# SECURITIES AND EXCHANGE COMMISSION

# FORM 6-K

Current report of foreign issuer pursuant to Rules 13a-16 and 15d-16 Amendments

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# **FILER**

# **RedHill Biopharma Ltd.**

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the month of June 2022 Commission File No.:001-35773

# **REDHILL BIOPHARMA LTD.**

(Translation of registrant's name into English)

21 Ha'arba'a Street, Tel Aviv, 6473921, Israel (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☑ Form 40-F □

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

The purpose of this Report on Form 6-K is to refile Exhibit 99.1, which was originally filed on Form 20-F on February 25, 2016 as Exhibit 4.7, to transition to the requirements set forth in Item 601(b) of Regulation S-K permitting registrants to omit confidential information from material contracts filed pursuant to Item 601(b)(10) without the need to submit a confidential treatment request to the Securities and Exchange Commission. The confidential information has been omitted from Exhibits 99.1 because it is both not material and would likely cause competitive harm to RedHill Biopharma Ltd. (the "Company") if publicly disclosed.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is the Exclusive License Agreement, dated March 30, 2015, by and between the Company and Apogee Biotechnology Corp.\*

\*Certain identified information has been omitted from this exhibit because such identified confidential information is both not material and would likely cause competitive harm to the Company if publicly disclosed.

This Form 6-K is incorporated by reference into the Company's Registration Statements on Form S-8 filed with the Securities and Exchange Commission on May 2, 2013 (Registration No. 333-188286), on October 29, 2015 (Registration No. 333-207654), on July 25, 2017 (Registration No. 333-219441), on May 23, 2018 (Registration No. 333-225122), on July 24, 2019 (File No. 333-232776), on March 25, 2021 (File No. 333-254692), on May 3, 2021 (File No. 333-255710) and on January 11, 2022 (File No. 333-262099) and the Registration Statements on Form F-3 filed with the Securities and Exchange Commission on July 24, 2019 (File No. 333-232777), on March 30, 2021 (File No. 333-254828) and on July 29, 2021 (File No. 333-258259).

# **SIGNATURES**

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

Date: June 1, 2022

REDHILL BIOPHARMA LTD. (the "Registrant")

By: /s/ Dror Ben-Asher Dror Ben-Asher Chief Executive Officer

# CERTAIN IDENTIFIED INFORMATION MARKED [\*\*\*] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

#### EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT is made and entered into as of March, \_\_\_\_2015 (the "Effective Date"), by and between Apogee Biotechnology Corp., a Pennsylvania corporation ("Apogee") and RedHill Biopharma Ltd., an Israeli company ("RedHill"). Apogee and RedHill each may be referred to herein individually as a "Party," or collectively as the "Parties".

WHEREAS, Apogee represents that it is the sole and exclusive owner of and has the right to grant a license to RedHill in respect of the Licensed Intellectual Property and Technology (as defined below), all on the terms set forth below;

WHEREAS, Apogee wishes to license to RedHill all Apogee's rights in and to ABC294640 and [\*\*\*\*] (as those terms are defined below) and all Licensed Intellectual Property and Technology, and RedHill wishes to receive such license from Apogee, to develop and commercialize products for all indications and for all uses, all on the terms set forth below; and

WHEREAS, the license to be granted shall be granted on an exclusive basis as more fully set out below.

## NOW THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

### 1. **DEFINITIONS**

1.1 For purposes of this Agreement, the following terms shall have the following meanings:

"ABC294640" means the small molecule Sphingosine Kinases (SK2) inhibitor which is known as ABC294640, in all formulations, doses, forms and combinations.

#### [\*\*\*\*].

"Affiliate" of a person means any other person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such first person. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" will mean the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of fifty percent or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity) of the other organization or entity or by contract relating to voting rights or corporate governance, or otherwise. "**Bankruptcy Event**" means a company (i) becomes insolvent or admits inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within [\*\*\*\*] days or is not dismissed or vacated within [\*\*\*\*] days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

"Business Day" means a day that is not a Saturday or Sunday or any other day on which banks in the United States and/or Israel are authorized or required by law to be closed.

