of the University, may submit requests to EDESA to make, use and practice portions of the Licensed Technology solely for the University's own non-commercial academic and teaching purposes provided that a specific request is submitted to EDESA by, or on behalf, of the University employee wishing to make such use, with such portions and purposes to be identified in the request. EDESA will not unreasonably withhold, condition or delay its consent to such YISSUM requests.

## ARTICLES CONFIDENTIALITY; PUBLICATION

### 8.1 Nondisclosure Obligation.

(a) Except as provided in this Section 8.1, all confidential or proprietary information disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates hereunder in connection with this Agreement, whether disclosed or provided prior to or after the Effective Date and whether provided orally, visually, electronically or in writing, shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, until five (5) years following the Term of this Agreement, except to the extent that such Information:

- (i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party under a confidentiality agreement, as documented by the receiving Party's business records;
- (ii) is or becomes part of the public domain through no fault of the receiving Party;
- (iii) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or
- (iv) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records.

All information disclosed by one Party to the other hereunder, other than described in Subsections (i) through (iv) above, is hereinafter referred to as "**Confidential Information**". The Information and the Licensed Technology and the terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties.

(b) Each Party may disclose Confidential Information of the other Party, without such other Party's prior written consent, to its and its Affiliates' directors, officers, employees, agents, consultants, Sublicensees, suppliers, and other persons or entities who:

- (i) need to know such Confidential Information to assist the Party in fulfilling its obligations hereunder or, the case of YISSUM, otherwise assists YISSUM in the Development or Commercialization of the Product outside of the Field; and
  - (ii) are bound by written confidentiality and non-use obligations consistent with those the Party uses to protect its own Confidential Information.
- (c) Each Party shall promptly disclose to the other Party the nature and scope of any breach of this provision by it, or its Affiliates, directors, officers, employees, agents, consultants, Sublicensees, suppliers, or other persons or entities permitted hereunder and the steps taken to contain and address the breach.
- (d) Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, to any person, entity, or government or Regulatory Authority to the extent that the law requires such disclosure, including filings pursuant to applicable securities or tax laws and regulations. The Party disclosing such Confidential Information shall take such actions as are reasonable to preserve the confidentiality of such Confidential Information, such as requesting confidential treatment. In addition, EDESA may also disclose YISSUM's Confidential Information, without the YISSUM's prior written consent, to any person, entity, or government or Regulatory Authority to the extent that such disclosure is necessary for obtaining, maintaining, or amending any Regulatory Approvals, seeking approval for reimbursement or pricing of a Product in the Territory or satisfying any other regulatory obligation regarding the Product. Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, pursuant to an order of a Regulatory Authority or court of competent jurisdiction, provided that it: (i) promptly notifies the other Party of the required disclosure in order to provide such Party an opportunity to take legal action to prevent or limit such disclosure and, if asked, reasonably assists the other Party in pursuing such action; and (ii) shall only disclose the Confidential Information to the minimum extent required by law.

## **8.2 Publicity; Use of Names.**

- (a) The Parties shall issue a mutually acceptable press release announcing the execution of this Agreement. A Party may issue any subsequent press release relating to this Agreement or activities conducted hereunder upon prior written approval of the other Party, such approval not to be unreasonably withheld or delayed; provided, however, that no approval of the other Party shall be required if a subsequent press release solely discloses the information that: (1) a milestone under this Agreement has been achieved and/or any payments associated therewith have been received; (2) the filing and/or Regulatory Approval of the NDA with the FDA or the EMEA generally has occurred (provided, however, that specific dates of filing shall not be disclosed); (3) commercial launch of the Product in any country or any information that has previously been approved and disclosed as permitted by this Section 8.2. In the case of items (1)-(3) of the preceding sentence,

the disclosing Party shall provide the other Party a copy of such proposed disclosures prior to the proposed release and consider in good faith any comments the other Party may make, where practicable, and in light of any reporting obligations of such disclosing Party under applicable laws, rules or regulations, including applicable securities law, Except as otherwise provided in this Section 8.2(a), neither Party shall use the name, trademark, trade name or logo of the other Party or its employees, or, in the case of YISSUM, the name or logo of the University or the name of its employees, in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party,

- (b) Notwithstanding the terms of this Article 8, either Party shall be permitted to disclose the existence and terms of this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable laws, rules or regulations, including the rules and regulations promulgated by securities law regulatory agencies or any other governmental agency, Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 8.2(b), the Parties shall consult with one another on the terms of this Agreement for which confidential treatment will be sought in making any such disclosure, If a Party wishes to disclose this Agreement or any of the terms hereof in accordance with this Section 8.2(b), such Party agrees, at its own expense, to seek confidential treatment of the portions of this Agreement or such terms as may be reasonably requested by the other Party, provided that the disclosing Party shall always be entitled to comply with legal requirements.
- (c) Either Party may also disclose the existence and terms of this Agreement to its legal counsel, investment bankers, accountants and advisors, and to potential Sublicensees, Third Party contractors, investors, lenders or acquirers, and their legal counsel, investment bankers, accountants and advisors, in each case under an agreement or in the case of legal counsel, a professional obligation, to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such Confidential Information solely for the purpose permitted pursuant to this Section 8.2(c).

## **ARTICLE 9 REPRESENTATIONS AND WARRANTIES**

### **9.1 Representations and Warranties of YISSUM.**

YISSUM represents and warrants to EDESA that as of the Effective Date:

- (a) subject to Section 9.1(d) below, it has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement, and to grant the license granted under Section 7.1, and the fulfillment of its obligations and performance of its activities hereunder will not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which YISSUM is currently bound;

- (b) to the Knowledge of YISSUM, there are no legal claims, judgments or settlements against or owed by YISSUM or pending legal claims or litigation, in each case relating to the Product the YISSUM Licensed Technology including, without limitation, legal claims made by the Researcher;
- (c) subject to Section I 3.11, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by YISSUM as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;
- (d) based on the accuracy of the information provided to YISSUM by the Researcher, YISSUM Controls the right, title and interest in and to the Licensed Technology, and has the right to grant to EDESA the licenses that it purports to grant hereunder and has not granted any Third Party rights that would interfere or be inconsistent with EDESA 's rights hereunder;
- (e) to the Knowledge of YISSUM, there is no action, suit, inquiry, investigation or other proceeding threatened, pending or ongoing brought by any Third Party that alleges the use of the Licensed Technology or the Development and/or Commercialization of the Product would infringe or misappropriate the intellectual property or intellectual property rights of any Third Party (and it has not received any notice alleging such an infringement or misappropriation). In the event that YISSUM becomes aware of any such action or proceeding, it shall promptly notify EDESA in writing;
- (f) YISSUM does not have any current knowledge that would cause any of its representations or warranties to EDESA to be incorrect or untrue.

## **9.2 Representations and Warranties and Covenants of EDESA.**

EDESA represents and warrants to YISSUM that as of the Effective Date:

- (a) it has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which EDESA is bound;
- (b) subject to Section 13.11, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by EDESA as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;
- (c) EDESA does not have any current knowledge that would cause any of its representations or warranties to YISSUM to be incorrect or untrue;

- (d)to the Knowledge of EDESA, neither EDESA nor any of its Affiliates, nor any of its employees or agents (i) is debarred, excluded, suspended, proposed for debarment or otherwise ineligible for participation in any federal, state or provincial health care program; (ii) has been convicted of or had a civil judgment rendered against it for commission of fraud or a criminal offense; and (iii) is presently indicted for or otherwise criminally or civilly charged by a governmental entity or agency with commission of any of the offenses set out in this paragraph;
- (e)EDESA (i) acknowledges that the Patents listed in Appendix B3 are currently in the process of being assigned in full to Yissum and, until such assignments are perfected, they are not part of the Licensed Technology; and (ii) that Yissum has agreed to included them as part of the Licensed Technology once such assignments have been perfected.

### **9.3 Representations and Covenants of Both Parties.**

Each Party shall, and shall cause its Affiliates and agents to, comply with laws, rules, regulations and guidelines and related to the performance of its obligations hereunder and applicable to such Party, including the United States Food, Drug and Cosmetics Act and the Food and Drugs Act (Canada) and the regulations promulgated thereunder, and their foreign counterparts.

### **9.4 No Other Representations or Warranties.**

- (a)EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. SPECIFICALLY,
- (b)IN PARTICULAR, YISSUM MAKES NO EXPRESS OR IMPLIED WARRANTIES THAT THE USE BY EDESA, ITS AFFILIATES OR ANY OTHER THIRD PARTY OF THE LICENSED TECHNOLOGY WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS OF ANY THIRD PARTY. IN ADDITION, NOTHING IN THIS AGREEMENT MAY BE DEEMED A REPRESENTATION OR WARRANTY BY YISSUM AS TO THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE LICENSED TECHNOLOGY, WHICH IS BEING LICENSED TO EDESA STRICTLY ON AN "AS IS" BASIS. YISSUM HAS NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY PRODUCT. TO THE EXTENT PERMITTED BY APPLICABLE LAW, NEITHER YISSUM NOR THE RESEARCHER, NOR TI-IE UNIVERSITY, NOR TI-IE REPRESENTATIVES OF YISSUM AND/OR OF THE UNIVERSITY SHALL HAVE ANY LIABILITY WHATSOEVER TO EDESA, AN AFFILIATE OR A SUBLICENSEE, OR TO ANY THIRD PARTY FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE WHETHER DIRECT OR INDIRECT, SUSTAINED BY EDESA, AN AFFILIATE OR A SUBLICENSEE, OR BY ANY THIRD PARTY, FOR ANY DAMAGE ASSESSED OR ASSERTED AGAINST EDESA, OR FOR ANY OTHER LIABILITY INCURRED BY OR IMPOSED UPON THE COMPANY OR ANY OTHER PERSON OR ENTITY, DIRECTLY OR INDIRECTLY ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM THIS AGREEMENT AND/OR TI-IE EXERCISE OF THE LICENSE, INCLUDING, (i) THE PRODUCTION, MANUFACTURE, USE, PRACTICE, LEASE, OR SALE OF ANY PRODUCT; (ii) THE USE OF THE LICENSED TECHNOLOGY; OR (i) ANY ADVERTISING OR OTHER PROMOTIONAL ACTIVITIES WITH RESPECT TO ANY OF THE FOREGOING.

## ARTICLE 10 INDEMNIFICATION

### 10.1 General Indemnity By EDESA.

EDESA shall indemnify and hold harmless YISSUM, its Affiliates, the University, and their respective directors, officers, employees and agents (individually and collectively, the "**YISSUM Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable legal fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") first arising after the Effective Date to the extent arising from: (a) the Development or Commercialization of the Product by EDESA or any of its Affiliates or Sublicensees; (b) the use of the Product manufactured or sold by EDESA or any of its Affiliates or Sublicensees by any purchasers thereof including any product liability claim; (c) the use by EDESA or any of its Affiliates or Sublicensees of the Licensed Technology; except to the extent such Losses result directly from, or arise directly out of, the gross negligent or willful misconduct of the YISSUM Indemnitee(s).

### 10.2 Limited Indemnity To Be Granted to EDESA.

In the event that the YISSUM Licensed Technology is licensed by YISSUM to a Third Party for Development and Commercialization outside the Field (a "**Non-Field License**"), YISSUM shall ensure that such Non-Field License include an obligation by such Third Party licensee to indemnify and hold harmless EDESA who will be included as a party similar to a YISSUM Indemnitee hereunder, along with its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**EDESA Indemnitee(s)**") from and against all Losses first arising after the execution of such Non-Field License to the extent arising from: (a) the Development or Commercialization of the YISSUM Licensed Technology outside the Field by such Third Party licensee; (b) the use of the Product manufactured or sold by Third Party licensee outside the Field by any purchasers thereof including any product liability claim; (c) the use by Third Party licensee of the Licensed Technology; except to the extent such Losses result directly from, or arise directly out of, the gross negligent or willful misconduct of the EDESA Indemnitee(s). Notwithstanding the foregoing, YISSUM's obligation pursuant to this Section 10.2 shall be contingent upon EDESA assuming a similar written obligation towards any Third Party licensee granted a Non-Field License.

### **10.3 Defense.**

If any such claims or actions are made, the YISSUM Indemnitee shall be defended at the EDESA's sole expense by counsel selected by EDESA and reasonably acceptable to the YISSUM indemnitee, provided that the YISSUM indemnitee may, at its own expense, also be represented by counsel of its own choosing. EDESA shall have the sole right to control the defense of any such claim or action, subject to the terms of this Article 10.

### **10.4 Settlement.**

EDESA may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment: (a) with prior written notice to the YISSUM indemnitee but without the consent of the YISSUM indemnitee, where the only liability to the Indemnitee is the payment of money and EDESA makes such payment; or (b) in all other cases, only with the prior written consent of the YISSUM indemnitee, such consent not to be unreasonably withheld.

### **10.5 Notice.**

The YISSUM indemnitee shall notify EDESA promptly of any claim, demand, action or other proceeding under Section 10.1 or Section 10.2 and shall reasonably cooperate with all reasonable requests of EDESA with respect thereto.

### **10.6 Permission by EDESA.**

The YISSUM indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of EDESA.

### **10.7 Limitation of Liability.**

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.7 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EDESA UNDER ARTICLE 10 OR ARTICLE 12.3, OR DAMAGES AVAILABLE FOR EITHER PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 8.



## 10.8 Insurance.

EDESA shall maintain in good standing throughout the Term of this Agreement and for a period of seven (7) years thereafter, product liability insurance policies in respect of the Product with an internationally recognized insurer or insurers licensed to do business in the Territory in an amount of not less than \$2.0 million per occurrence, and not less than \$2.0 million in the aggregate, on such terms and conditions as are customary in the industry. EDESA shall provide proof of such insurance to YISSUM within thirty (30) days of the Effective Date and thereafter from time to time within thirty (30) days of request of proof of such insurance.

## ARTICLE 11 INVENTIONS; PATENT PROVISIONS

### 11.1 Ownership of Intellectual Property.

As between the Parties, YISSUM shall remain the sole and exclusive owner of the Licensed Technology. EDESA shall be the sole and exclusive owner of all patents, trademarks, know-how, data and other intellectual property that is conceived, discovered, invented, made or first reduced to practice by, or on behalf of, EDESA on or after the Effective Date, including all improvements, variations, modifications or enhancements of the Licensed Technology conceived, discovered, invented, made or first reduced to practice by, or on behalf of, EDESA after the Effective Date and including the EDESA Data.

### 11.2 Patent Prosecution

EDESA will be responsible for preparing, filing, prosecuting and maintaining the Patents in Yissum's name, and may elect to file applications for such other patents as EDESA deems necessary to protect the Licensed Technology ("**Patent Management**"). EDESA will (a) provide to Yissum all material information and documents received, prepared or filed in connection with the Patents, (ii) consult with YISSUM before taking any substantive actions related to the Patent Management and (iii) consider all comments and changes suggested by YISSUM in relation to the Patent Management. If EDESA intends to abandon, allow to lapse, or not continue the Patent Management of any Patent, then EDESA will, not less than 60 days before any required action relating to such Patent, notify YISSUM and YISSUM will then have the right, at its option, to assume the Patent Management of such Patent, in which case such Patent will be excluded from the Licensed Technology. To assist EDESA with the Patent Management, YISSUM will, at the reasonable request of EDESA, cooperate with EDESA, including provision of required information, and will execute and deliver documents (including powers of attorney) and do such other reasonable acts as EDESA may request.

### 11.3 Fees

From May 9 2016, EDESA shall be responsible for (a) all costs associated with the Patent Management of the Patents listed in Appendices B(1) and B(2); and (b) fifty percent (50%) of all costs associated with the Patent Management of the Patents listed in Appendix 13(3) until such time as the Patents listed in Appendix B(3) are fully assigned to Yissum (the "**Full Assignment**"), at which point EDESA shall be responsible for all costs associated with the Patent Management of the Patents listed in Appendix 13(3). Within 60 days of the receipt of any invoice in relation to the

costs associated with the Patent Management of the Patents listed in Appendix B(3) until their Full Assignment, YISSUM will reimburse EDESA for one-half of such costs. Such Patent costs will not be refunded to YISSUM (in whole or in part) under any circumstances.

#### 11.4 Enforcement.

- (a) **Notice.** Each Party shall promptly provide, but in no event later than forty-five (45) days, the other with written notice reasonably detailing any known or alleged infringement or misappropriation of any Licensed Technology.
- (b) **Enforcement of Intellectual Property Rights.** EDESA shall have the right, but not the obligation, to institute and direct legal proceedings against any Third Party believed to be infringing or misappropriating or otherwise violating the Licensed Technology. YISSUM agrees to co-operate to the extent reasonably necessary, including signing of all necessary documents to vest in EDESA the right to start such legal proceedings, provided that all the direct and indirect costs and expenses of bringing and conducting the legal proceedings are paid by EDESA (except for the expenses of YISSUM's counsel, if any). All amounts recovered by EDESA as the result of such legal proceedings will accrue to the benefit of EDESA, provided that such amounts awarded as compensation for lost sales revenue will be included in EDESA's Sublicensing Revenue if the action occurs in any country in the territory EDESA does not directly commercialize the Product and treated as Net Sales in any country in the Territory that EDESA commercializes the Product (after deduction of EDESA's costs and expenses of legal proceedings) upon which Royalties will be paid to YISSUM.

#### 11.5 Defense.

- (a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the Development or Commercialization of the Product or use of the Licensed Technology infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than forty five (45) days, following receipt of such allegations.
- (b) In the event that a Party receives notice that it or any of its Affiliates have been individually named as a defendant in a legal proceeding by a Third Party alleging infringement of a Third Party's patents or other intellectual property right as a result of the Development or Commercialization of the Product or use of the Licensed Technology, such Party shall immediately notify the other Party in writing and in no event notify such other Party later than forty five (45) days after the receipt of such notice. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof. In such event, the Parties shall agree how best to mitigate or control the defense of any such legal proceeding; provided however, that EDESA shall assume the primary responsibility for the conduct of the defense of any such claim that is specific to the Field, at EDESA's expense, and YISSUM shall assume the primary responsibility for the conduct of the defense of any other such claim, at YISSUM's expense. Notwithstanding the foregoing, YISSUM may forego assuming the primary responsibility for the conduct of the defense of any such claim outside the Field, in which case EDESA shall have the right, but not the obligation, to assume such primary responsibility at its own expense. The Party that does not assume primary responsibility for the conduct of the defense shall have the right, but not the obligation, to participate and be separately represented in any such suit at its sole option and at its own expense. Each Party shall reasonably cooperate with the Party conducting the defense of the claim. If a Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement of a Third Party's patents or other intellectual property right as a result of the Development or Commercialization of the Product, the other Party shall be allowed to join in such **action, at its own expense.**

(c) **Status; Settlement.** The Parties shall keep each other informed of the status of and of their respective activities regarding any litigation or settlement thereof initiated by a Third Party concerning the Development or Commercialization of the Product or the Licensed Technology; provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this subsection 11.5(c) may be undertaken by a Party without the consent of the other Party which consent shall not be unreasonably withheld or delayed.

## ARTICLE 12

### TERM AND TERMINATION

#### 12.1 Term.

This Agreement shall be effective as of the Effective Date and shall expire on a country by-country basis on (a) the date of expiry of the last valid Patent in such country; (b) the date of expiry of any period of exclusivity granted to the Product by a Regulatory Authority in such country or (c) the date that is fifteen (15) years after the First Commercial Sale, whichever is last to occur, unless terminated earlier in accordance with this Agreement (the "**Term**").

#### 12.2 Termination for Cause.

(a) **Breach.** This Agreement may be terminated upon written notice by either Party if the other Party has materially breached its obligations under this Agreement and has not cured such breach within forty-five (45) days of receipt of written notice of such breach by the other Party.

(b) **Bankruptcy.** This Agreement may be terminated upon written notice by either Party if the other Party (i) makes a general assignment for the benefit of creditors; (ii) files any petition, or commences any proceeding voluntarily, for any relief under any bankruptcy or insolvency laws or any law relating to the relief of debtors; (iii) consents to the entry of an order in an involuntary bankruptcy or insolvency case; (iv) is the subject of an order or decree for relief against it by a court of competent jurisdiction in an involuntary case under any bankruptcy or insolvency laws or any law relating to the relief of debtors, which order or decree is unstayed and in effect for a period of 60 consecutive days; (v) is subject to appointment, with or without its consent, of any receiver, liquidator, custodian, assignee, trustee, sequestrator or other similar official of such other Party or any substantial part of its property; or (vi) admits in writing of its inability to pay its debts generally as they become due.

(c) **Failure to Develop.** If YISSUM alleges that EDESA has failed to use commercially reasonable efforts to Develop the Product, this Agreement may be terminated by YISSUM upon written notice to EDESA if commercially reasonable efforts to Develop the Product have not commenced within two hundred and sixty (260) days of receipt of written notice of such failure by EDESA.

### 12.3 Termination Without Cause.

EDESA may terminate this Agreement in its entirety if it decides, in its sole discretion, that the Development and Commercialization of the Product is no longer commercially viable.

### 12.4 Effect of Termination.

(a) Upon the termination of this Agreement, then:

- (i) The license granted to EDESA under Section 7.1 and any sublicenses that have been granted to a Sublicensee with respect to Licensed Technology shall terminate.
- (ii) Unless the Parties agree otherwise, all activities underway at the time of termination shall be terminated as soon as possible except for winding down activities (including such activities) in connection with any Clinical Trials (the cost of which shall continue to be borne by EDESA as provided in this Agreement until completion of such activities in the normal course). For the sake of clarity the costs of winding down activities shall include any incurred costs or otherwise unavoidable wind down costs that would otherwise have been payable by EDESA.
- (iii) Unless this Agreement is terminated by EDESA pursuant to Section 12.2(a) or 12.2(b), EDESA shall transfer and assign YISSUM, upon YISSUM's request, all of the EDESA Data and any patent applications and issued patents relating to the Product owned by EDESA (the "**EDESA Assigned IP**"), provided that YISSUM pays all reasonable, out-of-pocket expenses actually incurred by EDESA in connection with such transfer and assignment. EDESA shall fully cooperate with the Licensor to effect such transfer and assignment and shall execute any document and perform any acts required to do so. The EDESA DATA SHALL BE PROVIDED ON AN "AS IS, WHERE IS" BASIS WITHOUT ANY EXPRESS OR IMPLIED WARRANTIES AS TO THE FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR CONDITION OR AS TO THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON OR AS TO ANY OTHER MATTER.

- (iv) Without derogating from the force and effect of the foregoing assignment undertaking in Section 12.4(a)(iii), the Parties acknowledge and agree that if under applicable law the aforesaid assignment undertaking will not be fully enforceable, then the part (if any) of such undertaking which is enforceable shall remain in full force and effect, and the part (or whole) which is not enforceable shall be automatically replaced with an irrevocable grant by EDESA to YISSUM, binding upon all of EDESA'S acquirers, successors and assignees, of an unrestricted, perpetual, irrevocable, world-wide, royalty-free, exclusive license to use, exploit, Transfer and sub-license (on a multi-tier basis) the EDESA Assigned IP for any and all purposes and uses
- (v) Notwithstanding anything to the contrary in this Section 12.4, if this Agreement is terminated by EDESA pursuant to Section 12.2 or 12.3, EDESA shall have the right to sell its remaining inventory of Product(s) so long as EDESA has fully paid, and continues to pay fully when due, any and all Royalties and Sublicensee Fees owed to YISSUM hereunder based on such sales.
- (vi) Following any termination of this Agreement, YISSUM shall pay to EDESA [ ]% of the amounts received by YISSUM or its Affiliates as royalties or sublicensing fees arising from the license of the Licensed Technology to a Third Party, up to a maximum amount equal to twice the documented amount EDESA has expended on the Development or Commercialization of the Product. In furtherance of EDESA's right under this Section 12.4(vi), YISSUM shall provide prompt notice to EDESA upon the execution of any such license and shall thereafter provide to EDESA written reports for each Calendar quarter and each Calendar Year; each such report showing in relation to the reporting period, as applicable: the royalties and sublicensing fees received by YISSUM under such license. Reports in respect of a Calendar Quarter shall be due on the thirtieth (30th) day following the close of such Calendar Quarter and annual reports shall be due on the sixtieth (60th) day following the close of such Calendar Year. Royalties and sublicensing fees shown to have been received in each report shall be due and payable by YISSUM on the date such report is due. YISSUM shall keep complete and accurate records in sufficient detail to enable the royalties and sublicensing fees received by YISSUM under such license to be determined and EDESA shall have the right to audit such records on terms consistent with those set forth in Section 6.4 of this Agreement. For purposes of this Section 12.4(vi), the terms "royalties" and "sublicensing fees" in relation to amounts received from Third Parties shall have the same meanings as are set forth in this Agreement, but replacing references to "EDESA" with the name of the Third Party to whom YISSUM has licensed the Licensed Technology.
- (b) If either Party has the right to terminate this Agreement under Section 12.2, it may at its sole option, elect either to: (i) terminate this Agreement and pursue any legal or equitable remedy available to it; or (ii) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

## **12.5 Survival.**

Any payments accruing hereunder shall continue to be due and owing following termination of this Agreement. In addition, the following provisions shall survive the termination of this Agreement for any reason: Articles 1, 6.4, 8, 9, 10, 11, 12 and 13.

## **ARTICLE 13 MISCELLANEOUS**

### **13.1 Force Majeure.**

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly under take reasonable efforts necessary to mitigate such force majeure circumstances.

### **13.2 Assignment.**

Either Party may assign its rights or obligations under this Agreement without prior written notice to the other Party or as part of a sale of all or substantially all of its assets to a Third Party, provided that such Third Party agrees, in writing, to assume the assigning Party's obligations under this Agreement.

### **13.3 Severability.**

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

### **13.4 Notices.**

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by email (and promptly confirmed by personal delivery, registered or

certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to YISSUM, to:

YISSUM  
Attn: VP, Health Care  
Hi-Tech Park, Edmond J. Safra Campus,  
**Givat-Ram,**  
Jerusalem P.O. Box 39135, Jerusalem,  
Israel Email: shoshi.keynan@yissum.co.il

with a copy (which shall not constitute notice) to:

Attn: General Counsel  
Email: bob.trachtenberg@yissum.co.il

if to EDESA, to:

Edesa Biotech Inc.  
Attn: Director I 00 Spy Corn  
Markham, Ontario L3R5H6  
Email: par@exzell.com

with a copy (which shall not constitute notice) to:

Attn: Wojtek Baraniak ■  
Email: wbaraniak@fasken.com

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by email on a business day; (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth business day following the date of mailing if sent by mail.

### **13.5 Applicable Law and Litigation.**

This Agreement shall be governed by and construed in accordance with the laws of the England and Wales, without reference to any rules of conflict of laws. For controversies, claims and disputes not covered by the arbitration provisions pursuant to Section 13.14, and for injunctive or other equitable interim relief in relation to all controversies, claims and disputes arising out of or relating to this Agreement, the Parties irrevocably and unconditionally: (a) consent to the exclusive jurisdiction of the courts of England, located in London for any action, suit or proceeding and relating to injunctive or other equitable relief, and agree not to commence any action, suit or proceeding related thereto except in such courts; and (b) waive any objection to the laying of venue of any action, suit or proceeding in the courts of England, located in London and waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

### **13.6 Entire Agreement; Amendments.**

This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof are superseded by the terms of this Agreement. On the Effective Date, the confidentiality agreement between the Parties effective February 17 2016 shall terminate and all Confidential Information exchanged thereunder shall be deemed Confidential Information of the Party disclosing such information and protected under this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.

### **13.7 Independent Contractors.**

The Parties shall be independent contractors and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

### **13.8 Waiver.**

The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

### **13.9 Cumulative Remedies.**

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

### **13.10 Waiver of Rule of Construction.**

Each Party has had the opportunity to consult with legal counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

### **13.11 Further Assurances.**

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement. Each Party shall use its commercially reasonable efforts to take all actions necessary or advisable under applicable laws to consummate and make effective the transactions contemplated by this Agreement including the taking of such reasonable actions as are necessary to obtain any requisite approvals, consents, orders, exemptions or waivers by any governmental authority.



### 13.12 Construction.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. **References to "Section" or "Sections" are references to the numbered sections of this Agreement**, unless expressly stated otherwise.

### 13.13 Currency.

All payments under this Agreement shall be made in United States Dollars. All references to "dollars" or "\$" in this Agreement are to United States Dollars.

### 13.14 Dispute Resolution.

- (a) Any controversy, claim or dispute arising out of or relating to this Agreement shall first be submitted to the CEO of each Party for attempted resolution. If the CEOs of the Parties do not resolve such matter within thirty (30) days of the matter being submitted to them, then such matter shall be resolved through binding arbitration as follows. For the sake of clarity, this Section 13.14 is not intended to alter the rights of the Parties as established by Article 2, Governance, herein. The dispute shall be resolved by final and binding arbitration. The place of arbitration shall be London, England. The arbitration shall be in accordance with the rules of LCIA except as modified herein. The number of arbitrators shall be three. The language of the arbitration shall be English.
- (b) The Party wishing to commence an arbitration ("**Claimant**") shall notify the other party ("**Respondent**") in writing of its decision to commence arbitration hereunder (sometimes referred to in this Agreement as its "**demand for arbitration**"), setting out briefly its claims in its notice, and with its notice, name the arbitrator it is appointing.
- (c) The Respondent shall, within thirty (30) days of receipt of a demand for arbitration, notify the Claimant in writing of the name of the arbitrator it is appointing.
- (d) The third arbitrator shall be chosen by the first two arbitrators within twenty (20) days after the second of such arbitrators was appointed.
- (e) All arbitrators shall be chosen taking into account the type of issues to be addressed in the arbitration, whether legal, business, scientific, or a combination thereof, and having regard to their availability to conduct the arbitration within the times provided below. (The date on which the third arbitrator is appointed is the "**Arbitration Panel Finalization**").

- (f) Within thirty (30) days of completion of the hearing, the arbitrators shall render a reasoned arbitration award describing, in writing, the essential finding and conclusions on which the decision is based, including the calculation of any damages awarded. Any monetary award shall be made within thirty (30) days of the rendering of such award.
- (g) All information and documents in relation to the arbitration shall be deemed Confidential Information to the full extent permitted by law. No individual shall be appointed as an arbitrator unless the individual first agrees in writing to be bound by this subsection and to conduct the arbitration in a manner that in his/her judgment is most likely to maintain the confidentiality of Confidential Information. Neither Party may retain any expert in connection with the arbitration unless the expert first agrees in writing to be bound by this subsection, as applicable. The fact of and subject matter of the arbitration, including the fact that any dispute has been submitted to arbitration, and all evidence given and submissions made in connection with any arbitration, shall be Confidential Information, and shall be treated as such by the Parties and all persons employed by or contracted to them. Any meetings, conferences or hearings in connection with or during the arbitration may be attended only by those individual persons whose presence, in the opinion of the arbitral tribunal, is reasonably necessary for the determination or other resolution of the dispute and such person first agrees in writing to be bound by the provisions of these sections, as applicable. The obligations under this subsection continue notwithstanding any determination or other resolution of the arbitration.
- (h) The arbitrators shall be paid reasonable fees plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:
- (i) If the arbitrators rule in favour of one Party on all disputed issues in the arbitration, the losing Party shall pay 100% of such fees and expenses.
  - (ii) If the arbitrators rule in favour of one Party on some issues and the other Party on other issues, the arbitrators shall issue with the ruling a written determination as to how such fees and expenses shall be allocated between the Parties. The arbitrators shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the arbitration, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.
- (i) Any final award of the arbitrators shall be final, conclusive and binding on the Parties, and judgment may be entered in any court of competent jurisdiction. To the extent lawful, the Parties exclude any right of review or appeal to Canadian, United States, English, Israeli or other court, including in connection with any question of law arising in the arbitration or in connection with any award or decision made by the arbitrators, except as is necessary to recognize or enforce such award or **decision**.

### **13.15 Statute of Limitations.**

In no event will a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such a dispute between the Parties would otherwise be barred by the applicable statute of limitations.

### **13.16 Injunctive and Other Interim Relief.**

Nothing in this Agreement shall be construed as limiting in any way the right of a Party to seek injunctive or other interim relief from a court of competent jurisdiction with respect to any actual or threatened breach of this Agreement, or to preserve or protect any property or assets pending an arbitral award, or otherwise in support of the contemplated or pending arbitration. No such court application shall be taken as a waiver or impairment of arbitration.

### **13.17 Execution in Counterparts; Facsimile Signatures.**

This Agreement may be executed in counterparts, each of which counterpart, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or scanned and emailed copies shall be deemed to be original signatures.

*[Remainder of the Page Intentionally Left Blank]*

The Parties have executed this Agreement as of the Effective Date.

**YISSUM PHARMACEUTICALS INC>**

By: /s/ Shoshi Keynan  
Name: Shoshi Keynan  
Title: VP Licensing, Pharmaceuticals

By: /s/ Yaacov Michlin  
Name: Yaacov Michlin  
Title: CEO of Yisum

**RESEARCHER**

By: /s/ Saul Yedger  
Name: Saul Yedger  
Title: Professor

**EDESA BIOTECH INC.**

By: /s/ Pardeep Nijhawan  
Name: Pardeep Nijhawan  
Title: Director

By: \_\_\_\_\_  
Name:  
Title:

## Appendix A (Development Plan)

First 6 months from Execution of the Agreement

- External Review of the existing IND
- Preparation of regulatory documents for meeting with Regulatory Authorities
- Meeting with the Researcher to discuss potential research projects relevant to the development of the Product.

Within the 6-12 months from the Execution of the Agreement

- Request for meeting with or submission of questions to Regulatory Authorities
- Meeting/Interaction with Regulatory Authorities
- Review of feedback/responses from Regulatory Authorities
- Identification and engagement of CMO to produce Product Within the 12-18 months from Execution of the Agreement
- Submission of IND or equivalent if no additional studies are required by the regulatory authorities or initiation of any studies mandated by Regulatory Authorities to submit IND or equivalent

Within the 18-24 months from Execution of the Agreement

- Initiation of first clinical study if IND or equivalent if Regulatory Authorities required no additional studies for approval or completion and submission of **IND** or equivalent if additional pre-clinical studies were required by Regulatory Authorities.

Every additional 12 months

- Parties meet to discuss specific targets but EDESA will continue to use reasonable efforts to advance the Product.

**Appendix B  
(Patents)**

(1)Licensed Composition of Matter Patents:

Patent/ Application	Title	Yissum ref.
us 8,865,878	Use of Lipid Conjugates In the Treatment of Disease	2510-51
CA 2,558,416	Use of Lipid Conjugates In the Treatment of Disease	2510-18
EP 1758595	Use of Lipid Conjugates In the Treatment of Disease	

(2)Method of Use or Other patents.

Patent/ Application	Title	Yissum ref.
us 7,772,196	Use of Lipid Conjugates In the Treatment of Disease	2510-14
us 8,901,103	Use of Lipid Conjugates In the Treatment of Disease	2510-44
AU 2011201154	Use of Lipid Conjugates In the Treatment of Disease	2507-AU

(3)Patents need to be assigned to Yissum

Patent/ Application	Title	Yissum ref.
us 2014-0199241 us 14/115,869	LIPOSOMES COMPRISING POLYMER- CONJUGATED LIPIDS AND RELATED USES	4097-08
CA 2834918	LIPOSOMES COMPRISING POLYMER- CONJUGATED LIPIDS AND RELATED USES	4097-06
EP 2706988	LIPOSOMES COMPRISING POLYMER- CONJUGATED LIPIDS AND RELATED USES	4097-04
us 2015-0119567 us 14/525111	Lipid-polymer conjugates, their preparation and use thereof	3860-09
CA 2761590	Lipid-polymer conjugates, their preparation and use	3860-08

	thereof	
EI' 2429532	Lipid-polymer conjugates, their preparation and use thereof	3860-04

**FIRST AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT**

This First Amendment ("**First Amendment**"), effective as of April 3, 2017 ("**Effective Date**"), is entered into by and between Yissum Research Development Company of the Hebrew University of Jerusalem, an Israeli corporation with its principal office at Hi-Tech Park, Edmond J. Safra Campus, Givat-Ram, Jerusalem P.O. Box 39135, Jerusalem 91390 Israel ("**YISSUM**"), and Edesa Biotech Inc., an Ontario corporation with its principal office at 100 Spy Court, Markham, Ontario, L3R 5H6 ("**EDESA**"). YISSUM and EDESA may be referred to herein individually as a "**Party**" or collectively as the "**Parties**". Reference to a Party shall be deemed to include that Party's Affiliates.

**RECITALS:**

- A. The Parties executed a license agreement on June 29, 2016 (the "**License Agreement**") pursuant to which Yissum granted EDESA an exclusive, worldwide license to use the Licensed Technology for the Development and Commercialization of the Product in the Field in the Territory; and
- B. Pursuant to the License Agreement, the Licensed Technology did not include the Patents listed in Appendix B/3 annexed to the License Agreement (the "**B/3 Patents**") since at that time they were not fully assigned to YISSUM; but YISSUM had agreed to include them in the Licensed Technology upon full assignment of such patents to YISSUM.
- C. Pursuant to the License Agreement, EDESA agreed to pay fifty percent (50%) of all costs associated with the Patent Management of the B/3 Patents until YISSUM had received full assignment of such patents, at which point, EDESA would be responsible for one hundred percent (100%) of all costs associated with the Patent Management of the B/3 Patents.
- D. The Parties wish to amend Appendix B and certain sections of the License Agreement with respect to the B/3 Patents, as well as other patents.

In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

1. Interpretation and Definitions
  - 1.1. The preamble and appendices annexed to this First Amendment constitute an integral part hereof and shall be read jointly with its terms and conditions.
  - 1.2. In this Amendment, unless otherwise required or indicated by the context, the singular shall include the plural and *vice-versa*, the masculine gender shall include the female gender, and the use of the word "or" shall mean "and/or".
  - 1.3. The headings of the sections in this Amendment are for the sake of convenience only and shall not serve in the interpretation of the Agreement.



- 1.4. In this Amendment, capitalized terms shall have the meanings set forth in the License Agreement, unless provided otherwise herein.
2. The Parties acknowledge that the U.S. and Canadian patents that are part of the B/3 Patents have been fully assigned to YISSUM as of March 26, 2017 (the "**Assignment Date**") and shall be included in the Licensed Technology, and further acknowledge that by reason of such assignment, pursuant to section 11.3 of the License Agreement, EDESA is responsible for one hundred percent (100%) of all costs associated with the Patent Management of these patents as of the Assignment Date.
3. The following US patent, which was always owned solely by Yissum but was licensed to Celsus, shall be added to Appendix B/1 of the License Agreement:

US Patent No. 8,383,787: Use of Lipid Conjugates In the Treatment of Disease (Yissum Ref: 2510-90).
4. The Parties have agreed to update the version of Appendix B annexed to the License Agreement by replacing it in its entirety by the new Appendix B attached to this First Amendment.
5. This First Amendment shall be read together with the License Agreement and shall represent the complete current understanding between the Parties hereto with respect to the subject matter hereof.
6. Unless otherwise specifically stated in this First Amendment, all of the terms and conditions set forth in the Agreement remain in full force and effect. In any event of a conflict between and conditions contained in this First Amendment and the License Agreement, the terms contained in this First Amendment shall govern.
7. This First Amendment may be executed in counterparts and executed signature pages may be sent by fax and e-mail via PDF, all of which taken together shall be deemed to constitute one and the same instrument.

*[Signature on the next page]*

IN WITNESS WHEREOF, the parties have caused this First Amendment to be executed by their duly authorized representatives as of the Effective Date.

YISSUM

EDESA BIOTECH INC.

By: /s/ Shoshi Keynan

By: /s/ Pardeep Nijhawan

Name: Shoshi Keynan, Ph.D.

Name: Pardeep Nijhawan

Title: VP Licensing, Pharmaceuticals

Title: Director

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

Name: \_\_\_\_\_

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

**Prof. Yedgar Acknowledgment**

/s/ Saul Yedgar

## Appendix B

### (Patents)

#### (1) Licensed Composition of Matter Patents:

Patent/ Application	Title	Yissum ref
us 8,865,878	Use of Lipid Conjugates In the Treatment of Disease	2510-51
CA 2,558,416	Use of Lipid Conjugates In the Treatment of Disease	2510-18
EP 1758595	Use of Lipid Conjugates In the Treatment of Disease	2510-19
us 8,383,787:	Use of Lipid Conjugates In the Treatment of Disease	2510-60
us 2014-0199241 us 14/ 115,869	Liposomes comprising polymer- Conjugated lipids and uses	4097-08
CA 2834918	Liposomes comprising polymer- Conjugated lipids and uses	4097-06
us 2015-0119567 us 14/525111	Lipid-polymer conjugates, their preparation and uses thereof	3860-09
CA 2761590	Lipid-polymer conjugates, their preparation and uses thereof	3860-08

#### (2) Method of Use or Other patents.

Patent/ Application	Title	Yissum ref.
us 7,772,196	Use of Lipid Conjugates In the Treatment of Disease	2510-14
us 8,901,103	Use of Lipid Conjugates In the Treatment of Disease	2510-44
AU 2011201154	Use of Lipid Conjugates In the Treatment of Disease	2507-AU

(3) Patents still need to be assigned to Yissum and included in the Licensed Technology.

Patent/ Application	Title	Yissum ref.
EP 2706988	Liposomes comprising polymer-Conjugated lipids and uses	4097-04
EP 2429532	Lipid-polymer conjugates, their preparation and uses thereof	3860-04

**SECOND AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT**

This Second Amendment ("**Second Amendment**"), effective as of May 7, 2017 ("**Effective Date**"), is entered into by and between Yissum Research Development Company of the Hebrew University of Jerusalem, an Israeli corporation with its principal office at Hi-Tech Park, Edmond J. Safra Campus, Givat-Ram, Jerusalem P.O. Box 39135, Jerusalem 91390 Israel ("**YISSUM**"), and Edesa Biotech Inc., an Ontario corporation with its principal office at 100 Spy Court, Markham, Ontario, L3R 5H6 ("**EDESA**"). YISSUM and EDESA may be referred to herein individually as a "**Party**" or collectively as the "**Parties**". Reference to a Party shall be deemed to include that Party's Affiliates.

**RECITALS:**

- A. The Parties executed a license agreement on June 29, 2016, as amended on April 3, 2017 (collectively, the "**License Agreement**") pursuant to which Yissum granted EDESA an exclusive, worldwide license to use the Licensed Technology for the Development and Commercialization of the Product in the Field in the Territory; and
- B. Pursuant to the License Agreement, the Licensed Technology did not include the European Patents listed in Appendix B/3 annexed to the License Agreement (the "**European B/3 Patents**") since at that time they were not fully assigned to YISSUM; but YISSUM had agreed to include them in the Licensed Technology upon full assignment of such patents to YISSUM.
- C. Pursuant to the License Agreement, EDESA agreed to pay fifty percent (50%) of all costs associated with the Patent Management of the European B/3 Patents until YISSUM had received full assignment of such patents, at which point, EDESA would be responsible for one hundred percent (100%) of all costs associated with the Patent Management of the B/3 Patents.
- D. The Parties wish to amend Appendix Band certain sections of the License Agreement with respect to the B/3 Patents, as well as other patents.

In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

**1. Interpretation and Definitions**

- 1.1. The preamble and appendices annexed to this First Amendment constitute an integral part hereof and shall be read jointly with its terms and conditions.
- 1.2. In this Amendment, unless otherwise required or indicated by the context, the singular shall include the plural and *vice-versa*, the masculine gender shall include the female gender, and the use of the word "or" shall mean "and/or".