"**Combination Product**" means a product which comprises (a) a Product and (b) at least one other active ingredient or medical device, which, if administered or used independently of such Product, would have a clinical, diagnostic or therapeutic effect.

"Commercialization Partner" means a Sublicensee primarily responsible for commercial distribution and/or commercial promotion of a Product for sale.

"Commercially Reasonably Efforts" means, with respect to the development, regulatory, manufacturing, licensing and commercialization of ABC294640, the efforts and resources that are consistent with those utilized by a similarly situated biopharmaceutical company for its own internally discovered technology of similar commercial potential at a similar stage of development, taking into consideration its safety and efficacy, the cost to develop, the competitiveness of alternative technology, the nature and extent of their market exclusivity, the likelihood of regulatory approval, its profitability and all other relevant factors.

"Field of Use" means any and all indications and uses, including therapeutic, diagnostic and other human and/or animal uses.

"First Commercial Sale" means the first commercial transaction for which consideration is received by RedHill, its Affiliates or Sublicensees for the sale, use, lease, transfer or other disposition of a Product to or for the benefit of a third party, after Regulatory Approval has been granted by a Regulatory Authority responsible for the jurisdiction in which such first commercial transaction takes place; provided, that First Commercial Sale shall not include a transfer of the Product for testing purposes and/or a sale for experimental, promotional, compassionate named patient or test market purposes.

"Generic Product" means, with respect to any Product, any product that (a) is sold by a third party (i.e., other than RedHill or its Affiliates) that is not a Sublicensee of RedHill, under a Regulatory Approval granted by a Regulatory Authority to a third party; (b) is approved for one or more indications that are the same (or substantially the same) as one or more of the indications for which the Product is approved; and (c) is approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of the Product as determined by the applicable Regulatory Authority, including any product authorized for sale in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or in any other country or jurisdiction pursuant to all equivalents of such provisions. A product licensed or produced by RedHill or its Affiliates (i.e., an authorized generic product) will not constitute a Generic Product.



"Licensed Know-How" means all right, title and interest of Apogee and/or its Affiliates in and to technology, assets, intellectual property, trade secrets, inventions and invention disclosures and know-how whatsoever, including, for the avoidance of doubt, as is necessary and/ or useful in any way whatsoever for the development and/or commercialization of Products in the Field, including ABC294640 and [\*\*\*\*] and all analogs, including, all analogs of ABC294640 and all analogs of [\*\*\*\*] and all information whether patentable or not and physical objects related to Products or such analogs or that are otherwise necessary or useful to manufacture, have manufactured, and commercialize Products, including product data, product-related results and information, including clinical data, analytical test results, non-clinical pharmacology and safety data, other R&D data, Regulatory Documentation, manufacturing and formulation information of a like nature, copies of external service and other contracts and documentation, information and correspondence relating to the development, marketing approval, marketing, manufacture and other commercialization, all to the fullest extent known to, generated by, vested in (or licensed to) and/or controlled by Apogee and/or any of its Affiliates as of the Effective Date including the classes and types of Licensed Know-how listed in <u>Annex B</u> of this Agreement. For the avoidance of doubt, Licensed Know-How does not include the Patents.

#### "Licensed Intellectual Property and Technology" means the Patents and the Licensed Know-How.

"Net Sales" means the gross amounts actually received by RedHill or its Affiliates in respect of the sale of a Product by RedHill or its Affiliates, less, and following recovery of, the following items to the extent not already reflected in the gross amounts invoiced (collectively, the "Recognized Deductions"):

- (i) allowances or credits granted to and taken by customers (including wholesalers) including for damaged product, rejections, returns (including as a result of recalls), in respect of inventory management and stocking allowances and prompt payment and trade, cash and volume discounts;
- (ii) amounts incurred resulting from government (or any agency thereof) mandated rebate programs;
- (iii) freight, transport, packing, postage and insurance charges;
- (iv) taxes, including value added tax, tariffs or import/export or customs, duties;
- (v) rebates, charge backs and discounts paid or credited;
- (vi) bad debts;
- (vii) reasonable quantities of samples if no amounts are invoiced therefor; and any other payment which reduces gross revenue and is permitted to be deducted in calculating net sales in accordance with generally accepted accounting principles.