- 1.3. The headings of the sections in this Amendment are for the sake of convenience only and shall not serve in the interpretation of the Agreement.
- 1.4. In this Amendment, capitalized terms shall have the meanings set forth in the License Agreement, unless provided otherwise herein.

The Parties acknowledge that EP patent No. 2706988, entitled: LIPOSOMES COMPRISING POLYMER-CONJUGATED LIPIDS AND RELATED USES (Yissum's Ref. 4097-04) has been fully assigned to YISSUM as of March 26, 2017 (the "**Assignment Date**") and shall be included in the Licensed Technology, and further acknowledge that by reason of such assignment, pursuant to section 11.3 of the License Agreement, EDESA is responsible for one hundred percent (100%) of all costs associated with the Patent Management of this patent as of the Assignment Date.

2. EP Patent No. No. 2429532: LIPID-POLYMER CONJUGATES, THEIR PREPARATION AND USES THEREOF (Yissum's Ref: 3860-04), which was part of the European B/3 Patents has been abandoned and therefore is removed from the Licensed Technology effective retroactively as of June 29, 2016.
3. The Parties have agreed to update the version of Appendix B annexed to the License Agreement by replacing it in its entirety by the new Appendix B attached to this Second Amendment.
4. This Second Amendment shall be read together with the License Agreement and shall represent the complete current understanding between the Parties hereto with respect to the subject matter hereof.
5. Unless otherwise specifically stated in this Second Amendment, all of the terms and conditions set forth in the Agreement remain in full force and effect. In any event of a conflict between and conditions contained in this Second Amendment and the License Agreement, the terms contained in this Second Amendment shall govern.
6. This Second Amendment may be executed in counterparts and executed signature pages may be sent by fax and e-mail via PDF, all of which taken together shall be deemed to constitute one and the same instrument.

*[Signature on the next page]*

IN WITNESS WHEREOF, the parties have caused this First Amendment to be executed by their duly authorized representatives as of the Effective Date.

YISSUM

EDESA BIOTECH INC.

By: /s/ Yaron Danlely By: /s/ Pardeep Nijhawan

Name: Yaron Danlely Name: Pardeep Nijhawan

Title: CEO of Yissum Title: Director

By: /s/ Shoshi Keynan

Name: Shoshi Keynan, Ph.D.

Title: VP Licensing, Pharmaceuticals

**Prof. Yedgar Acknowledgment**

/s/ Saul Yedgar

## AppendixB

### (Patents)

#### (1) Licensed Composition of Matter Patents:

Patent/ Application	Title	Yissum rel
us 8,865,878	Use of Lipid Conjugates In the Treatment of Disease	2510-51
CA 2,558,416	Use of Lipid Conjugates In the Treatment of Disease	2510-18
EP 1758595	Use of Lipid Conjugates In the Treatment of Disease	2510-19
us 8,383,787:	Use of Lipid Conjugates In the Treatment of Disease	2510-60
us 2014-0199241 us 14/115,869	Liposomes comprising polymer- Conjugated lipids and uses	4097-08
CA 2834918	Liposomes comprising polymer- Conjugated lipids and uses	4097-06
us 2015-0119567 us 14/525111	Lipid-polymer conjugates, their preparation and uses thereof	3860-09
CA 2761590	Lipid-polymer conjugates, their preparation and uses thereof	3860-08
EP 2706988	Liposomes comprising polymer-Conjugated lipids and uses	4097-04

#### (2) Method of Use or Other patents.

Patent/ Application	Title	Yissum ref.
us 7,772,196	Use of Lipid Conjugates In the Treatment of Disease	2510-14
us 8,901,103	Use of Lipid Conjugates In the Treatment of Disease	2510-44
AU 2011201154	Use of Lipid Conjugates In the Treatment of Disease	2507-AU



**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

**EXCLUSIVE LICENSE AGREEMENT**

**by and between**

**CIPHER PHARMACEUTICALS INC.**

**and**

**EDESA BIOTECH INC.**

**June 15, 2016**

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## EXCLUSIVE LICENSE AGREEMENT

This Agreement (the "**Agreement**"), effective as of June 15, 2016 (the "**Effective Date**"), is entered into by and between Cipher Pharmaceuticals Inc., an Ontario corporation with its principal office at 2345 Argenta Road, Suite 100A, Mississauga, Ontario, L5N 8K4 ("**Cipher**"), and Edesa Biotech Inc., an Ontario corporation with its principal office at 100 Spy Court, Markham, Ontario, L3R 5H6 ("**Licensee**"). Cipher and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**". Reference to a Party shall be deemed to include that Party's Affiliates.

### RECITALS:

- A. Cipher owns Cipher IP relating to ASF-1096 (Levo-salbutamol and/or R-salbutamol) as further described in Schedule "A".
- B. Licensee is a pharmaceutical company having expertise in the discovery, development, manufacturing and commercialization of innovative human pharmaceutical products.
- C. Licensee wishes to develop, manufacture, and commercialize a pharmaceutical product or products that may Cover Cipher IP.
- D. Licensee and Cipher desire to enter into an agreement under which Licensee would obtain exclusive rights to the Cipher IP for therapeutic, prophylactic and diagnostic applications of the Product in human and veterinary medicine for Anorectal Disorders (as defined below) (collectively, the "**Field**").

In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

- 1.1. "**Adverse Event**" shall mean any undesirable medical occurrence in a patient or clinical investigation subject administered the Product and which does not necessarily have to have a causal relationship with the Product.
- 1.2. "**ADRC**" has the meaning set forth in Section 14.16.
- 1.3. "**Affiliate**" means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.3, "**control**" shall mean: (a) in the case of a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity; and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.
- 1.4. "**Anorectal Disorders**" means any condition that affects the anal region, including but not limited to hemorrhoids, tears, fistulas and abscesses.

- 1.5. "**Arbitration Panel Finalization**" has the meaning set forth in Section 14.16.
- 1.6. "**Biologics License Application**" means the request for permission to introduce, or deliver for introduction a biologic product into interstate commerce in the US, which request is filed with the FDA.
- 1.7. "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- 1.8. "**Calendar Year**" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.
- 1.9. "**cGMP**" means current good manufacturing practices as promulgated under the United States Federal Food, Drug, and Cosmetic Act, as amended, the *Food and Drugs Act* (Canada), and similar requirements of jurisdictions outside the United States and Canada applicable to manufacture of Clinical Materials or Product.
- 1.10. "**Cipher Data**" has the meaning ascribed to it in Section 6.1(b).
- 1.11. "**Cipher Field**" means the dermatological field and dermatological indications.
- 1.12. "**Cipher Indemnitee(s)**" has the meaning ascribed to it in Section I I. I.
- 1.13. "**Cipher IP**" means Cipher Licensed Patents and Cipher Licensed Know-How.
- 1.14. "**Cipher Licensed Know-How**" means all information and Know-How owned or Controlled by Cipher as of the Effective Date or at any time during the Term, that is necessary or useful for Licensee to exercise the rights licensed to it under this Agreement or to perform its obligations under this Agreement. Such Cipher Licensed Know-How shall include, in particular, all pre-clinical data, clinical data, formulation data (including batch records), chemistry, manufacturing and controls data and regulatory data including the Dossiers.
- 1.15. "**Cipher Licensed Patents**" means all:
- (a) Patent rights owned by Cipher as of the Effective Date or at any time during the Term as further described in Schedule "A", including the Patent rights that, from time to time, the Parties identify as, and agree in writing are, Cipher Licensed Patents;
  - (b) continuations, divisionals, renewals, continuations-in-part, and Patents of addition claiming priority to the Cipher Licensed Patents described in the foregoing subsection (a),
  - (c) restorations, extensions, supplementary protection certificates, reissues and re-examinations of the Cipher Licensed Patents described in the foregoing subsections (a) and (b),
- and foreign equivalents of the Cipher Licensed Patents described in the foregoing subsections (a), (b) and (c).
- (NaN. "**Claimant**" has the meaning set forth in Section 14.16.

- 1.17. "**Clinical Material(s)**" means the Product formulated in accordance with the Specifications and applicable Canadian, United States and/or foreign laws, rules and regulations: (a) for preclinical activities; and (b) for administration to subjects in clinical trials.
- 1.18. "**Clinical Trial(s)**" means all pre-clinical trials and activities, clinical trials and toxicology studies, in each with respect to the Product in the Field.
- 1.19. "**Commercialization**" or "**Commercialize**" means activities undertaken after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, pricing determination, sale, use and distribution (including importation and exportation) of a pharmaceutical product and post-launch medical activities, including without limitation: (a) manufacturing and distribution for commercial sale, (b) strategic marketing, sales force detailing, advertising, and market and product support; (c) medical education and liaison; (d) all customer support and product distribution, invoicing and sales activities; (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals; (f) target product profile, pricing, formulary and reimbursement related activities including pricing and reimbursement approvals; and (g) organizing formulary access and drug distribution.
- 1.20. "**Confidential Information**" has the meaning set forth in Section 9.1.
- 1.21. "**Control,**" "**Controls**" or "**Controlled by**" means (except as used in Section 1.3), with respect to any item of or right under Patents or Know-How, the ability of a Party (whether through ownership or license, other than pursuant to this Agreement) to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.
- 1.22. "**Cover**" or "**Covered**" means, with respect to Patents subject to this Agreement, in the absence of a license to an unexpired, valid claim thereof, the research, development, manufacture, use, sale, offer for sale, or importation of the applicable invention, discovery, process, or product would infringe such a claim (or, in the case of a claim that has not yet issued, would infringe such a claim if it were to issue).
- 1.23. "**Demand for Arbitration**" has the meaning set forth in Section 14.16.
- 1.24. "**Develop**" or "**Development**" or "**Developing**" means research, discovery, process development, manufacturing for preclinical and clinical uses, preparation for drug reimbursement, preparation and initiation of medical education and liaison activities and preclinical and clinical drug or biological development activities, including, without limitation, test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, approval and registration, in each case, of a Product for use in the Field.
- 1.25. "**Diligent Efforts**" means those efforts and resources commonly associated with the commercially reasonable business practices and standards in the research-based pharmaceutical industry to research, develop, manufacture or commercialize (as appropriate) a product or compound of similar market potential at a similar stage in its product.

- 1.26. "**Dossiers**" means any and all product registration and NDA applications, including all pre investigational new drug application consultations, and all supporting files, writings, data, studies, and reports, manufacturing information and clinical protocols and investigator information, in draft and compiled in final form and submitted to the competent local authorities for obtention of a product registration or NDA approval.
- 1.27. "**EMA**" means the European Medicines Evaluation Agency or any successor agency thereto.
- 1.28. "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.
- 1.29. "**Field**" has the meaning ascribed to it in the recitals.
- 1.30. "**First Commercial Sale**" means, with respect to the Product in the Field, the first sale to a Third Party for end use or consumption of the Product in the Field in a country in the Territory after Regulatory Approval of the Product in the Field has been granted by the Regulatory Authority of such country.
- 1.31. "**Good Clinical Practice**" means the current good clinical practice applicable to the clinical Development of the Product under applicable law, to the extent such standards are not less stringent than the U.S. current good clinical practice, including the ICH guidelines.
- 1.32. "**Good Laboratory Practice**" means the current good laboratory practice applicable to the Development of the Product under applicable law, to the extent such standards are not less stringent than the U.S. current good laboratory practice, including 21 C.F.R. Part 58.
- 1.33. "**ICH**" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 1.34. "**IFRS**" means International Financial Reporting Standards as the same may be in effect from time to time.
- 1.35. "**IND**" means an Investigational New Drug application in the United States, a Clinical Trial Application in Canada, or a foreign equivalent application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.36. "**Indication**" means any separate and distinct disease (or stage of disease), disorder or medical condition in humans or non-human animals which a Product is intended to treat, prevent, diagnose, monitor or ameliorate and which, for a Product candidate, is intended to be reflected in the labeling for such Product as an approved indication, and which, for an approved Product, is reflected in the labeling for such Product.
- 1.37. "**Indemnifying Party**" has the meaning ascribed to it in Section 11.3.
- 1.38. "**Indemnitee**" has the meaning ascribed to it in Section 11.3.
- 1.39. "**Information**" means any and all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information and data, in any tangible or intangible form, including all Know-How.



- 1.40. "**Know-How**" means (a) any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data and (b) any proprietary biological, chemical or physical materials.
- 1.41. "**Knowledge**" shall mean actual knowledge of any of the current officers of the Party.
- 1.42. "**Licensee Data**" has the meaning ascribed to it in Section 6.1(b).
- 1.43. "**Licensee Indemnitee(s)**" has the meaning ascribed to it in Section 11.2.
- 1.44. "**Licensee Licensed Know-How**" means all Know-How (excluding any Patents) Controlled by Licensee as of the Effective Date or at any time during the Term, that is: (a) related to the Product (or a composition containing the Product, or the manufacturing or use of the Product); and (b) reasonably necessary for Cipher to exercise the rights licensed to it under this Agreement or to perform its obligations under this Agreement, or to continue Development or Commercialization of the Product for use in the Cipher Field.
- 1.45. "**Licensee Licensed Patents**" means any and all Patents owned by Licensee at any time during the Term, that are necessary or reasonably useful for Cipher to exercise the rights licensed to it under this Agreement or to perform its obligations under this Agreement or to continue Development or Commercialization of the Product for use in the Cipher Field.
- 1.46. "**Licensee Trademarks**" means any and all Trademarks Controlled by Licensee at any time during the Term that are registered for or apply to the Product.
- 1.47. "**NDA**" or "**New Drug Application**" means an application submitted to FDA pursuant to 21 U.S.C. § 505(b) or a Canadian or foreign equivalent application or submission to a Regulatory Authority which contains complete details of the manufacture and testing of a new drug, for purposes of obtaining Regulatory Approval for such new drug in the applicable jurisdiction, for a particular Indication, and also includes a Biologics License Application.
- 1.48. "**Net Sales**" means the gross amount invoiced by Licensee or its Affiliates to unrelated Third Parties (excluding any Sublicensee) for sales of the Product in the Field in the Territory, less:
- (a) Trade, quantity and cash discounts actually allowed or paid;
  - (b) Commissions, discounts, refunds, rebates (including but not limited to wholesaler fees), chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price;
  - (c) Actual Product returns and allowances;
  - (d) Any sales, use, excise, value added taxes or similar taxes measured by the billing amount, when included in billing;

- (e) Any freight, postage, shipping, and insurance charges related to delivery of the Product from applicable warehouse all to the extent included in the third party invoices; and
- (f) custom, import and export duties actually paid.

Any refund or reimbursement of any of the foregoing amounts previously deducted from Net Sales shall be appropriately credited to Net Sales, or adjusted through allowances, upon receipt thereof.

For greater certainty "Net Sales" shall not include sales or transfers between members of the group comprised of Licensee, Sublicensees, and their Affiliates.

For greater certainty, provision of Product for the purpose of conducting Clinical Trials in order to obtain Regulatory Approvals shall not be deemed to be a sale.

Such amounts shall be determined from the books and records of Licensee or its Affiliates, as applicable, maintained in accordance with IFRS, consistently applied. Licensee further agrees that in determining such amounts, it will use Licensee's then current standard procedures and methodology, including Licensee's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars, consistently applied.

- 1.49. "**Patent(s)**" means: (a) all patents and patent applications in any country or supranational jurisdiction; and (b) any provisionals, substitutions, divisions, continuations, continuations in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, of any such patents or patent applications.
- 1.50. "**Phase III Clinical Study**" means a human clinical study to confirm with statistical significance the efficacy and safety of the Product in the Field performed to obtain Regulatory Approval for the Product in any country.
- 1.51. "**Product**" means ASF-1096 (Levo-salbutamol and/or R-salbutamol) and any product that is Covered by Cipher Licensed Patents.
- 1.52. "**Regulatory Approval(s)**" means all approvals or authorizations by Regulatory Authorities necessary to market and sell the Product in the Field in the applicable jurisdiction.
- 1.53. "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, reimbursement or pricing of a Product in the Territory, including in the United States the FDA, and in Canada, Health Canada.
- 1.54. "**Respondent**" has the meaning set forth in Section 14.16.
- 1.55. "**Specifications**" means the Licensee's specifications for the Product.
- 1.56. "**Subcontractors**" has the meaning set forth in Section 3.3.
- 1.57. "**Sublicensee**" means a Third Party that is granted a sublicense under the licenses granted to a Party under this Agreement.

- 1.58. "**Sublicensing Fees**" has the meaning set forth in Section 7.2.
- 1.59. "**Sublicensing Revenue**" means the net amount of all revenues, royalties, receipts, and monies, including, without limitation, upfront payments, milestone payments, and license fees, earned or received by Licensee and its Affiliate(s) from Sublicensee(s) with respect to the Product.
- 1.60. "**Technology Transfer**" has the meaning set forth in Article 4.
- 1.61. "**Term**" has the meaning set forth in Section 13.1.
- 1.62. "**Territory**" means the entire world.
- 1.63. "**Third Party**" means an entity other than: (a) Licensee and its Affiliates; and (b) Cipher and its Affiliates.
- 1.64. "**Trademark(s)**" means all granted trademarks and all trademark applications in any country or supranational jurisdiction and/or any other trademark used for the promotion, marketing, distribution, use and/or sale of Product.
- 1.65. "**United States**" or "**US**" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

## ARTICLE 2 SCOPE AND GOVERNANCE

### 2.1. General.

- (a) **Scope.** Pursuant to and subject to the terms of this Agreement: (a) Licensee will be responsible for the Development and Commercialization of the Product in the Territory in the Field with the goal of obtaining Regulatory Approval for the Product, as soon as commercially reasonable; (b) Licensee will have exclusive rights to Commercialize the Product as further set forth in Section 8.1 in exchange for royalty and other payments to be made to Cipher as described in Article 7; and (c) responsibility for manufacture of Clinical Materials and Product shall be as detailed in Article 4.
- (b) **Guiding Principles.** The committee set forth in this Article 2 shall perform its responsibilities under this Agreement based on the principles of good faith, prudence and good scientific and business judgment. The committee shall not have any power to amend, modify or waive compliance under this Agreement. Notwithstanding anything to the contrary in this Agreement, no decision by either Party, or any committee set forth in this Article 2, will be effective if such decision requires the other Party to breach any obligation under this Agreement or to perform any activities that are materially different or greater in scope than those provided for specifically under this Agreement.

### 2.2. Joint Steering Committee.

- (a) **Membership.** The Parties hereby establish a Joint Steering Committee, or JSC, to coordinate and oversee activities of the Parties under this Agreement. The JSC shall consist of two (2) representatives from each Party although the JSC may change the size of the JSC from time to time by mutual consent of the members of the JSC. Each Party shall notify the other of its representatives to the JSC within thirty (30) days of the Effective Date. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC shall be chaired first by a representative of Licensee from the period from the Effective Date through **July 1, 2017** and thereafter the chairperson position shall rotate annually on **July 1**, with Cipher to appoint the chairperson for the second annual term, and so forth thereafter. The chairperson shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within thirty (30) days thereafter. Each Party may replace any of its appointed JSC representatives, including a chairperson, at any time upon five (5) days' prior written notice to the other Party.

- (b) **Responsibilities.** The responsibilities of the JSC shall be:
- (i) to provide a vehicle by which the Parties may provide to each other information regarding the Development of the Product in their respective Field;
  - (ii) to provide a vehicle by which Licensee and Cipher can share and discuss the data, results and intellectual property generated by, on behalf of or under the direction of, Cipher, Licensee or their respective Affiliates with respect to the Product and by which Licensee and Cipher can provide input regarding the Parties' intellectual property strategies in respect of the Product;
  - (iii) to facilitate the exchange of Information between the Parties with respect to the Development activities hereunder and to establish procedures for the efficient sharing of Information necessary for the Parties to fulfill their respective responsibilities with respect to the Development of the Product hereunder;
  - (iv) to discuss collaborative approaches to ensure commercial viability of the Product both within and outside of the Field;
  - (v) to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties.

### 2.3. JSC Meetings.

JSC meetings shall be held quarterly, or on any other schedule agreed upon by the Parties. With the consent of the representatives of each Party serving on the JSC, other representatives of each Party may attend meetings as non-voting observers (provided such non-voting observers have confidentiality obligations to such Party that are at least as stringent as those set forth in this Agreement). A JSC meeting may be held by audio, video or other electronic means with the consent of each Party, but at least one meeting per year shall be held in person. Each Party shall be responsible for all of its own expenses of participating in the JSC meetings.

## ARTICLE 3 PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

### 3.1. Overview.

From and after the Effective Date, Licensee shall have full responsibility and authority, at its sole cost and expense, for the conduct of all Clinical Trials and for the Development and Commercialization of the Product in the Field in the Territory. Responsibility for regulatory matters will be as set forth in Article 6.

### 3.2. Conduct of Development and Commercialization.

Licensee shall use Diligent Efforts to Develop and Commercialize the Product in the Field in the Territory, in compliance with the terms and conditions of this Agreement and with a goal to maximize profits from Net Sales of the Product in the Field in the Territory. As between Licensee and Cipher, Licensee shall have the sole right and obligation to determine all pricing of the Product in the Field. In addition, each Party and any Affiliate(s), contractor(s) or Sublicensee(s) performing activities in connection with the Development and Commercialization of the Product shall comply with: (i) all applicable Good Laboratory Practices, Good Clinical Practices and applicable cGMP requirements; and (ii) all applicable laws and regulations. Licensee shall report to the JSC at each JSC meeting as to the status of Development and Commercialization of the Product in the Field.

Without limiting the foregoing:

- (a) Licensee shall, at its own cost, use Diligent Efforts to complete a proof of concept study with respect to the Product in the Field;
- (b) Development and Commercialization of the Product in the Field shall be carried out by Licensee so as to not actively unreasonably hinder, impede or impair the Commercialization of the Product for use in the Cipher Field by Cipher, its Affiliates or Third Parties contracting with Cipher. The Parties agree that any pricing decisions by Licensee for Product in the Field shall not constitute an active unreasonable hindrance, impediment, or impairment of the Commercialization of the Product for use in the Cipher Field by Cipher, its Affiliates or Third Parties contracting with Cipher. Except as otherwise stated in this paragraph, any dispute associated with or related to the determination of whether Development and/or Commercialization of the Product by Licensee in the Field actively hinders, impedes or impairs Commercialization of the Product for use in the Cipher Field by Cipher, its Affiliates or Third Parties contracting with Cipher shall be addressed in accordance with Section 14.15; and
- (c) Licensee shall not apply to register and/or use in connection with the Development and Commercialization of Product any Trademarks owned by Cipher.

### 3.3. Rights to Engage Subcontractors.

Except as set forth below, Licensee shall have the right to engage Third Party contractors to perform any of its activities or obligations hereunder, provided that Licensee shall be responsible for ensuring that, prior to any such engagement, any subcontractors are subject to written agreements containing terms and conditions: (i) consistent with the relevant terms and conditions of this Agreement protecting the rights of Cipher under this Agreement including imposing obligations of confidentiality on each such subcontractor; (ii) that vests ownership of any and all inventions developed by such subcontractor that is Covered by the Products in the course of performing such subcontracted work in Licensee; and (iii) that does not impose any payment obligations or liability on Cipher without the prior written consent of Cipher, (such subcontractor, a "**Subcontractor**").

**ARTICLE 4  
MANUFACTURE AND SUPPLY**

The Parties will negotiate, in good faith, determining which Party or Third Party will manufacture and supply Product and Clinical Materials to Licensee. If the Parties determine that Cipher is not responsible for the manufacture and supply of Product for Licensee, Cipher shall provide to the manufacturer access to all Product Information, manufacturing Know-How, and any and all original processes, records, and any other Information reasonably necessary to have the Product and Clinical Materials manufactured in accordance with the applicable Specifications ("**Technology Transfer**"), provided that such manufacturer agrees to keep any Confidential Information confidential in accordance with the provisions set out in this Agreement. In the event the Parties agree that Cipher will be responsible for the manufacture and supply of Product and Clinical Materials to Licensee, the Parties shall negotiate the terms and conditions (including as to pricing) of a manufacturing agreement pursuant to which Cipher shall manufacture and supply Product or Clinical Materials for Licensee.

**ARTICLE 5  
RECORDS**

Each Party shall maintain appropriate records of: (a) all significant Development, manufacturing and Commercialization events and activities conducted by it or on its behalf related to the Product; and (b) all significant Information generated by it or on its behalf in connection with research and Development of Products under this Agreement, in each case in accordance with such Party's usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in good scientific manner, all significant work done and results of studies and trials undertaken, and further shall be at a level of detail appropriate for patent and regulatory purposes. If reasonably necessary for a Party to perform its work under this Agreement or to exercise its rights under this Agreement, that Party may request that, and the other Party shall provide within a reasonable time frame, such information and data regarding its activities hereunder as is reasonably available and reasonably related to the activities under this Agreement. Neither Party is required to generate additional data or prepare additional reports to comply with the foregoing obligation. All such reports, Information and data provided shall be subject to the provisions of Article 9.

**ARTICLE 6  
REGULATORY**

**6.1. Regulatory Obligations.**

- (a) Licensee shall be responsible for and shall have the sole right to control, all regulatory activities and strategy associated with IND, NDA and all other regulatory submissions, all Regulatory Approvals, and the maintenance of such submissions and Regulatory Approvals, in each case with respect to the Product in the Field, including communicating and preparing and filing all reports including all INDs and NDAs with the applicable Regulatory Authorities. Cipher shall cooperate with Licensee as requested in preparing and filing all such reports, and Cipher shall provide Licensee with all available information, including regulatory, technical and clinical data concerning the Product, and any Dossiers related to the Product, to enable Licensee to prepare and file such reports. Licensee shall pay all governmental fees associated with obtaining and maintaining any and all Regulatory Approvals including any establishment license fees of Licensee or Third Parties which must be paid with respect to facilities used in the manufacture of the Product by or on behalf of Licensee in the Field.

- (b) Cipher shall have the right to access and use in a timely manner any and all data and results related to the Product that is generated by, on behalf of or under the direction of, Licensee or its Affiliates with respect to the Product (including all data or results contained or referenced in Licensee's submissions or applications for Regulatory Approvals with respect to the Product, including all reports, correspondence and conversation logs) (the "**Licensee Data**"), for the purpose of Development and Commercialization of the Product in the Cipher Field, and Cipher may cross reference all such data in Cipher's submissions or applications for Regulatory Approvals.
- (c) Licensee shall have access and the right to use, in a timely manner any and all data and results related to the Product that is generated by, on behalf of or under the direction of, Cipher or its Affiliates with respect to the Product (including all data or results contained or referenced in Cipher's submissions or applications for Regulatory Approvals with respect to the Product, including without limitation, all reports, correspondence and conversation logs) (the "**Cipher Data**"), for the purpose of Development and Commercialization of the Product within the Field, and Licensee may cross reference all such data in Licensee's submissions or applications for Regulatory Approvals.
- (d) As between the Parties, and excluding any Cipher Data, Licensee shall own all right, title and interest in Licensee Data. As between the Parties, and excluding any Licensee Data, Cipher shall own all right, title and interest in Cipher Data.

## 6.2. Safety Reporting.

- (a) **Adverse Event Procedures.** Licensee shall be responsible for all regulatory activities including: (i) management and monitoring of safety and Adverse Event/experience information for the Product in the Field; (ii) regulatory reporting; (iii) managing the global safety data base; and (iv) reviewing and approving of safety information for inclusion in the Product label in the Territory, in each case with respect to the Product in the Field.
- (b) **Safety Agreement.** Representatives of each Party from the affected areas will begin meeting as soon as possible but no later than sixty (60) days after the Effective Date of this Agreement and will work in good faith together to develop a Safety Agreement within an agreed reasonable time to describe safety data transfers, and Adverse Event handling and reporting to Regulatory Authorities, which shall include timely reporting to the other Party of Adverse Events and access to any relevant safety data by each Party.
- (c) **Third Parties.** Each Party agrees that if it contracts with a Third Party for clinical research to be performed by such Third Party relating to the Product, that Party agrees to require such Third Party to report to the contracting Party the information set forth above.

## 6.3. Recalls.

Licensee shall be responsible for any recall decision and the conduct of any recall in respect of the Product in the Field, including the costs and expenses thereof. If Licensee recalls, detains or retains such Product (voluntarily, or by order of a Regulatory Authority), Cipher shall reasonably cooperate in such actions, at Licensee's sole expense. Cipher shall be responsible for any recall decision and the conduct of any recall in respect of the Product in the Cipher Field, including the costs and expenses thereof. If Cipher recalls, detains or retains such Product (voluntarily, by order of a Regulatory Authority), Licensee shall reasonably cooperate in such actions, at Cipher's sole expense

**6.4. Pricing and Reimbursement.**

Licensee shall be solely responsible for setting the price for Product in the Field to be sold by Licensee, and shall do so without discussion or consultation with Cipher. Cipher may provide to Licensee, in writing, suggested resale prices or price ranges and any lawfully derived market studies or data, provided, however, that no such data is obtained from another Cipher collaborator and, provided, further, however, that Licensee shall determine its selling price in its sole discretion without discussion or consultation with Cipher regarding such suggested prices, price levels, market studies or data. Cipher shall be solely responsible for setting the price for Product in the Cipher Field to be sold by Cipher, and shall do so without discussion or consultation with Licensee. Licensee may provide to Cipher, in writing, any lawfully derived market studies or data, provided, however, that Cipher shall determine its selling price in its sole discretion without discussion or consultation with Licensee regarding such market studies or data. The foregoing shall not apply with regard to Product to be sold from one Party to the other, which price shall be established by agreement.

**ARTICLE 7  
PAYMENTS**

**7.1. Milestone Payments.**

Licensee shall immediately notify Cipher of the achievement of any of the following development and commercial milestones, all for the Product in the Field. Licensee shall pay to Cipher the milestone payments listed below which shall be non-refundable and non-creditable and are due and payable within thirty (30) days of the receipt by Licensee of an invoice for payment from Cipher:

Upon enrollment of the first study subject in a Phase III Clinical Study	[ ]
Upon receipt of Regulatory Approval from the FDA	[ ]
First Commercial Sale	[ ]
First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in those countries in which the Licensee directly Commercializes	[ ]
First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in those countries in which the Licensee directly Commercializes	[ ]
First occurrence of \$[ ] million in aggregate Net Sales in a Calendar Year in those countries in which the Licensee directly Commercialize	[ ]

Upon the first occurrence of each \$[ ] million incremental increase in aggregate Net Sales in a Calendar Year beyond \$[ ] million in countries in which the Licensee directly Commercializes, Licensee shall pay Cipher a milestone payment equivalent to [ ]% of the value of the aggregate Net Sales in such Calendar Year. For example, upon the first occurrence of aggregate Net Sales in a Calendar Year reaching \$[ ] million, Licensee shall pay Cipher \$[ ] million.



## 7.2. Product Royalties.

Licensee shall pay to Cipher a royalty of [ ]% of Net Sales of the Product in the Field in the countries in the Territory where it directly Commercializes the Product. Licensee shall pay to Cipher an amount equal to [ ]% of Sublicensing Revenue received by Licensee and its Affiliates ("**Sublicensing Fees**") in the countries in the Territory where it does not directly Commercialize the Product.

## 7.3. Royalty Stacking.

The parties recognize and agree that, in order to Develop and Commercialize the Product in the Field, it may be necessary for Licensee and/or its Sublicensees to make use of and/or incorporate multiple elements of intellectual property from multiple sources. Licensee and/or its Sublicensees will determine, in their sole judgment, which elements of intellectual property are necessary and/or desirable for the Development and/or Commercialization of the Product. Royalty payments or license fees to third parties may occur if intellectual property owned by a third party is required or desirable for the Commercialization of the Product in the Field and Territory. All types of payments to third parties that Licensee and/or its Sublicensees have determined and/or may determine are necessary or desirable to obtain licenses or other rights to use or incorporate intellectual property or products other than the Products in the Field and Territory, will be creditable against royalties otherwise owed to Cipher hereunder, provided that such payments must have been made in good faith. Notwithstanding the foregoing, at no point shall Cipher's [ ]% royalty on Net Sales, nor Cipher's [ ]% share of the Sublicensing Revenue be reduced by more than [ ]% due to payments to third parties in respect of other licenses required to Develop and Commercialize the Product in the Field in the Territory.

## 7.4. Reports; Payment of Royalty.

- (a) During the Term, following the First Commercial Sale of the Product, Licensee shall furnish to Cipher a quarterly written report for the Calendar Quarter showing: (i) the Net Sales of the Product in the Field in countries in which the Licensee directly commercializes as well as on a country-by-country basis (in countries in which the Licensee directly commercializes) during the reporting period and the royalties payable under this Agreement in respect thereof; and (ii) Sublicensing Revenues during the reporting period and the Sublicensing Fees payable under this Agreement in respect thereof on a country by-country basis.
- (b) Reports shall be due on the thirtieth (30th) day following the close of each Calendar Quarter. Royalties and Sublicensing Fees shown to have accrued by each royalty report shall be due and payable in accordance with Section 7.1. Licensee shall keep complete and accurate records in sufficient detail to enable the royalties and Sublicensing Fees payable hereunder to be determined. The quarterly written reports contemplated by this Section 7.3 shall include, at a minimum, the total sales units showing the number of doses sold and Net Sales on a country-by-country basis, where available, as well as a breakdown of all Sublicensing Revenues (broken down by upfront, milestone, royalty, license and other payments) on a country-by-country basis. For each country, the total gross sales, all deductions (broken down separately by each of the categories set out in clauses (a) to (f) of the definition of "Net Sales" and separately setting forth any adjustments thereto due to refunds or reimbursements of deducted amounts) and total Net Sales of Product for the quarter shall also be provided.

## 7.5. Audits.

- (a) Licensee will keep and maintain (and to the extent applicable, will cause its Affiliates, and their respective sub-licensees, distributors, assignees and transferees to keep and maintain) proper and complete records and books of account in such form and detail as is necessary for the determination of the amounts payable by Licensee (on behalf of itself and its Affiliates and their respective sub-licensees, distributors, assignees and transferees) to Cipher under this Agreement and for the purposes of this Agreement.
- (b) Upon the written request of Cipher and not more than once in each Calendar Year, Licensee shall permit an independent certified public accounting firm of nationally recognized standing (that has been retained on an hourly or flat fee basis and receives no contingency fee or other bounty or bonus fee) selected by Cipher and reasonably acceptable to Licensee, at Cipher's expense, to have access during normal business hours to such of the records of Licensee as may be reasonably necessary solely to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request. This right to audit shall remain in effect throughout the life of this Agreement and for a period of thirty-six (36) months after the termination of this Agreement.
- (c) Cipher shall share the accounting firm's written report with Licensee within five (5) days of its receipt by Cipher. If such accounting firm identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date Cipher delivers to Licensee such accounting firm's written report so concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Cipher unless the underpayment exceeded the greater of: A) ten percent (10%) of the amount owed by Licensee to Cipher for such Calendar Year; or B) \$25,000.00, in which case, Licensee shall pay to Cipher the reasonable fees charged by such accounting firm, which fees shall not exceed \$40,000 CAD. Licensee shall pay interest on the amounts owed to Cipher, said interest shall be calculated as being 2% greater than the U.S. commercial prime rate as published by the Wall Street Journal on the date of the first discrepancy identified in the audit, and shall accrue from the date payments should have been made.
- (d) Licensee shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to make reports to Licensee, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by an independent certified public accountant selected by Licensee to the same extent required of Licensee under this Agreement.
- (e) Cipher shall treat all financial information subject to review in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Licensee or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

## 7.6. Payment Exchange Rate.

All payments to be made by one Party to the other under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to a bank account designated in writing by the Party receiving the payment. In the case of sales outside the United States, royalty payments by Licensee to Cipher shall be converted to United States Dollars in accordance with the following: the rate of currency conversion shall be calculated using a simple average of mid-month and month-end rates as provided by the spot rate as published by The Wall Street Journal, New York City Edition for such accounting period.

**7.7. Tax Withholding.**

The Parties will withhold taxes with respect to payments under this Agreement under applicable law. Each Party will provide documentation to the other Party as evidence of the accuracy and payment of any such withholding tax, as applicable.

**7.8. Late Payments.**

The paying Party shall pay interest to the receiving Party on the aggregate amount of any undisputed invoices that are not paid on or before the date the payment of such invoices are due under this Agreement at a rate per annum equal to the lesser of one percent (1%) per month or the highest rate permitted by applicable law, calculated on the number of days such payments are paid after the date payment of such invoices is due and compounded monthly.

**ARTICLE 8  
LICENSES; EXCLUSIVITY**

**8.1. License to Licensee.**

- (a) **Exclusive License and Sublicenses.** Subject to the terms and conditions of this Agreement, Cipher hereby grants to Licensee and its Affiliates an exclusive (except with respect any rights retained by Cipher under Section 8.1(b)), royalty-bearing license in the Territory in the Field, with the right to grant sublicenses, under the Cipher IP and the Cipher Data, as necessary for the Development and Commercialization of the Product in the Field.
- (b) **Cipher Retained Rights.** Notwithstanding the rights granted to Licensee in Section 8.1(a), Cipher retains the following:
  - (i) the right to manufacture or have manufactured Product or Clinical Materials for use pursuant to this Agreement as provided in and in accordance with Article 4; and
  - (ii) the right to Develop or Commercialize or conduct any other activities involving the Product in the Cipher Field.

**8.2. Sublicensing.**

Licensee shall have the right to grant Sublicenses under the Cipher IP to Sublicensees on terms that are consistent with those granted to Licensee pursuant to this Agreement.

**8.3. License to Cipher.**

- (a) Licensee hereby grants Cipher an exclusive, royalty-free license, with the right to grant sublicenses to Third Parties in accordance with this Section 8.3(b), under the Licensee Licensed Patents, Licensee Licensed Know-How and Licensee Data solely (i) to manufacture Clinical Materials or the Product to the extent contemplated by Article 4, and (ii) to make or Develop, manufacture or Commercialize Products in the Cipher Field as contemplated by Section 8.1(b) of this Agreement.

- (b) Cipher shall only have the right to grant a sublicense to a Third Party pursuant to Section 8.3(a) if (i) Cipher has provided Licensee with reasonable written notice prior to granting any such sublicense to a Third Party and such written notice identifies the applicable Sublicensee; and (ii) Cipher causes each Sublicensee to enter into an agreement with Cipher. Each sublicense agreement shall (1) be in writing; (2) be subject to and consistent with, the terms of this Agreement; (3) preclude assignment of such sublicense agreement and sublicensing of the licenses granted under such sublicense agreement to any Third Parties without Licensee's prior written consent, such consent not to be unreasonably withheld or delayed (4) terminate upon the termination of this Agreement in accordance with the terms hereof, and (5) include Licensee as an intended third party beneficiary with the right to enforce the terms of such sublicense agreement.

#### **8.4. No Implied Licenses.**

Except as explicitly set forth in this Agreement, neither Party nor its Affiliates grants any license, express or implied, under its intellectual property rights to the other Party. Without limiting the foregoing, this Agreement and the licenses and rights granted herein do not and shall not be construed to confer any rights upon either Party or its Affiliates by implication, estoppel, or otherwise as to any of the other Party's or its Affiliates' intellectual property, except as otherwise expressly set forth herein.

#### **8.5. Registration and Recordation of License.**

If this Agreement or any license herein granted is required to be registered with or reported to a national or supranational agency of any country in which Licensee would do business, Licensee shall, at its expense, undertake such registration or report, and provide prompt notice and appropriate verification of the act or registration, report or any agency ruling resulting from such registration to Cipher. Any formal recordation of this Agreement or any license herein granted which is required by the law of any country, as a prerequisite to enforceability of the Agreement or license in the courts of any such country or for other reasons, shall be carried out by Licensee at its expense, and appropriately verified proof of such recordation shall be promptly provided to Cipher.

#### **8.6. Non-Compete.**

Licensee agrees that neither it nor any of its Affiliates shall, at any time during the Term, Develop or Commercialize the Product for use in the Cipher Field, nor will Licensee Develop or Commercialize any product that could act as a substitute for the Product in the Cipher Field. Cipher agrees that neither it nor any of its Affiliates shall, at any time during the Term, Develop or Commercialize the Product in the Field nor will Cipher Develop or Commercialize any product that could act as a substitute for the Product in the Field. The Parties agree that the Development and Commercialization of the Product by Cipher in the Cipher Field and the Development and Commercialization of the Product by Licensee in the Field are in compliance with this Section 8.6.

## **ARTICLE 9 CONFIDENTIALITY; PUBLICATION**

#### **9.1. Nondisclosure Obligation.**

- (a) Except as provided in this Section 9.1, all Information and any other confidential or proprietary information disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates hereunder in connection with this Agreement, whether disclosed or provided prior to or after the Effective Date and whether provided orally, visually, electronically or in writing, shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, until ten (10) years following the Term of this Agreement, except to the extent that such Information:

- (i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business **records**;
- (ii) is or becomes part of the public domain through no fault of the receiving Party;
- (iii) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or
- (iv) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records.

All information disclosed by one Party to the other hereunder, other than described in Subsections (i) through (iv) above, is hereinafter referred to as "**Confidential Information**".

- (b) Each Party may disclose Confidential Information of the other Party, without such other Party's prior written consent, to its Affiliates' directors, employees, agents, consultants, Sublicensees, suppliers, and other persons or entities who:
  - (i) need to know such Confidential Information to assist the Party in fulfilling its obligations hereunder;
  - (ii) need to know such Confidential Information to assist Cipher or Licensee, as the case may be, in the Development or Commercialization of the Product for use in the Cipher Field or the Field, respectively; and
  - (iii) are bound by written confidentiality and non-use obligations consistent with those the Party uses to protect its own Confidential Information.
- (c) Each Party shall promptly disclose to the other Party the nature and scope of any breach of this provision by it, or its Affiliates, directors, officers, employees, agents, consultants, Sublicensees, suppliers, or other persons or entities permitted hereunder and the steps taken to contain and address the breach.
- (d) Each Party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, to any person, entity, or government or regulatory authority to the extent that the law requires such disclosure, including filings pursuant to applicable securities or tax laws and regulations. The Party disclosing such Confidential Information shall take such actions as are reasonable to preserve the confidentiality of such Confidential Information, such as requesting confidential treatment. In addition, it may also disclose the other Party's Confidential Information, without the other Party's prior written consent, to any person, entity, or government or Regulatory Authority to the extent that such disclosure is necessary for obtaining, maintaining, or amending any Regulatory Approvals or satisfying any other regulatory obligation regarding the Product. Each party may also disclose the Confidential Information of the other Party, without such other Party's prior written consent, pursuant to an order of a Regulatory Authority or court of competent jurisdiction, provided that it: (i) promptly notifies the other Party of the required disclosure in order to provide such Party an opportunity to take legal action to prevent or limit such disclosure and, if asked, reasonably assists the other Party in pursuing such action; and (ii) shall only disclose the Confidential Information to the minimum extent required by law.