Even if there is overlap between any of the Recognized Deductions, each individual item shall be deducted only once in the overall Net Sales calculation.

Notwithstanding the foregoing, for the purposes of this definition, the transfer of a Product by RedHill or one of its Affiliates to another Affiliate of RedHill or to a Sublicensee for resale is not a sale.

For Net Sales of a Product sold or supplied as a "Combination Product", the Net Sales of such a Combination Product in a country will be determined by multiplying the Net Sales of such Combination Product in such country by the fraction of A/A+B, where A is the average unit selling price during the period in respect of which Net Sales are being calculated of the Product sold separately in that country and B is the total average unit selling price during the period in respect of which Net Sales are being calculated of the other product or device included in the Combination Product, when sold separately in that country. If neither the Product nor the other product or device included in the Combination Product are sold separately during the period in respect of which Net Sales are being calculated, then the Parties shall, considering the costs incurred by RedHill bringing about the Combination Product, in good faith negotiate the value of the other product or device or device included in the Combination Product that are to be deducted from the Net Sales of the Combination Product in determining the Net Sales of the Product contained in the Combination Product, it being agreed that absent such mutual agreement as to the proportion of such Combination Product to be attributed to the Product, the Parties shall mutually appoint an independent expert to determine such proportion.

"**Patents**" means all U.S. and non-U.S. patents and patent applications, including those listed in **Annex A**, and (a) any substitutions, divisions, continuations, continuations-in-part (but only to the extent that they cover the same invention claimed in the foregoing), reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such U.S. and non-U.S. patents or patent applications, (b) any patents issuing from any applications filed after the Effective Date and that claim priority from any of the aforesaid patents or patent applications or from which any of such patents or patent application claim priority, in respect of all of which Apogee or any of its Affiliates is as of the date of this Agreement or during the term of this Agreement becomes owner or controller.

"**person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

"**Product(s)**" means any product, including ABC294640 and [\*\*\*\*], and all analogs, including, all analogs of ABC294640 and all analogs of [\*\*\*\*], in each case in all current and future formulations, doses, forms and combinations whatsoever, for human and animal use, the manufacture, use, offer for sale, sale or importation of which by RedHill would, absent the License (as defined below), infringe a Valid Claim in a jurisdiction in the Territory where such a Valid Claim exists.

"**Regulatory Approval**" means (a) in the United States approval by the US FDA of an NDA (New Drug Application), or the equivalent application for marketing approval, and satisfaction of any related applicable US FDA registration and notification requirements (if any) and (b) in a market other than the United States, approval by regulatory authorities having jurisdiction over such country of a single application or set of applications equivalent to an NDA and satisfaction of any related applicable regulatory and notification requirements (if any).

"Regulatory Authority" means any applicable government entity regulating or otherwise exercising authority with respect to the development and commercialization of a Product.

"**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), all supporting documents and all clinical studies and tests, including the manufacturing batch records for Product to be assigned, relating to a Product, and all data contained in any of the foregoing, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

"**Regulatory Exclusivity**" means, with respect to any country, an additional market protection, other than Patent protection, granted by a Regulatory Authority in such country which confers an exclusive commercialization period during which RedHill, its Affiliates or its Sublicensees have the exclusive right to market, price, and sell a Product in such country through a regulatory exclusivity right, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity.

"Royalty Term" means the period, on a country by country and Product by Product basis, commencing on the date of the First Commercial Sale in such country and ending on the later of:

- (i) the expiration of the last to expire Patent [\*\*\*\*] that covers a Product in such country, [\*\*\*\*]; and
- (ii) in a country that provides Regulatory Exclusivity for a Product, the expiration of such Regulatory Exclusivity.

"Sublicense" means a sublicense from RedHill or its Affiliates to any other person under the License granted pursuant to this Agreement and the term "Sublicensee" shall be construed accordingly and shall include any Commercialization Partner. Any Sublicense may include the right to grant further Sublicenses. For the avoidance of doubt, a RedHill Affiliate shall not be considered a Sublicensee.