## 9.2. Publicity; Use of Names.

- (a) The Parties shall issue a mutually acceptable press release announcing the execution of this Agreement. A Party may issue any subsequent press release relating to this Agreement or activities conducted hereunder upon prior written approval of the other Party, such approval not to be unreasonably withheld or delayed; provided, however, that no approval of the other Party shall be required if a subsequent press release solely discloses the information that: (1) a milestone under this Agreement has been achieved and/or any payments associated therewith have been received; (2) the filing and/or approval of the NDA with the FDA or the EMEA generally has occurred (provided, however, that specific dates of filing shall not be disclosed); (3) commercial launch of the Product in any country or any information that has previously been approved and disclosed as permitted by this Section 9.2. In the case of items (1)-(3) of the preceding sentence, the disclosing Party shall provide the other Party a copy of such proposed disclosures prior to the proposed release and consider in good faith any comments the other Party may make, where practicable, and in light of any reporting obligations of such disclosing Party under applicable laws, rules or regulations, including without limitation, applicable securities law. Except as otherwise provided in this Section 9.2(a), neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party.
- (b) Notwithstanding the terms of this Article 9, either Party shall be permitted to disclose the existence and terms of this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable laws, rules or regulations, including without limitation the rules and regulations promulgated by securities law regulatory agencies or any other governmental agency. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 9.2(b), the Parties shall consult with one another on the terms of this Agreement for which confidential treatment will be sought in making any such disclosure. If a Party wishes to disclose this Agreement or any of the terms hereof in accordance with this Section 9.2(b), such Party agrees, at its own expense, to seek confidential treatment of the portions of this Agreement or such terms as may be reasonably requested by the other Party, provided that the disclosing Party shall always be entitled to comply with legal requirements.
- (c) Either Party may also disclose the existence and terms of this Agreement to its legal counsel, investment bankers, accountants and advisors, and to potential Sublicensees, Third Party contractors, investors, lenders or acquirers, and their legal counsel, investment bankers, accountants and advisors, in each case under an agreement or in the case of legal counsel, a professional obligation, to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such Confidential Information solely for the purpose permitted pursuant to this Section 9.2(c).

**ARTICLE 10**  
**REPRESENTATIONS AND WARRANTIES**

**10.1. Representations and Warranties of Cipher.**

Cipher represents and warrants to Licensee that as of the Effective Date:

- (a) To Cipher's knowledge of Cipher, Schedule "A" is a true and complete list of all of the Cipher Licensed Patents existing in the Territory and that it owns or controls all right, title and interest in and to the Cipher Licensed Patents and to the Cipher Licensed Know-How;
- (b) it has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement, and to grant the licenses granted under Section 8.1, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which Cipher is bound;
- (c) to the knowledge of Cipher, there are no legal claims, judgments or settlements against or owed by Cipher or pending legal claims or litigation, in each case relating to the Product, the Cipher Licensed Patents or the Cipher Licensed Know-How;
- (d) subject to Section 14.11, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Cipher as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;
- (e) it Controls the right, title and interest in and to the Cipher Licensed Patents and the Cipher Licensed Know-How, and has the right to grant to Licensee the licenses that it purports to grant hereunder and has not granted any Third Party rights that would interfere or be inconsistent with Licensee's rights hereunder;
- (f) it is not aware of any other Patents, Know How or other intellectual property right Controlled by Cipher or its Affiliates, other than that which is licensed hereunder to Licensee, which the Development, manufacture, use and/or Commercialization of the Product as contemplated hereunder would infringe;
- (g) it is not aware of any other Patents, Know How or other intellectual property right which the Development, manufacture, use and/or Commercialization of the Product as contemplated hereunder would infringe;
- (h) to the knowledge of Cipher, there is no action, suit, inquiry, investigation or other proceeding threatened, pending or ongoing brought by any Third Party that alleges the use of the Cipher Licensed Patents, Cipher Licensed Know-How or the Development, manufacture, Commercialization and/or use of the Product would infringe or misappropriate the intellectual property or intellectual property rights of any Third Party (and it has not received any notice alleging such an infringement or misappropriation). In the event that Cipher becomes aware of any such action or proceeding, it shall promptly notify Licensee in writing;

- (i) to the knowledge of Cipher, neither Cipher nor any of its Affiliates, nor any of its employees or agents: (i) is debarred, excluded, suspended, proposed for debarment or otherwise ineligible for participation in any federal, state or provincial health care program; ("Debarred"); and
- (j) Cipher does not have any current knowledge that would cause any of its representations or warranties to Licensee to be incorrect or untrue.

**10.2. Representations and Warranties and Covenants of Licensee.**

Licensee represents and warrants to Cipher that as of the Effective Date:

- (a) it has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement, to grant the licenses granted under Section 8.2, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation or court or administrative order by which Licensee is bound;
- (b) subject to Section 14.11 all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Licensee as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;
- (c) Licensee does not have any current knowledge that would cause any of its representations or warranties to Cipher to be incorrect or untrue;
- (d) it has no products that could be used as a substitute for the Product in the Field;
- (e) To the knowledge of Licensee, neither Licensee nor any of its Affiliates, nor any of its employees or agents, (i) is debarred, excluded, suspended, proposed for debarment or otherwise ineligible for participation in any federal, state or provincial health care program ("Debarred").

**10.3. Representations and Covenants of Both Parties.**

Each Party shall, and shall cause its Affiliates and agents to, comply with applicable laws, rules, regulations and guidelines of health regulatory authorities having jurisdiction in the Territory and related to the performance of its obligations hereunder, including the United States Food, Drug and Cosmetics Act and the *Food and Drugs Act* (Canada) and the regulations promulgated thereunder, and their foreign counterparts; all applicable federal, provincial, state and foreign laws and regulations applicable to health care fraud and abuse, kickbacks, physician self-referral and false claims; and local laws and regulations regarding the advertisement, sale and promotion of pharmaceutical products, in each case as amended from time to time.

**10.4. No Other Representations or Warranties.**

EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.



## ARTICLE 11 INDEMNIFICATION

### 11.1. General Indemnity By Licensee.

Licensee shall indemnify and hold harmless Cipher, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Cipher Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable legal fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") first arising after the Effective Date to the extent arising from: (a) the Development or Commercialization of the Product in the Field by Licensee or any of its Related Parties or Subcontractors; (b) the use of the Product in the Field manufactured or sold by Licensee or any of its Related Parties or Subcontractors by any purchasers thereof including, without limitation, any product liability claim; (c) the use by Licensee or any of its Related Parties or Subcontractors of the Cipher Licensed Patents and the Cipher Licensed Know-How in accordance with this Agreement; (d) the negligence, fraud or willful misconduct of Licensee in the performance of this Agreement; or (e) Licensee's material breach of this Agreement, except to the extent such Losses arise out of any of Cipher Indemnitee's negligence, illegal conduct or fraud, willful misconduct, or breach of this Agreement.

### 11.2. General Indemnity By Cipher.

Cipher shall indemnify and hold harmless Licensee, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Licensee Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable legal fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") first arising after the Effective Date to the extent arising from: (a) the Development or Commercialization of the Product in the Cipher Field by Cipher or any of its Related Parties or Subcontractors; (b) the use of the Product in the Cipher Field manufactured or sold by Cipher or any of its Related Parties or Subcontractors by any purchasers thereof including any product liability claim; (c) the use by Cipher or any of its Related Parties or Subcontractors of the Licensee Licensed Know-How and Licensee Data in accordance with this Agreement; (c) the negligence, fraud or willful misconduct of Cipher in the performance of this Agreement; or (e) Cipher's material breach of this Agreement, except to the extent such Losses arise out of any of Licensee Indemnitee's negligence, fraud, willful misconduct, or breach of this Agreement.

### 11.3. Defined Indemnification Terms.

Either of the Licensee Indemnitee or the Cipher Indemnitee shall be an "**Indemnitee**" for the purpose of this Article 11 and Article 12, and the Party that is obligated to indemnify the Indemnitee under Section 11.1 or Section 11.2 or Section 12.4 shall be the "**Indemnifying Party**".

### 11.4. Defense.

If any such claims or actions are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this Article 11.

**11.5. Settlement.**

The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment: (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee, where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment; or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld. Notwithstanding the foregoing, the Indemnifying Party shall not consent to entry of any judgment or enter into any settlement of a Third Party claim without the consent of the Indemnitee if the effect thereof is (a) to permit any injunction, declaratory judgement, other order or other non-monetary relief to be entered, directly or indirectly, against any Indemnitee; or (b) to ascribe any fault on any Indemnitee in connection with such defense.

**11.6. Notice.**

The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Section 11.1 or Section 11.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

**11.7. Permission by Indemnifying Party.**

The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

**11.8. Limitation of Liability.**

NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.8 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER ARTICLE 11 OR ARTICLE 12.4, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9.

**11.9. Insurance.**

Each Party shall maintain in good standing throughout the Term of this Agreement and for a period of seven (7) years thereafter, product liability insurance policies in respect of the Product with an internationally recognized insurer or insurers licensed to do business in the Territory in an amount of not less than \$5 million per occurrence, and not less than \$5 million in the aggregate, on such terms and conditions as are customary in the industry. Each Party shall provide proof of such insurance to the other Party within thirty (30) days of the Effective Date and thereafter from time to time within thirty (30) days of request of proof of such insurance.

**ARTICLE 12**  
**INVENTIONS; PATENT PROVISIONS**

**12.1. Ownership of Intellectual Property.**

As between the Parties, Cipher shall remain the sole and exclusive owner of all Cipher Licensed Patents, Cipher Licensed Know-How, Trademarks owned by Cipher and Cipher Data, and Licensee shall remain the sole and exclusive owner of all Licensee Licensed Patents, Licensee Trademarks, Licensee Licensed Know-How and Licensee Data. Each Party shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice by or on behalf of such Party, together with all intellectual property rights therein.

**12.2. Improvements**

For greater certainty, as between Licensee and Cipher, Licensee shall own all right, title and interest in and to any improvements to the Cipher Licensed Patents developed by Licensee.

**12.3. Enforcement.**

- (a) **Notice.** Each Party shall promptly provide, but in no event later than forty five (45) days, the other with written notice reasonably detailing any known or alleged infringement, misappropriation or other violation or challenge to the validity, scope or enforceability of any Patent or Trademark, or misappropriation or other violation of Know-How or Confidential Information, in each case owned or Controlled by the other Party with respect to the Product.
- (b) **Enforcement of Intellectual Property Rights.** The sole owner or Party Controlling Patents, Trademarks, Know-How or Confidential Information shall have, except as set out to the contrary in this subsection, the exclusive right to institute and direct legal proceedings against any Third Party believed to be misappropriating or otherwise violating such Patents, Trademarks, Know-How or Confidential Information. For clarity, Cipher shall have the first right to initiate a lawsuit against a person accused of misappropriating or otherwise violating Cipher Licensed Know-How and/or Cipher Licensed Patents. If Cipher does not cause the accused person to cease misappropriating or otherwise violating Cipher Licensed Know-How or Cipher Licensed Patents, or commence a lawsuit against the accused person if necessary, within forty-five (45) days after notice of violation of such Cipher Licensed Know-How and/or Cipher Licensed Patents, then Licensee shall be entitled (but shall not be obligated) to take all actions reasonably necessary to cause the accused person to cease misappropriating or otherwise violating Cipher Licensed Patents or Cipher Licensed Know-How, including commencement of a lawsuit against the accused person if necessary; provided, however, that Licensee shall consult in advance with Cipher regarding such action and may not undertake any enforcement action without the prior approval of the JSC, such approval not to be unreasonably withheld. The primary objective of any enforcement action shall be to preserve exclusivity for the Product and uses thereof in the major pharmaceutical markets. Other objectives shall be subservient to this primary objective. All amounts recovered from enforcement of any such rights by either Party relating to the intellectual property licensed under this Agreement shall be first used to reimburse each Party's costs and expenses incurred in connection with such action, and any remainder of such recovery shall be retained by the Party instituting the action, provided that any remainder retained by Licensee with respect to the enforcement of Cipher Licensed Know-How and/or Cipher Licensed Patents shall be treated as Net Sales and shall be subject to Licensee's royalty payment obligations at the applicable rate specified in Section 7.2.

- (c) **Cooperation in Enforcement Proceedings.** For any action by a Party pursuant to subsection 12.2(b), in the event that such Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute all documents necessary for such Party to initiate, prosecute and maintain such action. If either Party initiates an enforcement action pursuant to subsection 12.3(b), then the other Party shall cooperate to the extent reasonably necessary and at the first Parties' sole expense (except for the expenses of the non-controlling Party's counsel, if any). Upon the reasonable request of the Party instituting any such action, such other Party shall join the suit and can be represented in any such legal proceedings using counsel of its own choice. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof.
- (d) **Settlement.** The Parties shall keep each other informed of the status of and of their respective activities regarding any enforcement action pursuant to subsection 12.3(b). Neither Party shall settle any litigation or legal proceeding to enforce Cipher Licensed Patent without the other Party's written authorization, not to be unreasonably withheld.

#### 12.4. Defense.

- (a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the Development, Commercialization, manufacture or use of the Product or any technology or intellectual property licensed by a Party under this Agreement infringes, misappropriates or otherwise violates the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than thirty (30) business days, following receipt of such allegations.
- (b) In the event that a Party receives notice that it or any of its Affiliates have been individually named as a defendant in a legal proceeding by a Third Party alleging infringement, misappropriation or violation of a Third Party's Patents or other intellectual property right as a result of the Development, Commercialization, manufacture or use of the Product or any technology or intellectual property licensed by a Party under this Agreement, such Party shall immediately notify the other Party in writing and in no event notify such other Party later than thirty (30) business days after the receipt of such notice. The Parties agree that Licensee shall assume the primary responsibility for the conduct of the defense of any such claim that is specific to the Field, at Licensee's expense, and Cipher shall assume the primary responsibility for the conduct of the defense of any other such claim, at Cipher's expense. The Party that does not assume primary responsibility for the conduct of the defense shall have the right, but not the obligation, to participate and be separately represented in any such suit at its sole option and at its own expense. Each Party shall reasonably cooperate with the Party conducting the defense of the claim. If a Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement, misappropriation or violation of a Third Party's Patents or other intellectual property right as a result of the manufacture, production, use, development, sale or distribution of Products, the other Party shall be allowed to join in such action, at its own expense.
- (c) **Status; Settlement.** The Parties shall keep each other reasonably informed of the status of and of their respective activities regarding any litigation or settlement thereof initiated by a Third Party concerning a Party's Development, Commercialization, manufacture or use of the Product or any technology or intellectual property licensed by a Party under this Agreement; provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this subsection 12.4(c) may be undertaken by a Party without the consent of the other Party which consent shall not be unreasonably withheld or delayed; provided that such consent shall not be required to the extent that the settlement does not (a) adversely affect the validity, enforceability or scope of, or admit non infringement of any of a Party's Patents, Know-How or other intellectual property rights; (b) give rise to liability of such other Party or its Sublicensees; or (c) grant to a Third Party a license or covenant not to sue under, or with respect to, any intellectual property that the other Party owns or to which the other Party otherwise has exclusive rights.

**ARTICLE 13**  
**TERM AND TERMINATION**

**13.1. Term and Expiration.**

The term of this Agreement (the "**Term**") shall expire upon the 20th anniversary of the First Commercial Sale, unless terminated earlier pursuant to Sections 13.2, 13.3 or the launch of the first generic entrant. The Term shall be automatically renewed for additional successive one (1) year periods.

**13.2. Termination for Cause.**

This Agreement may be terminated at any time during the Term upon written notice by either Party if the other Party is (i) in breach of its payment obligations under this Agreement (ii) is in violation of its obligation to maintain insurance pursuant to 11.9; or (iii) in material breach of its other obligations under this Agreement and, in each case, has not cured such breach within forty-five (45) days after notice requesting cure of the breach (where reasonable steps have been taken to address non-payment within forty five (45) days); provided, however, that if such breach is not reasonably subject to cure within forty-five (45) days, subject to reasonably diligent efforts being undertaken within forty-five (45) days, the breaching Party shall not be deemed in breach provided it uses reasonable best efforts to cure such breach as promptly as possible. In addition, either Party may, at its option, terminate this Agreement, and all rights granted herein upon the occurrence of any of the following events of default:

- (a) the filing by the other Party of any petition or any application seeking reorganization, readjustment or rearrangement of the business of Licensee under any federal or provincial law relating to bankruptcy or insolvency;
- (b) the making by the other Party of any assignment or attempted assignment for the benefit of creditors;
- (c) the other Party becoming insolvent, as evidenced, for example (without limitation) by (i) the appointment of a receiver or a receiver manager for all or substantially all of the property of the other Party, (ii) the inability of the other Party to pay its liabilities generally as they become due, (iii) the termination of a majority of the other Party's employees, or (iv) the other Party ceasing, or imminently ceasing by way of a third party petition remaining in place for 30 days, to carry on business;

- (d) any resolution passed, order made, or other steps taken by the other Party for the winding up, liquidation or other termination of the existence of the other Party; or
- (e) if the other Party assigns or attempts to assign this Agreement or any rights hereunder contrary to this Agreement without the prior written notification of the Party.

### **13.3 Termination Without Cause.**

Upon sixty (60) days prior written notice to Cipher, Licensee may terminate this Agreement in its entirety without cause.

### **13.4 Effect of Termination.**

- (a) Upon the termination of this Agreement:
  - (i) Within sixty (60) days of expiration of termination of this Agreement (or such later date with respect to those costs that are incurred but cannot be reported as of such date), Licensee shall pay Cipher all undisputed amounts due to Cipher under this Agreement as of the effective date of such expiration or termination.
  - (ii) Notwithstanding anything to the contrary in this Section 13.4, if this Agreement terminates pursuant to Section 13.2 or 13.3 at the request of Licensee, Licensee shall have the right to sell its remaining inventory of Product(s) so long as Licensee has fully paid, and continues to pay fully when due, any and all undisputed invoiced amounts corresponding to Royalties and Sublicensee Revenues owed to Cipher hereunder based on such sales.
  - (iii) Notwithstanding Section 13.4, Licensee will not terminate the license granted to Cipher pursuant to Section 8.3 of this Agreement under the Licensee Licensed Patents, the Licensee Licensed Know-How, and Licensee Data, regulatory materials and other information related to the Product solely to manufacture clinical Materials or to make, Develop, manufacture or Commercialize Products within the Cipher Field.
  - (iv) The license granted to Licensee under Section 8.1 and any sublicenses that have been granted to a Sublicensee with respect to Cipher IP shall terminate.
  - (v) Except as otherwise provided under this Agreement or otherwise agreed by the Parties, all activities underway at the time of termination shall be terminated as soon as possible except that all costs of continuing studies or Clinical Trials or winding down activities shall continue to be borne by the Parties as provided in this Agreement until completion of such activities in the normal course. For the sake of clarity the costs of winding down activities shall include any incurred costs or otherwise unavoidable wind down costs that would otherwise have been payable by Licensee.
- (b) If either Party has the right to terminate this Agreement under Section 13.2, it may at its sole option, elect either to: (i) terminate this Agreement and pursue any legal or equitable remedy available to it; or (ii) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

**13.5 Survival.**

Any undisputed payments accruing hereunder shall continue to be due and owing following termination of this Agreement. In addition, the following provisions shall survive the termination of this Agreement for any reason: Articles 1, 5, 6.1(b), 7.5, 8.2, 9, 10, 11, 12, 13 and 14.

**ARTICLE 14  
MISCELLANEOUS**

**14.1. Force Majeure.**

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake reasonable efforts necessary to mitigate such force majeure circumstances.

**14.2. Assignment.**

Neither Party may assign its rights or obligations under this Agreement without providing prior written notice to the other Party.

**14.3. Severability.**

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**14.4. Notices.**

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by email (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Cipher, to:

Cipher Pharmaceuticals Inc.  
Attn: Shawn Patrick O'Brien, President & CEO  
2345 Argentia Road, Suite 100A  
Mississauga, Ontario  
L5N 8K4  
Email:

with a copy (which shall not constitute notice) to:

Torys LLP  
79 Wellington Street West  
Box 270, TD Centre  
Toronto, ON  
Attn: Cheryl Reicin, Esq.  
Email: creicin@torys.com

if to Licensee, to:

Edesa Biotech Inc.  
Attn: Pardeep Nijhawan, Director  
100 Spy Court  
Markham, Ontario  
L3R5H6  
Email: par@exzell.com

with a copy (which shall not constitute notice) to:

Borden Ladner Gervais LLP  
Scotia Plaza, 40 King Street W.  
Toronto, ON  
M5H3Y4  
Attn: Lydia Wakulowsky  
Email: lwakulowsky@blg.com

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by email on a business day; (b) on the business day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth business day following the date of mailing if sent by mail.

#### **14.5. Applicable Law and Litigation.**

This Agreement shall be governed by and construed in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, without reference to any rules of conflict of laws. For controversies, claims and disputes not covered by the arbitration provisions pursuant to Section 14.16, and for injunctive or other equitable interim relief in relation to all controversies, claims and disputes arising out of or relating to this Agreement, the Parties irrevocably and unconditionally: (a) consent to the exclusive jurisdiction of the courts of the Province of Ontario, Canada for any action, suit or proceeding and relating to injunctive or other equitable relief, and agree not to commence any action, suit or proceeding related thereto except in such courts; and (b) waive any objection to the laying of venue of any action, suit or proceeding in the courts of the Province of Ontario, Canada and waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

#### **14.6. Entire Agreement; Amendments.**

This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof are superseded by the terms of this Agreement. On the Effective Date, the confidentiality agreement between the Parties effective November 25, 2015 shall terminate and all Confidential Information exchanged thereunder shall be deemed Confidential Information of the Party disclosing such information and protected under this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.



**14.7. Independent Contractors.**

The Parties shall be independent contractors and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

**14.8. Waiver.**

The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

**14.9. Cumulative Remedies.**

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

**14.10. Waiver of Rule of Construction.**

Each Party has had the opportunity to consult with legal counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**14.11. Counterparts.**

The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the parties.

**14.12. Further Assurances.**

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement. Each Party shall use its commercially reasonable efforts to take all actions necessary or advisable under applicable laws to consummate and make effective the transactions contemplated by this Agreement including the taking of such reasonable actions as are necessary to obtain any requisite approvals, consents, orders, exemptions or waivers by any governmental authority.

**14.13. Construction.**

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. References to "Section" or "Sections" are references to the numbered sections of this Agreement, unless expressly stated otherwise.

#### **14.14. Currency.**

All payments under this Agreement shall be made in United States Dollars. All references to "dollars" or "\$" in this Agreement are to United States Dollars.

#### **14.15. Use of Third Parties.**

It is understood that when a Party engages any Third Party to manufacture the Product, that engagement may require a limited license or limited sublicense of rights obtained from the other Party under this Agreement. The Party engaging such Third Party (or non-licensed Affiliate) may disclose Confidential Information of the other Party solely as necessary to fulfill the business purposes of the engagement, and then only pursuant to terms and conditions that are substantially as protective of that Confidential Information as the terms and conditions of this Agreement. Notwithstanding any delegation of obligations under this Agreement by a Party to its Affiliates or to a Third Party, whether related to manufacturer of the Product or otherwise, the Party shall remain primarily liable and responsible for the performance of all of its obligations under this Agreement and for causing such Affiliates or Third Parties to act in a manner consistent herewith. In addition, such Party shall assure that any intellectual property developed by its Affiliates or such Third Parties shall be Controlled by that Party. The Party contracting with such Third Party shall not agree to any term that would make it unable to comply with its obligations under this Agreement. Cipher shall not engage any Third Party manufacturer without the prior written consent of Licensee, not to be unreasonably withheld.

#### **14.16. Dispute Resolutions.**

- (a) Any controversy, claim or dispute arising out of or relating to this Agreement shall first be submitted to the CEO of each Party for attempted resolution. If the CEOs of the Parties do not resolve such matter within thirty (30) days of the matter being submitted to them, then such matter shall be resolved through binding arbitration as follows. For the sake of clarity, this Section 14.16 is not intended to alter the rights of the Parties as established by Article 2, Governance, herein. The dispute shall be resolved by final and binding arbitration. The place of arbitration shall be the City of Toronto, Ontario, Canada. The arbitration shall be in accordance with the rules of ADRChambers ("**ADRC**") except as modified herein. The number of arbitrators shall be three. The language of the arbitration shall be English.
- (b) The Party wishing to commence an arbitration ("**Claimant**") shall notify the other party ("**Respondent**") in writing of its decision to commence arbitration hereunder (sometimes referred to in this Agreement as its "**demand for arbitration**"), setting out briefly its claims in its notice, and with its notice, name the arbitrator it is appointing.
- (c) The Respondent shall, within thirty (30) days of receipt of a demand for arbitration, notify the Claimant in writing of the name of the arbitrator it is appointing.

- (d) The third arbitrator shall be chosen by the first two arbitrators within twenty (20) days after the second of such arbitrators was appointed.
- (e) All arbitrators shall be chosen taking into account the type of issues to be addressed in the arbitration, whether legal, business, scientific, or a combination thereof, and having regard to their availability to conduct the arbitration within the times provided below. (The date on which the third arbitrator is appointed is the "**Arbitration Panel Finalization**").
- (f) Within thirty (30) days of completion of the hearing, the arbitrators shall render a reasoned arbitration award describing, in writing, the essential finding and conclusions on which the decision is based, including the calculation of any damages awarded. Any monetary award shall be made within thirty (30) days of the rendering of such award.
- (g) All information and documents in relation to the arbitration shall be deemed Confidential Information to the full extent permitted by law. No individual shall be appointed as an arbitrator unless the individual first agrees in writing to be bound by this subsection and to conduct the arbitration in a manner that in his/her judgment is most likely to maintain the confidentiality of Confidential Information. Neither Party may retain any expert in connection with the arbitration unless the expert first agrees in writing to be bound by this subsection, as applicable. The fact of and subject matter of the arbitration, including the fact that any dispute has been submitted to arbitration, and all evidence given and submissions made in connection with any arbitration, shall be Confidential Information, and shall be treated as such by the Parties and all persons employed by or contracted to them. Any meetings, conferences or hearings in connection with or during the arbitration may be attended only by those individual persons whose presence, in the opinion of the arbitral tribunal, is reasonably necessary for the determination or other resolution of the dispute and such person first agrees in writing to be bound by the provisions of these sections, as applicable. The obligations under this subsection continue notwithstanding any determination or other resolution of the arbitration.
- (h) The arbitrators shall be paid reasonable fees plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:
  - (i) If the arbitrators rule in favour of one Party on all disputed issues in the arbitration, the losing Party shall pay 100% of such fees and expenses.
  - (ii) If the arbitrators rule in favour of one Party on some issues and the other Party on other issues, the arbitrators shall issue with the ruling a written determination as to how such fees and expenses shall be allocated between the Parties. The arbitrators shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the arbitration, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.
- (i) Any final award of the arbitrators shall be final, conclusive and binding on the Parties, and judgment may be entered in any court of competent jurisdiction. To the extent lawful, the Parties exclude any right of review or appeal to Canadian, United States or other courts, including in connection with any question of law arising in the arbitration or in connection with any award or decision made by the arbitrators, except as is necessary to recognize or enforce such award or decision.

**14.17. Statute of Limitations.**

In no event will a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such a dispute between the Parties would otherwise be barred by the applicable statute of limitations.

**14.18. Injunctive and Other Interim Relief.**

Nothing in this Agreement shall be construed as limiting in any way the right of a Party to seek injunctive or other interim relief from a court of competent jurisdiction with respect to any actual or threatened breach of this Agreement, or to preserve or protect any property or assets pending an arbitral award, or otherwise in support of the contemplated or pending arbitration. No such court application shall be taken as a waiver or impairment of arbitration.

**14.19. Time of the Essence.**

Time shall be of the essence with respect to any payment owed or any other obligation of a Party hereunder.

**14.20. Execution in Counterparts; Facsimile Signatures.**

This Agreement may be executed in counterparts, each of which counterpart, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or scanned and emailed copies shall be deemed to be original signatures.

**14.21. Performance by Affiliates.**

To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party shall cause its Affiliates to perform such obligations. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; provided, however the Parties shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

*[Remainder of the Page Intentionally Left Blank]*

The Parties have executed this Agreement as of the Effective Date.

**CIPHER PHARMACEUTICALS INC.**

By: /s/ Shawn Patrick O'Brien  
Name: Shawn Patrick O'Brien  
Title: President & CEO

By: /s/ Norm Evans  
Name: Norm Evans  
Title: CFO

**EDESA BIOTECH INC.**

By: /s/ Pardeep Nijhawan  
Name: Pardeep Nijhawan  
Title: Director

By: /s/ Michael Brooks  
Name: Michael Brooks  
Title: Vice President

## Schedule "A"

<b>Country</b>	<b>Registration No. or Application No.</b>
Australia	2006233502
Belgium	1719507
Brazil	PI609361-2
Canada	2604758
China	ZL 2006800165347
EU	1719507
Israel	186491
Japan	5021621
South Korea	10-1355422
Mexico	281857
Norway	331211
New Zealand	562940
Poland	1719507
Russian Federation	016082
Thailand	0601001702
Taiwan	1366457
USA	8,426,475

**CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

**LICENSE AND DEVELOPMENT AGREEMENT**

This License and Development Agreement ("Agreement") is made effective as of [date] ("Effective Date") by and between Pendopharm, a division of Pharmascience Inc, located at 6111 Royalmount, Suite 100, Montreal, Quebec, H4P 2T4, Canada (hereinafter "Pendopharm"), and Edesa Biotech Inc., a Canadian corporation having its principal place of business at 100 Spy Court Markham, Ontario, L3R 5H6, Canada (hereinafter "Edesa").

**RECITALS**

**WHEREAS**, Edesa Controls the rights to certain intellectual property rights and know-how with respect to two novel agonists in specific formulations (EB02 Topical cream, EB03 Suppository and EB04);

**WHEREAS**, Edesa is planning to perform proof-of-concept clinical trials for EB02 and EB04;

**WHEREAS**, Pendopharm is a specialty pharmaceutical company active in the development and marketing of specialty pharmaceutical products in Canada;

**WHEREAS**, Pendopharm desires to obtain from Edesa certain exclusive rights to use the US Data Package (as hereinafter defined) and the New Drug Application ("NDA") created in respect of EB02, EB03 and EB04 to prepare a New Drug Submission ("NDS") to the competent Regulatory Authority in Canada, in order to obtain Marketing Authorization (as defined below) in Canada for EB02, EB03 and EB04;

**WHEREAS**, Pendopharm also desires to obtain certain exclusive rights with respect to importation, distribution, marketing and sale of EB02, EB03 and EB04 in the territory of Canada;

**WHEREAS**, Edesa is willing to (i) grant such exclusive right to use the US Data Package to Pendopharm and the NDA if Edesa owns or controls such NDA for use in the preparation of an NDS in the territory of Canada; and (ii) grant Pendopharm certain exclusive rights under its intellectual property rights and know-how with respect to importation, distribution, marketing and sale of EB02, EB03 and EB04 in the territory of Canada;

**WHEREAS**, Pendopharm is entering into this Agreement knowing that a complete US Data Package and NDA meeting the requirements of the FDA in order to obtain a Marketing Authorization for use of the Licensed Products will be available if and only if the proof of concept clinical trials are successful and Edesa can continue to raise further funds in future rounds of financing, otherwise Pendopharm acknowledges that a US Data Package and NDA may never be completed or available.

**NOW, THEREFORE**, Edesa and Pendopharm, intending to be legally bound, hereby agree as follows:

## ARTICLE 1 DEFINITIONS

In this Agreement, the below terms and expressions shall have the following meanings, and such meanings shall apply equally to both the singular and plural forms of the terms defined:

### 1.1. Definitions.

- (a) "Acceptance to Proceed" shall have the meaning set forth in Section 2.3.
- (b) "Affiliate" shall mean any corporation or other entity, which directly or indirectly controls, is controlled by or is under common control with a Party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.
- (c) "Agreement" shall mean this License and Development Agreement and its Exhibits.
- (d) "Alliance Manager" shall mean a representative appointed by each of the Parties responsible for the tasks set forth in Section 4.2(c).
- (e) "Applicable Law" shall mean all applicable law, rules and regulations, including any rules, regulations, guidelines or other requirements of any Regulatory Authority that may be in effect from time to time.
- (f) "Business Day" shall mean a day other than a Saturday or Sunday or any public holiday on which banking institutions in Toronto or Montreal, Canada, are closed for business.
- (g) "Calendar Quarter" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.
- (h) "Calendar Year" shall mean each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.
- (i) "Cipher Agreement" shall mean the exclusive license agreement between the **Cipher Pharmaceuticals Inc** and Edesa dated as of June 15th 2016.
- (j) "Claim" has the meaning set forth in Section 7.3(b).
- (k) "Confidential Information" shall have the meaning set forth in Section 12.1(a).
- (l) "Control" shall mean, with respect to any item of Information, Regulatory Documentation, Patent, Licensed Technology or Intellectual Property Right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the assignments, license and other grants of rights in this Agreement) to assign or grant a license, sublicense or other right to or under, such Information, Regulatory Documentation, Patent, Licensed Technology or Intellectual Property Right as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.



- (m) "Development" shall mean all activities related to preclinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance and quality control related to the foregoing manufacturing activities, clinical studies and post-approval studies, including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of drug approval applications, regulatory affairs with respect to the foregoing and all other activities otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining marketing authorization. When used as a verb, "Develop" shall mean to engage in Development.
- (n) "Drug Master File" shall mean the drug master file filed with a Regulatory Authority with respect to the Licensed Products that will be created as development of the products occurs.
- (o) "Edesa" shall have the meaning set forth in the first and opening paragraph of this Agreement.
- (p) "Edesa License" shall have the meaning set forth in Section 5.1.
- (q) "Edesa IP Improvements" shall have the meaning set forth in Section 7.1(b).
- (r) "Effective Date" shall have the meaning set forth in the first and opening paragraph of this Agreement.
- (s) "EMA" shall mean the European Medicines Agency.
- (t) "Existing Edesa IP" shall have the meaning set forth in Section 7.1(a).
- (u) "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- (v) "Field" shall mean human therapeutic use in the conditions of hemorrhoids and anal fissures.
- (w) "First Commercial Sale" shall mean, with respect to a Licensed Products in the Territory, the first commercial sale of such product after Marketing Authorization for such product has been granted by Health Canada.
- (x) "Health Canada" means the Canadian Federal Department known as Health Canada and any successor agency thereto.

- (y) "Indemnified Party" shall have the meaning set forth in Section 9.5.
- (z) "Information" shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information including study designs and protocols; assays and biological methodology; whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed, including the Regulatory Documentation.
- (aa) "Intellectual Property Rights" shall mean all rights in and to ideas, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information in whatever form, including patents, utility patents, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, provided that such rights or property are considered as intellectual property according to the Applicable Law ("Intellectual Property").
- (bb) "Knowledge" and/or "known" shall mean, with respect to any representation or warranty or other statement in this Agreement qualified by knowledge of a Party, the actual knowledge of the members of the management board of such Party.
- (cc) "Licensed Know-How" shall mean all Information not generally known to the public and not covered or claimed by published Licensed Patents, which Edesa owns, has under license, or otherwise Controls on the Effective Date and at all times during the Term necessary for Pendopharm to exploit the Licensed Products and Licensed Patents.
- (dd) "Licensed Patents" shall mean all existing or future regular, continuation, divisional, continuation-in-part, re-exam, reissue, term extended patent and patent applications ("Patents") in the Territory directly or indirectly claiming priority to or immediately derived from the patent applications licensed to Edesa under the Yissum Agreement and/or Cipher Agreement, as listed in Exhibit 1.37.
- (ee) "Licensed Products(s)" shall mean EB02, a topical anorectal formulation of Hyaluronic Acid (HA) conjugated with dipalmitoyl phosphatidyl-ethanolamine (DPPE), EB03, an anorectal suppository formulation of Hyaluronic Acid (HA) conjugated with dipalmitoyl phosphatidyl-ethanolamine (DPPE) **licensed pursuant to the Yissum Agreement** and EB04, a topical anorectal formulation of Levo-salbutamol **licensed pursuant to the Cipher Agreement**.
- (ff) "Licensed Technology" shall mean the Licensed Patents and the Licensed Know-How.

(gg) "Losses" shall have the meaning set forth in Section 9.1.

- (hh) "Marketing Authorization" shall mean, with respect to the Territory, authorization from the Regulatory Authority necessary to commercially distribute, sell or market the Licensed Products in the Territory.
- (ii) "NDA" shall mean a New Drug Application, and which consists of at least a complete registration file in Common Technical Document (CTD) format.
- (jj) "NDS" shall mean a New Drug Submission which consists of at least a complete registration file in Common Technical Document (CTD) format.
- (kk) "Net Sales" shall mean with respect to the Licensed Products for any period, means the gross amount invoiced and billed by Pendopharm or its Affiliates to unrelated Third Parties (excluding any Sublicensee) for the Product in the Territory, less:
- (i) Trade, quantity and cash discounts actually allowed or paid;
  - (ii) Commissions, discounts, refunds, rebates (including wholesaler fees), chargebacks, retroactive price adjustments, and any other allowances actually allowed or paid which effectively reduce the net selling price;
  - (iii) Actual Product returns and allowances;
  - (iv) Any sales, use, excise, value added taxes or similar taxes measured by the billing amount, when included in billing;
  - (v) Any freight, postage, shipping, and insurance charges related to delivery of the Product from an applicable warehouse, all to the extent included in the third party invoices; and
  - (vi) Custom, import and export duties actually paid.

Any refund or reimbursement of any of the foregoing amounts previously deducted from Net Sales shall be appropriately credited to Net Sales, or adjusted through allowances, upon receipt thereof.

For greater certainty "Net Sales" shall not include (i) sales or transfers between members of the group comprised of Pendopharm, Sublicensees, and their Affiliates; (ii) provision of Product for the purpose of conducting Clinical Trials in order to obtain Regulatory Approvals; (iii) disposal of reasonable quantities of Licensed Products for promotional or advertising purposes or regulatory or governmental purposes, but not to exceed 5% of Gross Sales ; and (iv) transfers or dispositions of reasonable quantities of Licensed Products to patients unable to purchase the Licensed Products, but not to exceed 5% of Gross Sales.

Such amounts shall be determined from the books and records of Pendopharm or its Affiliates or Sublicensees, as applicable, maintained in accordance with IFRS, consistently applied, except where IFRS is not the standard, in which case whatever the accounting standard is in effect will be applied.

Once the Licensed Products are approved for sale in the Territory by the applicable Regulatory Authority, if the Licensed Products are sold as part of a bundled transaction and there is no individual price for the Licensed Products in the transaction documentation (agreement, invoice etc.), the amount to be included in Net Sales shall be determined based on the pro rata allocation of the amount invoiced for all products included in such bundled transaction, based on the average per unit net sales price (calculated for the Calendar Quarter being reported) for such Licensed Products and the average per unit net sales price (calculated for the Calendar Quarter being reported) for every other product included in such bundled transaction and the number of units of Licensed Products and every other product included in such bundled transaction.

(11) "Pendopharm License" has the meaning ascribed to it in Section 5.2.

(mm) "Pendopharm IP" shall have the meaning ascribed to it in Section 7.1(c).

(nn) "Pendopharm IP Improvements" shall have the meaning ascribed to it in Section 7.1(d).

(oo) "Parties" shall mean Pendopharm and Edesa and " " shall mean either one of them.

(pp) "Payment" shall have the meaning set forth in Section 6.2(d).

(qq) "Regulatory Approval" shall mean any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Products, including, where applicable, (i) pricing or reimbursement approval, (ii) pre- and post-approval marketing authorizations, (iii) labeling approval, (iv) technical, medical and scientific data.

(rr) "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Development and exploitation of the Licensed Products.

(ss) "Regulatory Documentation" shall mean all applications, registrations, licenses, authorizations and approvals, including all Regulatory Approvals, the US Data Package, all correspondence submitted to or received from Regulatory Authorities and all supporting documents and all clinical studies and tests relating to the Licensed Products and all data contained in any of the foregoing, including, if applicable, all investigational new drug applications, marketing authorization applications, regulatory drug lists, advertising and promotion documents, clinical data, adverse event files and complaint files.

(tt) "Rest of the World" shall mean any country of the world other than the Territory.

- (uu) "Sublicensee" shall mean any Affiliate of Pendopharm or Third Party to whom Pendopharm has sublicensed its rights to the Licensed Products in accordance with Section 5.3.
- (vv) "Territory" shall mean Canada, including all provinces and territories.
- (ww) "Term" shall have the meaning set forth in Section 10.1.
- (xx) "Third Party" shall mean any person or entity other than Edesa or Pendopharm and their respective Affiliates.
- (yy) "Trademarks" shall have the meaning ascribed to it in Section 7.4.
- (zz) "US Data Package" shall mean all clinical and non-clinical data (including without limitation all Development, formulation and manufacturing information (including the open part of the Drug Master File), Information and Regulatory Documentation owned or Controlled by Edesa, to be used for the submission of an NDA to the U.S. Food and Drug Administration ("FDA") for obtaining Marketing Authorization for sale of the Licensed Products in the USA.
- (aaa) "Yissum Agreement" shall mean the exclusive license agreement between the Yissum Research Development Company and Edesa dated as of June 29, 2016.

## ARTICLE 2 DEVELOPMENT AND DATA SHARING

### 2.1. USA Development.

Edesa shall use reasonable commercial efforts to Develop the Licensed Products in the indications of hemorrhoids (with respect to EB02) and anal fissures (with respect to EB04) for the purposes of obtaining Regulatory Approval with the FDA.

### 2.2. Provision of US Data Package.

On a Licensed Product by Licensed Product basis, Edesa agrees to provide Pendopharm with the US Data Package within sixty (60) Business Days of submission of the NDA to the FDA in the United States. Within the ninety (90) day period following the provision of the US Data Package to Pendopharm, Edesa will use reasonable efforts to answer potential questions Pendopharm may have and, upon Pendopharm's request, provide any additional documents relating to the US Data Package that Edesa may have in its possession or Control.

### 2.3. Acceptance to Proceed.

Within ninety (90) days of its receipt of the US Data Package, Pendopharm will, on a Licensed Product by Licensed Product basis, inform Edesa in writing if Pendopharm would like to proceed with the preparation and submission of a Marketing Authorization application for the Licensed Products to the competent Canadian Regulatory Authority ("Acceptance to Proceed").

#### **2.4. Failure to provide Acceptance to Proceed.**

If Pendopharm does not provide Edesa with the Acceptance to Proceed within the period provided for in Section 2.3, Edesa will be entitled to, for the Licensed Product for which Pendopharm has not provided its Acceptance to Proceed, remove the Licensed Product from the scope of the license granted in this Agreement with immediate effect by giving written notice to Pendopharm, whereby all rights to that specific Licensed Product in the Territory granted to Pendopharm under this Agreement shall revert back to Edesa and Section 10.7(a) shall apply.

#### **2.5. Development Responsibility.**

If Pendopharm declares Acceptance to Proceed, Pendopharm will be responsible for obtaining Marketing Authorization and any other Regulatory Approvals which may be required in the Territory for the sale and marketing of the Licensed Product in the Field and for generating any additional data which may be required for obtaining Marketing Authorization in the Territory at its own cost.

#### **2.6. Marketing Authorization Application.**

Pendopharm shall, at the earliest possible time after receipt of the US Data Package from Edesa, discuss with the competent Canadian Regulatory Authority whether Marketing Authorization in the Territory can be obtained on the basis of the US Data Package or whether additional clinical studies have to be performed in the Territory. If no further clinical studies should be required, Pendopharm will, subject to Section 2.3, use reasonable efforts to submit a Marketing Authorization application for the Licensed Products to the competent Regulatory Authority in the Territory.

#### **2.7. Additional Clinical Studies and further Development.**

- (a) Scope. If after discussions with the competent Regulatory Authorities in the Territory, Pendopharm is required to conduct further clinical studies or further Development, Pendopharm shall establish the scope and the design of any studies required in the Territory in order to obtain the Marketing Authorization for the Licensed Products, and shall seek Edesa prior written approval of the clinical studies or further Development, such consent shall not be unreasonably withheld or delayed.
- (b) Regulatory Approval. Subject to Section 2.9, Pendopharm shall use reasonable commercial efforts to initiate the clinical studies or further Development without delay.
- (c) Ownership of Data from Additional Clinical Studies. As between Pendopharm and Edesa, Pendopharm shall own all data arising from the additional clinical studies conducted or Development done by Pendopharm in the Territory and Pendopharm hereby agrees to assign all right, title and interest therein to Edesa at Termination in accordance with Section 10.7(a).

#### **2.8. Clinical Trial Material.**

If Pendopharm determines that clinical studies shall be performed in the Territory, Edesa will supply the required clinical supply of the Licensed Products to Pendopharm at actual cost. Detailed supply terms and responsibilities of the Parties regarding quality will be agreed in a separate supply agreement prior to the commencement of the supply of Licensed Products to Pendopharm, with the proviso that such additional terms must reasonably enable Edesa to meet the terms agreed with Edesa's contract manufacturer.

## **2.9. Data Sharing.**

The Parties will establish a shared website for the exchange of the information in relation to the Licensed Products to be exchanged between the Parties pursuant to the terms of this Agreement. Edesa will commence providing information pertaining to the US Data Package to Pendopharm after completion of the proof of concept clinical trials for each of the products and as such information becomes available. Each Party shall provide to the other Party copies of all clinical and non-clinical data and other results and analyses with respect to any Development activities with respect to the Licensed Products in the Field, for each of the Licensed Products and when and as such data, results and analyses become available and as soon as reasonably practicable. Subject to Applicable Law in the relevant territory, the aforesaid obligation shall also include data generated by Edesa's licensees and/or Pendopharm's Sublicensees, but shall, for purposes of clarity, exclude any commercial information. Such clinical and non-clinical data shall be prepared in the English language and in a format generally accepted by Regulatory Authorities, such as the FDA, Health Canada and/or the EMA. Further, any clinical studies undertaken by or on behalf of a Party shall include consents and authorizations which allow release of all protected health information of the study participants to the other Party and its licensees to the extent permitted by the Applicable Law and such releases and/or authorizations shall contain language which makes it clear to the study participant that any information related to the Licensed Products shall be kept confidential. Each Party shall furnish to the other Party regularly, at least every half a year, reports including the clinical and non-clinical data generated by it in the preceding half a year. For the avoidance of doubt, both Parties agree to only enter into any agreements with Sublicensees and/or Third Parties if the Sublicensee/Third Party undertakes the same obligations regarding disclosure and access to clinical and non-clinical data as Pendopharm undertakes pursuant to this Agreement, in particular pursuant to the foregoing sentences.

## **2.10. Pricing and Reimbursement Approvals.**

Pendopharm shall be responsible for all pricing and reimbursement approval proceedings relating to the Licensed Products in the Territory.

## **2.11. Regulatory Records.**

Pendopharm and Edesa each shall maintain, or cause to be maintained, records of their respective Development activities with respect to the Licensed Products in the Field in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of their respective Development activities, and which shall be retained by such Party for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Not more than once in a Calendar Year, each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy any such records of the other Party. A Party shall provide the other Party with such additional information regarding the Development activities in relation to this Agreement as such Party may reasonably request from time to time.

## **2.12. Alliance Management pre-Commercialization.**

After execution of this Agreement, Pendopharm and Edesa shall appoint one representative of each organization who will meet by teleconference at least two (2) times per year until the end of Phase III clinical trials in order to update each other on medical affairs and regulatory affairs and other relevant matters related to the Licensed Products in the Territory. Each party will use reasonable efforts to satisfy the requests of the other representative for access to specific information and documentation.

## **ARTICLE 3 REGULATORY**

### **3.1. Adverse Event Reporting.**

Subject to the terms of this Agreement, no later than three (3) months before market launch in the Territory, Edesa and Pendopharm shall discuss and develop mutually acceptable guidelines and procedures for (a) the investigation, exchange, receipt, recordation, communication (as between the Parties) and exchange of Adverse Event Experience information and all other information required by either Party in order to meet its pharmacovigilance responsibilities and (b) for the handling of any oral or written communication of dissatisfaction regarding the identity, quality, durability, reliability or performance of the Licensed Products, including appearance, low fills, foreign materials, foreign product, defective packaging or defective labeling. "Adverse Event Experience" shall mean (i) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity and (ii) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use or occurring following administration, of the Licensed Products in humans, occurring at any dose, whether expected or unexpected and whether or not considered related to or caused by the Licensed Products, including such an event or experience as occurs in the course of the use of the Licensed Products in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected pharmacological or biological therapeutic action of the Licensed Products, and including those events or experiences that are required to be reported to any Regulatory Authority in the Territory.

### **3.2. Recall of Licensed Products.**

- (a) In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with the Licensed Products or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the Party notified of or desiring such recall or similar action shall, within twenty-four (24) hours, advise the other Party thereof by telephone (and confirm by email or facsimile), email or facsimile.
- (b) Pendopharm will use best efforts to withdraw the Licensed Products from the market without delay, if Edesa or any Regulatory Authority demands a recall of the Licensed Products in the Territory.
- (c) Pendopharm shall bear all reasonable costs of recall of the Licensed Products in the Territory except if such recall is due to Edesa's negligence or willful misconduct, in which event Edesa shall bear the costs of said recall. For the purpose of this Agreement, costs of a recall shall not include loss of profit of either Party.



**ARTICLE 4**  
**SUPPLY AND COMMERCIALIZATION**

**4.1. Supply of Licensed Products.**

Edesa will supply the Licensed Products to Pendopharm subject to the terms of a separate supply agreement, the terms of which shall be agreed by the parties in good faith, with the proviso that such additional terms must reasonably enable Edesa to meet the terms agreed with Edesa's contract manufacturer. On a product by product basis, the parties will enter into good faith negotiations within thirty (30) days of Edesa's receipt of Pendopharm's Acceptance to Proceed.

**4.2. Commercialization**

- (a) **General.** Pendopharm shall have sole responsibility for the commercialization of the Licensed Products in the Territory, and all costs and expenses associated with its commercialization of the Licensed Products in the Territory shall be borne by Pendopharm. Pendopharm may, in its sole discretion, choose whether to commercialize the Licensed Products itself or, subject to Section 5.3, to collaborate with Affiliates, Sublicensees or distributors.
- (b) **Compliance with Laws.** Pendopharm shall comply in all material respects with all Applicable Law with respect to the commercialization of the Licensed Products in the Territory. In this regard, Edesa shall provide Pendopharm with all information required in order for Pendopharm to comply with the Patented Medicines Price Review Board (PMPRB) Regulations.
- (c) **Alliance Management.** After completion of a positive phase III clinical trial of at least one of the Licensed Products, Pendopharm and Edesa shall appoint one representative of each organization ("Alliance Manager") who will meet by teleconference at least two (2) times per year during the Term in order to update each other on commercial activities (including, but not limited to, marketing and reimbursement, sales performance, key market information, forecasts), medical affairs, regulatory affairs, and supply chain activities, changes, and plans relevant to the Licensed Products in the Territory. Each party will use reasonable efforts to satisfy the requests of the other Party's Alliance Manager for access to specific information and documentation.
- (d) **Marketing and Promotion.** Once Market Authorization has been granted for each of the Licensed Products, Pendopharm shall be responsible for:
  - (A) the marketing and promoting the Licensed Products in the Territory, which shall include sales and marketing activities, managing tender processes and submissions (public, hospitals and federal programs), reimbursement activities, information exchange with Regulatory Authorities and customers.

- (B) communicating with customers, hospitals, pharmacies, payers and other health care professionals.
- (C) using commercially reasonable efforts for the commercialization of the Licensed Products.
- (D) the provision of all customer service, query handling, maintenance and development of customer data in the Territory.
- (e) Ownership of Customer Data. All customer data remains at all times the property of Pendopharm. Notwithstanding the foregoing, if this Agreement is terminated pursuant to Section 10.3 by Edesa, Pendopharm shall transfer customer data to Edesa.
- (f) Training. Edesa shall have the right, at its own cost, to provide trainings to Pendopharm's sales representatives or product trainings, if Edesa considers this necessary or useful, the frequency and location of such trainings to be agreed on by the parties.
- (g) Marketing Material. Edesa will provide international marketing materials, to Pendopharm in electronic form. Pendopharm will be responsible for ensuring that said marketing materials comply with Applicable Law prior to using them in the Territory.
- (h) Conditions of Sale by Pendopharm. Pendopharm has sole responsibility for the terms and conditions of sale of the Licensed Products to customers in the Territory.

## **ARTICLE 5 GRANT OF LICENSE**

### **5.1. Grant of License Rights to Pendopharm.**

During the Term of this Agreement, Edesa hereby grants to Pendopharm the following licenses:

- (a) an exclusive, royalty-bearing, non-sublicensable, non-transferable license to use the US Data Package and, to the extent referenced in the US Data Package, the Licensed Technology, for the sole purpose of preparing the Canadian data package to obtain Market Authorization for the Licensed Products to allow Pendopharm to distribute, market and sell Licensed Products in the Field in the Territory; and
- (b) the event Pendopharm obtains Market Authorization for such Licensed Products in the Territory, an exclusive, royalty-bearing, sublicensable, non-transferable license to distribute, market and sell the Licensed Products in the Field in the Territory.

(collectively, the "Edesa License").

### **5.2. Grant of License Rights to Edesa.**

During the term of this Agreement, Pendopharm hereby grants to Edesa, an exclusive, royalty-free, sub-licensable:

- (a) right to use the clinical trial data, if Development is required pursuant to Section 2.7; and
- (b) right to use and reproduce and amend the NDS, outside of the Territory. (collectively, the "Pendopharm License").

### **5.3. Pendopharm Sublicenses.**

- (a) Pendopharm shall have the right to sublicense its rights granted pursuant to Section 5.1(b), provided that the sublicense shall be at arm's length, conform to the terms hereof, and (A) if granted to Affiliates of Pendopharm, be notified to Edesa promptly after the grant of such sublicense and (B) if granted to any Third Parties, be subject to the prior written consent of Edesa, which consent shall not be unreasonably withheld, conditioned or delayed (C) each sublicense agreement will contain terms and conditions:
  - (i) specifying that such written agreement terminates upon termination of this Agreement;
  - (ii) consistent with the relevant terms and conditions of this Agreement protecting the rights of Edesa under this Agreement including imposing obligations of confidentiality on each such sublicensee;
  - (iii) that assign and transfer all right, title and interest in and to any and all inventions or work product developed by such Sublicensee relating to the Licensed Products in the course of performing activities under such sublicense to Edesa;
  - (iv) that do not impose any payment obligations or liability on Edesa without the prior written consent of Edesa;
  - (v) that Pendopharm shall require each Sublicensee to provide it with regular written royalty reports that include at least the detail that Pendopharm is required to provide to Edesa pursuant to this Agreement which reports, Pendopharm shall have the right to provide to Edesa upon request;
  - (vi) that Pendopharm shall provide Edesa with an executed copy of each sublicense agreement within five (5) Business Days of its execution.

### **5.4. Retained Rights.**

Except as expressly provided herein, the parties grant no other right or license to the other party, including any rights or licenses to the Licensed Patents, the Licensed Know-How, any other Patents or other Intellectual Property Rights, or any improvements to any of the foregoing.

**ARTICLE 6  
PAYMENTS**

**6.1. Royalty Payments Pendopharm.**

- (a) General. In consideration of the Edesa License provided hereunder, Pendopharm shall pay to Edesa a tiered royalty in the amounts set forth in Section (c) below on all Net Sales by Pendopharm or its Sublicensees of all Licensed Products in the Territory.
- (b) Royalty Term. Pendopharm's obligation to pay royalties shall expire, on a Licensed Product-by-Licensed Product basis, on the later to occur of:
  - (i) 13<sup>th</sup> anniversary of the First Commercial Sale of the Licensed Product in the Territory,
  - (ii) the expiration date in the Territory of the last-to-expire Patent of the Licensed Patents relating to the Licensed Product,
  - (iii) the expiration date of the applicable regulatory or data exclusivity covering the Licensed Product in the Territory,
 (as applicable, the "Royalty Term").
- (c) Tiered Royalty Rate. Pendopharm will pay to Edesa royalties, on a Licensed Product by Licensed Product basis, at the following rates:

Annual Net Sales (Canadian dollars)	Royalty Rate
Aggregate annual Net Sales for each Licensed Product less than or equal to [ ] million Canadian dollars (\$[ ]) )	[ ]% of Net Sales
Aggregate annual Net Sales for each Licensed Product greater than [ ] million Canadian dollars (\$[ ]) and less than or equal to \$[ ]	[ ]% of Net Sales
Aggregate annual Net Sales for each Licensed Product greater than [ ] million Canadian dollars (\$[ ]) )	[ ]% of Net Sales

- (d) Royalty Payment Reports, Exchange Rates. From the date of First Commercial Sale of the Licensed Products until the expiration of the Term, Pendopharm shall within **[thirty (30) days]** after each Calendar Quarter pay to Edesa the royalties due under this Agreement for such Calendar Quarter and furnish to Edesa a written quarterly report showing: (i) the Net Sales of the Licensed Products sold by Pendopharm and its Sublicensees during the reporting period; and (ii) the royalties due thereon.
- (e) Generic Competition. At such time as a generic equivalent is available for sale in the Territory by a Third Party, Edesa authorizes Pendopharm and its Affiliates to market a generic **[equivalent to be supplied]** by Edesa ("Authorized Generic") in the Territory. The royalties payable by Pendopharm to Edesa for Authorized Generic will be equal to [ ] percent ([ ]%) of the Royalty Rates referred to in Section 6.1(c).

- (f) Taxes.
  - (i) General. Any taxes, levies or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by any one of the Parties ("Withholding Party") on account of monies payable to the other Party under this Agreement shall, be deducted from the amount of monies otherwise payable to the other Party under this Agreement and shall be paid or remitted to the applicable governmental authority within the time required by Applicable Law. The Withholding Party shall secure and send to the other Party within a reasonable period of time proof that any such Taxes required to be withheld by the Withholding Party have been duly paid or remitted for the benefit of the other Party.

## **6.2. Audits, Audit Disputes.**

- (a) Audits. Upon advance notice of not less than thirty (30) days, Pendopharm, following the First Commercial Sale of the Licensed Products, shall permit Edesa or an independent auditor designated by Edesa (each a "Representative") to have access during normal business hours to such books and records of Pendopharm as may be reasonably necessary to verify the accuracy of the royalty reports and other Payments described herein. Such audit will not be conducted more often than once in a calendar year.
- (b) Auditor's Fees. The fees charged by such auditor shall be paid by Edesa unless the audit discloses that the royalties or other Payments payable by Pendopharm for the audited period are underpaid by more than five percent (5%), in which case Pendopharm shall pay the reasonable fees and expenses charged by such auditor and, as the case may be, a further amount equal to the amount of the underpaid royalty or Payments plus interest. Any overpayment will be refundable or credited against future royalties. Pendopharm shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensees to make reports to Pendopharm, to keep and maintain books and records of sales made pursuant to such sublicense and to grant access to such books and records to Edesa's Representative to the same extent required of Pendopharm under this Agreement. Edesa agrees that all information subject to review under this Section 6.2 or under any sublicense agreement will be confidential and that Edesa will cause its Representative to retain all such information in confidence in accordance with the confidentiality provisions of Article 12.
- (c) Audit Dispute. In the event of a dispute regarding such books and records, including the amount of royalties and other Payments owed to Edesa hereunder, Edesa and Pendopharm shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for decision to a certified public accounting firm mutually selected by each Party's certified public accountants or to such other Third Party as the Parties shall mutually agree ("Expert"). The decision of the Expert shall be final and the costs of such decision as well as the initial audit shall be borne between the Parties in such manner as the Expert shall determine. Not later than ten (10) days after such decision and in accordance with such decision, Pendopharm shall pay the underpaid royalties and other Payments or Edesa shall reimburse such excess payments, as applicable.

- (d) Payment. All Payments to be made under this Agreement shall be made in CAD. Pendopharm shall pay interest to Edesa on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to one percent (1%) per month, calculated on the number of days such payments are paid after the date such payments are due and compounded monthly.

## ARTICLE 7 INTELLECTUAL PROPERTY

### 7.1. Ownership of Existing IP, Inventions and Joint Inventions. Licenses.

- (a) Existing Edesa IP. As between the Parties, Edesa shall own or Control, all Information, Licensed Technology, Licensed Products and the US Data Package and any Intellectual Property Rights therein, existing on the Effective Date ("Existing IP").
- (b) Edesa IP Improvements All modifications or improvements to the Existing IP, conceived, prepared, developed or created either solely by Edesa, or jointly with Pendopharm, shall be the exclusive property of Edesa (the "Edesa IP Improvements"). Any Improvement shall be included within the definition of Licensed Know-How and shall become subject to the terms of this Agreement.
- (c) Pendopharm IP. As between the Parties, Pendopharm shall own or Control, the right to use the clinical trial data, if Development is required pursuant to Section 2.7, the Trademarks and any Intellectual Property Rights therein ("Pendopharm IP").
- (d) Pendopharm IP Improvements All modifications or improvements to the Pendopharm IP, conceived, prepared, developed or created either solely by Pendopharm, or jointly with Edesa, shall be the exclusive property of Pendopharm (the "Pendopharm IP Improvements"). Any Pendopharm IP Improvements shall be included within the definition of the Pendopharm License and shall become subject to the terms of this Agreement.
- (e) Ownership of Regulatory Approvals. As between Pendopharm and Edesa, Pendopharm shall own all right, title and interest in and to all Regulatory Approvals with respect to the Licensed Products in the Territory.

### 7.2. Maintenance and Prosecution of Licensed Patents.

Edesa or its licensees, through patent attorneys or agents of its or their choice and at its or their sole cost and expense, shall have the right, but not the obligation, to file, obtain, prosecute and maintain the Licensed Patents and all foreign counterparts thereof owned or Controlled by Edesa on the Effective Date and at all times during the Term. With respect to the Territory, Edesa shall not, and shall perform reasonable endeavours to procure that its licensees other than Pendopharm, do not, abandon or cease the prosecution of any such application for a Licensed Patents or permit any registration of a Licensed Patents issuing therefrom to lapse without first notifying Pendopharm and permitting Pendopharm to continue the preparation, filing, prosecution and maintenance of such applications or registrations or pay any required fees in the name of Edesa, at Pendopharm's expense and through patent attorneys of its choice. Pendopharm shall not become an assignee of any Licensed Patent as a result of its continuing the prosecution or registration of a Patent or paying any fees according to this Section 0. If Pendopharm makes such expenses, Pendopharm shall have the right to deduct such expenses from any royalty payment to be made to Edesa pursuant to Section 6.1.

### **7.3. Enforcement and Third Party Infringement Claims.**

- (a) **Rights and Procedures.** A party shall notify the other party of any infringement, misappropriation or other violation of the Intellectual Property Rights of the other party of which it becomes aware. The other party may, at its sole discretion, bring proceedings or take such action as it may deem appropriate to stop any such infringement, misappropriation or other violation. If the other party does take any such action or proceedings, the parties shall cooperate at their own expense, in such action. The parties shall not be permitted to bring proceedings or take other actions in respect of infringement, misappropriation or violation of the other parties Intellectual Property Rights without the prior written consent of the other party.
- (b) **Claims.** If any third party commences an action or proceeding claiming the infringement, misappropriation or other violation of its Intellectual Property Rights by a party (a "Claim"), the parties shall immediately notify each other party once they become aware of the Claim. Each party shall, at its sole discretion, either defend any such Claim on its own, permit the other party to participate in the defence of any Claim, or permit the other party to defend such Claim on its own. Neither party shall settle any Claim without the prior written consent of the party. The parties shall cooperate at their own expense, in any such defence of a Claim.

### **7.4. Trademarks.**

Subject to Sections 10.4 and 10.5, Pendopharm shall be authorized to select the trademark(s) for the Licensed Products(s) in the Territory in accordance with Applicable Law and the requirements of the Regulatory Authority (the "Trademarks"). Pendopharm shall own the Trademarks and shall be solely responsible for the prosecution, registration and maintenance of the Trademarks.

### **7.5. PM(NOC) Litigation.**

Pendopharm shall have the first right to commence and control any application under the Patented Medicines (Notice of Compliance) Regulations ("PM(NOC)") in connection with the Licensed Products in the Territory. Accordingly, Edesa shall advise Pendopharm within thirty (30) days of any grant of any of its patents and/or patent applications with respect to the Licensed Products, subject to Edesa having learnt of said grant. In such case, Pendopharm shall be responsible for all legal costs it incurs in pursuing any such application, and Pendopharm shall be entitled to retain any award of costs granted in its favor. The Party who commenced and controlled such an application shall also have the sole obligation to defend any proceeding under Article 8 of the PM(NOC) in respect of a withdrawn, dismissed or discontinued application commenced by that Party under the PMNOC, including the obligations to pay all legal costs incurred in defending such proceeding and all awards of damages and costs made by the court. Edesa, at the request of Pendopharm, shall cooperate in all reasonable respects with Pendopharm in the pursuit or defense of such claims including, but not limited to, Edesa accepting to be added as a party to said application or claim where necessary.

#### **7.6. Patent Registry.**

Edesa shall consult and cooperate with Pendopharm with a view to obtaining issued Licensed Patents that meet the criteria for listing on the Patent Register of Health Canada pursuant to the Patented Medicines (Notice of Compliance) Regulations ("Patent List"). Edesa consents to Pendopharm including any such issued Licensed Patents on the Patent List for the Licensed Products and will provide any necessary assistance to Pendopharm in order to list the issued Licensed Patents in a timely manner.

### **ARTICLE 8 REPRESENTATIONS AND WARRANTIES**

#### **8.1. Representation and warranties of Edesa.**

Edesa hereby represents and warrants to Pendopharm that, as of the Effective Date and unless otherwise set forth below, at all times during the Term:

- (a) Edesa has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any material contractual obligation, including the Yissum Agreement or the Cipher Agreement, or a court or administrative order by which Edesa is bound.
- (b) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Edesa as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.
- (c) Edesa does not have any current knowledge that would cause any of its representations or warranties to Pendopharm to be incorrect or untrue.
- (d) to the knowledge of Edesa, neither Edesa nor any of its Affiliates, nor any of its employees or agents (i) is debarred, excluded, suspended, proposed for debarment or otherwise ineligible for participation in any federal, state or provincial health care program; (ii) has been convicted of or had a civil judgment rendered against it for commission of fraud or a criminal offense; and (iii) is presently indicted for or otherwise criminally or civilly charged by a governmental entity or agency with commission of any of the offenses set out in this paragraph.



- (e) Edesa shall, and shall cause its Affiliates and agents to, comply with laws, rules, regulations and guidelines and related to the performance of its obligations hereunder and applicable including the *Food and Drugs Act* (Canada) and its regulations promulgated thereunder.
- (f) Edesa has, and shall maintain during the Term, facilities, personnel, experience and expertise sufficient in quality and quantity to perform its obligations hereunder and it shall so perform with reasonable due care and in conformity with current generally accepted industry standards and procedures applicable in the Territory.
- (g) Edesa shall comply during the Term of this Agreement, at its sole cost and expense, with all Applicable Law in force in the Territory pertaining to and in relation to Edesa's activities with regard to the Licensed Products and the performance of its obligations under this Agreement.
- (h) to Edesa Knowledge, as of the Effective Date, there is no civil, criminal or administrative judgment, action, suit, demand, claim, hearing, notice of violation or investigation proceeding, pending or threatened against Edesa that could materially and adversely affect the ability of Edesa to carry out its obligations under this Agreement.
- (i) Edesa shall immediately notify Pendopharm if, at any time during the Term of this Agreement, Edesa becomes aware that it, or any of its Affiliates is convicted of an offense that would subject Pendopharm or Edesa to exclusion, suspension or debarment from any program in relation to the activities contemplated under this Agreement.
- (j) Edesa takes all commercially reasonable precautions, in line with industry norms, to protect its confidential information and intellectual property from unauthorized disclosure.

## **8.2. Representation and warranties of Pendopharm.**

Pendopharm hereby represents and warrants to Edesa that as of the Effective Date and, unless otherwise set forth below, at all times during the Term:

- (a) Pendopharm has the full right, power and authority to enter into this Agreement, to perform its obligations under this Agreement and the fulfillment of its obligations and performance of its activities hereunder.
- (b) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Pendopharm as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.
- (c) Pendopharm does not have any current knowledge that would cause any of its representations or warranties to Edessa to be incorrect or untrue.

- (d) to the knowledge of Pendopharm, neither Pendopharm nor any of its Affiliates, nor any of its employees or agents (i) is debarred, excluded, suspended, proposed for debarment or otherwise ineligible for participation in any federal, state or provincial health care program; (ii) has been convicted of or had a civil judgment rendered against it for commission of fraud or a criminal offense; and (iii) is presently indicted for or otherwise criminally or civilly charged by a governmental entity or agency with commission of any of the offenses set out in this paragraph.
- (e) Pendopharm shall, and shall cause its Affiliates and agents to, comply with laws, rules, regulations and guidelines and related to the performance of its obligations hereunder and applicable including the *Food and Drugs Act* (Canada) and its regulations promulgated thereunder.
- (f) Pendopharm has, and shall maintain during the Term, facilities, personnel, experience and expertise sufficient in quality and quantity to perform its obligations hereunder and it shall so perform with reasonable due care and in conformity with current generally accepted industry standards and procedures applicable in the Territory.
- (g) Pendopharm shall comply during the Term of this Agreement, at its sole cost and expense, with all Applicable Law in force in the Territory pertaining to and in relation to Pendopharm's activities with regard to the Licensed Products and the performance of its obligations under this Agreement.
- (h) to Pendopharm's Knowledge, as of the Effective Date, there is no civil, criminal or administrative judgment, action, suit, demand, claim, hearing, notice of violation or investigation proceeding, pending or threatened against Pendopharm that could materially and adversely affect the ability of Pendopharm to carry out its obligations under this Agreement.
- (i) Pendopharm shall immediately notify Edessa if, at any time during the Term of this Agreement, Pendopharm becomes aware that it, or any of its Affiliates is convicted of an offense that would subject Edessa or Pendopharm to exclusion, suspension or debarment from any program in relation to the activities contemplated under this Agreement.
- (j) Pendopharm takes all commercially reasonable precautions, in line with industry norms, to protect its confidential information and intellectual property from unauthorized disclosure.
- (k) Pendopharm shall only use Confidential Information, Information and Regulatory Documentation within the Territory in accordance with the terms and conditions of this Agreement.

### **8.3. No Reliance by Third Parties.**

The representations and warranties of each Party set forth in this Agreement are intended for the sole and exclusive benefit of the other Party hereto, and may not be relied upon by any Third Party.

## ARTICLE 9 INDEMNIFICATION

### 9.1. Pendopharm Indemnity Obligations.

Pendopharm agrees to defend, indemnify and hold Edesa, its Affiliates, its sub-contractors and its licensees and their respective directors, officers, employees and agents (each a "Edesa Indemnity Party") harmless against any and all claims, suits, judgments, losses, liabilities, damages, costs, fees and expenses (including reasonable attorneys' fees) (collectively, "Losses") resulting from or arising out of (i) the negligence or willful misconduct on the part of Pendopharm, its Affiliates, sub-contractors and Sublicensees and their respective directors, officers, employees and agents (each a "Pendopharm Indemnity Party") in relation to the carrying out of this Agreement, (ii) the negligent or willful breach by a Pendopharm Indemnity Party of any terms of this Agreement, or (iii) the breach, whether negligent or not, of any of Pendopharm's representations and warranties in Article 8 of this Agreement by a Pendopharm Indemnity Party, except for those Losses which Edesa has an obligation to indemnify a Pendopharm Indemnity Party pursuant to Section 9.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability, and provided further that Pendopharm shall not be obligated to indemnify any Edesa Indemnity Party for any Losses to the extent such Losses arise as a result of negligence or willful misconduct on the part of such Edesa Indemnity Party.

### 9.2. Edesa Indemnity Obligations.

Edesa agrees to defend, indemnify and hold Pendopharm, its Affiliates, its sub-contractors and its Sublicensees and their respective directors, officers, employees and agents harmless against any and all Losses resulting from or arising out of (i) the negligence or willful misconduct on the part of any Edesa indemnity Party in relation to the carrying out of this Agreement, (ii) the negligent or willful breach by a Edesa Indemnity Party of any terms of this Agreement, or (iii) the breach, whether negligent or not, of any of Edesa's representations and warranties in Article 8 of this Agreement by an Edesa Indemnity Party, except for those Losses which Pendopharm has an obligation to indemnify a Edesa Indemnity Party pursuant to Section 9.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability, and provided further that Edesa shall not be obligated to indemnify any Pendopharm Indemnity Party for any Losses to the extent such Losses arise as a result of negligence or willful misconduct on the part of such Pendopharm Indemnity Party.

### 9.3. Survival.

The indemnification obligations set forth in this Article 9 shall survive the termination or expiration of this Agreement and remain in full force and effect for a term ending three (3) years after the end of the shelf life of the last Licensed Products sold by Pendopharm, its Affiliates or a Sublicensee in relation to any claim based on events which occur during the Term hereof.

### 9.4. Limitation of Liability.

TO THE FULL EXTENT ALLOWED BY LAW THE PARTIES EXCLUDE ANY LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER LEGAL THEORY, FOR CONSEQUENTIAL, SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR EXEMPLARY DAMAGES OR OTHER SIMILAR OR LIKE DAMAGES OR DAMAGES FOR LOSS OF PROFITS, REVENUES OR DATA, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

## 9.5. Indemnification Claims

- (a) **Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates and Sublicensees and their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement ("Indemnified Party"). The Indemnified Party shall give the indemnifying Party prompt written notice ("Indemnification Claim Notice") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 9.1 or 9.2, as applicable. In no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all notices and documents received in respect of any Losses and claims asserted by Third Parties ("Third Party Claims").
  
- (b) **Control of Defense.** At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice or such shorter delay as may be required in order to ensure a timely response to any Third Party Claims. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, and nothing shall constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 9.S(c), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of suit) and any Third Party Claims incurred by the indemnifying Party in its defense of the Third Party Claim.
  
- (c) **Right to Participate in Defense.** Without limiting Section 9.S(b) above, any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless, subject to any potentially required consent of an insurer, if applicable, (i) the employment thereof has been specifically authorized by the indemnifying Party in writing, (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.5(b) or has assumed defence and then failed to diligently defend the Third Party Claim (in which case the Indemnified Party shall control the defense) or (iii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

- (d) Settlement. With respect to any Third Party Claims relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. Notwithstanding the foregoing, in such a case the indemnifying Party agrees to consult with the Indemnified Party in good faith in relation to any settlement. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.5(b), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed. The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.
- (e) Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each Indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making the indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and documented out-of-pocket expenses in connection therewith.

## ARTICLE 10 TERM AND TERMINATION

### 10.1. Term.

This Agreement will enter into effect on the Effective Date and remain in effect until expiration as described in Section 6.1(b) or until termination in accordance with Sections 10.2 to 10.6 hereof.

### 10.2. Termination by Pendopharm.

Pendopharm shall have the right to terminate this Agreement upon one-hundred and twenty (120) days prior written notice to Edesa.

### 10.3. Termination by Edesa

Edesa shall have the right to terminate this Agreement upon thirty (30) days written notice to Pendopharm, in the event Edesa (i) is unable to recruit the requisite number of participants in the proof of concept clinical study or (ii) the proof of concept clinical study is unable to be completed due to a failure of obtaining the required approval (e.g. ethics board approval) or has been terminated due to concerns regarding the safety of participants following the use of the Licensed Products.

### 10.4. Termination for Material Breach.

If either Party commits a material breach of this Agreement, the other Party shall have the right to terminate this Agreement by giving written notice to the breaching Party in sufficient detail to ascertain and respond to the alleged breach. Termination shall take effect sixty (60) days after receipt of such notice by the breaching Party unless within the same time period the breach has been cured.

### 10.5. Liquidation, Bankruptcy, Insolvency.

To the extent permitted under Applicable Law, if one of the Parties shall go into liquidation, other than for the purpose of a bona fide reorganization, or a receiver or trustee be appointed for its property or estate, or if such Party files for a voluntary petition in bankruptcy or application for insolvency or is adjudged bankrupt or insolvent, and whether or not any of the aforesaid acts be the outcome of a voluntary act of that Party, the other Party shall be entitled to terminate this Agreement forthwith by written notice to the first Party.

### 10.6. Termination of the Yissum or the Cipher Agreement

- a) In the event that the Yissum Agreement is terminated and Edesa no longer controls the Licensed Products identified as EB02 and EB03, this Agreement will immediately terminate in respect of EB02 and EB03 upon receipt of written notice from Edesa to Pendopharm.

- b) In the event that the Cipher Agreement is terminated and Edesa no longer controls the Licensed Product identified as EB04, this Agreement will immediately terminate in respect of EB04 upon receipt of written notice from Edesa to Pendopharm of such termination.

**10.7. Effects of Termination.**

- (a) With the exception of termination pursuant to Section 10.4 where Pendopharm is the breaching party, the following shall occur in the event of termination pursuant to Sections 10.2 to 10.6:
- (i) the Edesa License and the Pendopharm License shall terminate immediately;
  - (ii) Pendopharm shall cease all sales of the Licensed Products within 90 days from the date of termination;
  - (iii) Pendopharm shall assign and set over to Edesa, all right, title and interest in the Pendopharm IP, the Pendopharm IP Improvements and the Regulatory Approvals in the Territory;
  - (iv) Pendopharm shall provide to Edesa, at its own expense, any and all documents, Information, data files, records, and other materials, relevant for the Development, manufacture and commercialization of the Licensed Products in the Territory in its possession, and all Confidential Information and other data, files, records and other materials received from Edesa, provided, however, that Pendopharm shall be permitted to retain one (1) copy of such Confidential Information and other materials for the sole purpose of performing any continuing obligations hereunder or for archival purposes. All retained Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 12.1(a).
- (b) In the event of termination pursuant to Section 10.4 where Edesa is the breaching party, the following shall occur at Termination:
- (i) the Edesa License and the Pendopharm License shall terminate immediately;
  - (ii) each Party shall return all Confidential Information and all other Information, data, files, records and other materials received from the other Party required to commercialize the Licensed Products in the Territory, in accordance with Section 12.3 hereof.
- (c) In the event of termination pursuant to Section 10.6 (a), the provisions of this Agreement shall remain in full force and effect in respect of the Licensed Product identified as EB04. Similarly, in the event of termination pursuant to Section 10.6 (b), the provisions of this Agreement shall remain in full force and effect in respect of the Licensed Products identified as EB02 and EB03.

- (d) Surviving Provisions. In any event, any termination or expiration of this Agreement, shall be without prejudice to:
- (i) the confidentiality rights and obligations under Article 12 that survive termination or expiration;
  - (ii) any other rights or remedies which either Party may then or thereafter have hereunder; and
  - (iii) either Party's obligation to make any payments due pursuant to this Agreement which accrue prior to termination or expiration, and at the time of termination or expiration, all such payments due shall be made in full within forty-five (45) days unless the Parties agree otherwise.

## **ARTICLE 11 FORCE MAJEURE**

Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or be in breach of this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, earthquakes, embargoes, epidemics, war, acts of war, terrorist acts, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, act of God or acts, omissions or delays in acting by any Regulatory Authority or the other Party; provided, however, that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of non-performance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed. The affected Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure, stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effects. In the event that such force majeure event (i) lasts for more than one hundred eighty (180) days and (ii) has a material adverse effect on the performance of the obligations of the affected Party, the non-affected Party shall have the right to terminate this Agreement upon written notice to the affected Party.

## **ARTICLE 12 CONFIDENTIALITY**

### **12.1. Nondisclosure Obligations.**

- (a) General. At all times during the term of this Agreement and for a period of ten (10) years thereafter, either Party ("Receiving Party") shall, and shall cause its officers, directors, employees and agents to, keep strictly confidential, and not publish or otherwise disclose, and not use for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party ("Disclosing Party"), except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of the Receiving Party's obligations hereunder and provided that such disclosure is made on a need-to-know basis on conditions that the party to which such disclosure is made, prior to the disclosure of the Confidential Information, signed a written confidentiality agreement under which it undertakes to keep the Confidential Information confidential for the same time periods and to the same extent as provided for under this Agreement. "Confidential Information" shall mean any information provided by one Party to the other Party relating to the terms of this Agreement and the collaboration of the Parties hereunder, including any Information relating to the Licensed Technology, the Development or commercialization of the Licensed Products, the Marketing Authorizations and other Regulatory Approvals, or the scientific, regulatory or business affairs or other activities of either Party to the extent, permitted under Applicable Law. The US Data Package and all other data and information resulting from clinical studies shall be the Confidential Information of the Party that owns such data and information.



- (b) Limitations. The obligation not to use and disclose Confidential Information shall not apply to any part of such Confidential Information that can be shown by written documents:
- (i) is, at the time of disclosure by the Disclosing Party to the Receiving Party or thereafter becomes part of the public domain other than by unauthorized acts of the Receiving Party;
  - (ii) has been disclosed to the Receiving Party by a Third Party, provided such Third Party was in lawful possession of the Confidential Information and was under no confidentiality obligation vis-a-vis the Disclosing Party;
  - (iii) prior to disclosure by the Disclosing Party, was already in the legal possession of the Receiving Party; provided such Confidential Information was not obtained directly or indirectly from the Disclosing Party pursuant to another confidentiality agreement between the Parties;
  - (iv) has been independently developed by the Receiving Party without any reference to the Disclosing Party's Confidential Information;
- (c) In addition to the foregoing limitations, Confidential Information can be disclosed:
- (i) to government or other Regulatory Authorities to the extent that such disclosure is reasonably necessary to obtain an issuance of a Licensed Patent or Regulatory Approvals and Marketing Authorizations for and to Commercialize the Licensed Products, provided that the Receiving Party notifies the Disclosing Party reasonably in advance of such disclosure; or
  - (ii) pursuant to interrogatories, requests for information or documents, subpoena, court order, civil investigative demand issued by a court or governmental agency or as otherwise required by Applicable Law, provided that, to the extent reasonably practicable, the Receiving Party notifies the Disclosing Party immediately upon receipt thereof and grants the Disclosing Party the possibility to seek legal protection against such disclosure and limits the scope of disclosure to that portion of the Confidential Information that is legally required to be disclosed.

**12.2. Terms. Publications. Press Release.**

- (a) Terms of this Agreement, Press Release.
  - (i) Edesa and Pendopharm each agree not to disclose any terms or conditions of this Agreement or the Agreement as such to any Third Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, except as required by Applicable Law.
  - (ii) Neither Party shall originate any publicity, news release or public announcement, written or oral relating to this Agreement, including its existence or the negotiations without the prior written approval of the other Party, which approval shall not be unreasonably withheld, except as required by Applicable Law or the rules of a stock exchange.

**12.3. Return of Confidential Information.**

Upon the effective date of expiration or termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such other Party does not retain rights hereunder: (i) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes as well as electronic copies which are automatically generated by computer systems during back up procedures. All retained Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 12.1.

**ARTICLE 13  
MISCELLANEOUS**

**13.1. Entire Agreement.**

This Agreement together with the Exhibits hereto contains the entire understanding of the Parties with respect to the subject matter hereof. All prior express or implied agreements and understandings, either oral or written, are superseded by this Agreement. This Agreement may be amended and the written form requirement set forth herein may be waived only by a written instrument duly executed by all Parties hereto.

**13.2. Assignment.**

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

- (a) Assignment. Neither Party may assign any of its rights or benefits under this Agreement, or transfer any of its duties or obligations, in whole or in part, except with the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign this Agreement to an Affiliate without the consent of the other Party, provided that such assigning Party shall at all times remain liable for the assignee's compliance with the terms of this Agreement.

- (b) Effects. Any assignment or transfer by a Party other than in accordance with the terms hereof shall be null and void and shall entitle the other Party to terminate this Agreement with immediate effect.

**13.3. Notice.**

Any notice required or permitted hereunder shall be in writing, shall refer specifically to this Agreement, and shall be delivered personally by hand, by an overnight courier service or by facsimile transmission, and shall be addressed to the Party to whom it is to be given at the address or facsimile number shown below:

If to Pendopharm: Pendopharm, a division of Pharmascience Inc.  
6111 Royalmount Avenue, Suite 100  
Montreal, Quebec, H4P 2T4

Attention: Vice-President, Pendopharm  
Fax No.: 514-807-9483

with a copy to: General Counsel and Corporate Secretary  
Fax No.: (514) 342-3654

If to Edesa: Edesa Biotech Inc.  
100 Spy Court, Markham, Ontario, L3R 5H6

Attention: CEO  
Fax No.: 905-475-9962

with a copy to: ●  
Fax No.: ●

Each Party may, at any time, substitute for its previous record address any other address by giving prior written notice of the substitution in accordance with this Section 13.3. Any such notice shall be deemed to have been given and received on the date of delivery, if received prior to 5:00 p.m. local time, on a Business Day. If the notice is received after 5:00 p.m., local time on a Business Day, or is received on a day which is not a Business Day, then such notice shall be deemed to have been given and received on the first Business Day thereafter.

**13.4. Waiver.**

The failure of either Party to insist upon the strict performance of any provisions hereof or to exercise any right or remedy shall not be deemed a waiver of any right or remedy with respect to any existing or subsequent breach or default; the election by either Party of any particular right or remedy shall not be deemed to exclude any other; and all rights and remedies shall be cumulative.

### **13.5. Severability.**

In the event any provisions of this Agreement are or become invalid or unenforceable the remaining provisions of this Agreement shall remain in effect. The invalid or unenforceable provisions shall be replaced by a valid or enforceable one which most closely reflects the original commercial intent of the Parties.

### **13.6. Governing Law and Dispute Resolution.**

- (a) Laws. This Agreement shall be governed by and construed in accordance with the laws of the Province of Quebec and the laws of Canada which apply therein, without regards to any conflict of law provisions.
- (b) Dispute Resolution. Any dispute, disagreement, controversy or claim arising out of or relating to this Agreement, shall be exclusively submitted to the courts of the Province of Quebec, Canada.

### **13.7. Non-Solicitation.**

During the Term and for a period of two (2) years thereafter, neither Party shall actively recruit or solicit any employee of the other Party or its Affiliates. For the avoidance of doubt, nothing shall limit a Party from engaging in general recruitment efforts through advertisements so long as the employees of the other Party and its Affiliates are not specifically targeted in such recruitment effort.

### **13.8. Independent Contractors.**

It is expressly agreed that Edesa and Pendopharm shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Edesa nor Pendopharm shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party to do so.

### **13.9. Mutual Cooperation.**

Each of the Parties shall use all reasonable efforts to take, or cause to be taken, all action or do or cause to be done, and to assist and cooperate with each other Party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement (in each case, to the extent that the same is within the control of such Party).

### **13.10. Further Assurances.**

Each Party shall promptly do, execute, deliver or cause to be done, executed and delivered all further acts, documents and things in connection with this Agreement that the other Party may reasonably require for the purposes of giving effect to this Agreement.

### **13.11. Language.**

The parties have expressly required that this Agreement and all documents and notices relating hereto be drafted in English. *Les parties aux presentes ont expressement exige que la presente convention et tous les documents et avis qui y sont afferents soient rediges en anglais.*

### **13.12. Counterparts.**

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

*[Signature page follows.]*

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

For and on behalf of

**PENDOPHARM, A DIVISION OF  
PHARMASCIENCE INC.**

By: /s/ David Goodman

\_\_\_\_\_  
Name: David Goodman



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

For and on behalf of

**EDESA BIOTECH INC.**

By: /s/ Pardeep Nijhawan

\_\_\_\_\_  
Name: Pardeep Nijhawan

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

**EXHIBIT 1.37**

**Edesa Licensed Patents (as of July 31, 2017)**

CA 2,558,416

CA 2,834,918

CA 2,761,590

CA 2,604,758