"Sublicense Consideration" means all consideration actually received in respect of a Product by RedHill or its Affiliates from Sublicensees, including payments (x) as upfront or milestone payments in respect of a Sublicense ("Sublicense Milestone Consideration") and (y) as royalties on account of sales of a Product effected by such Sublicensees, including, as to Commercialization Partners, purchase price paid and all other consideration by them to RedHill or its Affiliates for Product ("Sublicense Sales Consideration"), excluding in all instances, (i) loan proceeds paid to RedHill by a Sublicensee in an arms'-length, full recourse debt financing to the extent that such loan is not forgiven; and (ii) equity (and conditional equity, such as warrants, convertible debt and the like) investments in RedHill or any Affiliate thereof by a Sublicensee up to the amount of the fair market value of the equity purchased on the date of the investment; (iii) patent prosecution costs incurred or which shall be incurred by RedHill; (iv) the cost and financing of research and/or development activities or services performed or to be performed by RedHill or expended or to be expended by RedHill; and (v) marketing expenses which have been or shall be expended by RedHill.

"Valid Claim" means a claim of any issued and unexpired patent included in the Patents whose validity, enforceability, or patentability has not been affected by any of the following: (a) lapse, abandonment, revocation, dedication to the public, or disclaimer; (b) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction; or (c) admission of invalidity or unenforceability through reissue, disclaimer or otherwise. If a claim of a pending patent application has not been issued as a claim of an issued patent within five (5) years after the earliest priority date for such claim, then such claim shall cease to be a Valid Claim unless and until such claim becomes an issued claim of an issued patent.

"Territory" means the entire world.

1.2 **Interpretation**. As used in this Agreement, any reference to gender shall include all genders and any reference to the plural shall include the singular, and the singular shall include the plural. When a reference is made in this Agreement to a section, such reference shall be to a section of this Agreement, unless otherwise clearly indicated to the contrary. Whenever the words "include," "includes" or "including" are used in this Agreement they shall be deemed to be followed by the words "without limitation." The words "hereof," "herein" and "herewith" and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement, and annex, article, section, paragraph, exhibit, annex and schedule references are references to the annex, articles, sections, paragraphs, exhibits, annexes, and schedules of this Agreement, unless otherwise specified. The captions contained in this Agreement are for convenience only and shall not be deemed a part hereof or affect the interpretation or construction of any provision hereof.

# 2. LICENSE GRANT

2.1 **Scope of License**. Subject to the terms and conditions of this Agreement, Apogee hereby grants to RedHill an exclusive (including as to Apogee itself), worldwide and, subject to the termination rights herein, irrevocable and perpetual, license under the Licensed Intellectual Property and Technology (the "License").

2.2 **Sublicenses**. The License is Sublicensable (and further Sublicensable, including through multiple tiers) in whole or in part, to third parties in accordance with the terms of this Agreement. The granting of Sublicenses shall be at RedHill's sole and exclusive discretion and RedHill shall have the sole and exclusive power to determine the identity of any Sublicensee, the applicable licensee fees or royalty rates, if any, and other terms and conditions of any Sublicense. For the avoidance of doubt, RedHill shall be entitled to conduct or to perform any activity in respect of a Product by means of any third party sub-contractor, and such conduct, in and of itself, shall not automatically be considered to be a grant of a Sublicense hereunder. RedHill shall have the right to exercise such License through its Affiliates, provided, however, that RedHill shall remain responsible for the compliance by its Affiliates with the applicable terms of this Agreement. For the avoidance of doubt, the payment obligations with respect to RedHill shall apply in the same manner to each Affiliate, and as a result, Net Sales shall include Net Sales by an Affiliate and the occurrence of any milestone with respect to RedHill.

2.3 **Registration**. RedHill shall have the right, on its own account and at its own expense, to register as the exclusive licensee of the rights in and to the Licensed Intellectual Property and Technology for the purpose of developing, manufacturing, commercializing, making, using, selling, offering for sale and importing Products in the Territory and Apogee shall, at the sole expense of RedHill, execute all documentation reasonably requested by RedHill and otherwise cooperate with RedHill in order to ensure such registration.

2.4 **Limitations on Other Licenses**. During the Term, Apogee shall not, without RedHill's prior written consent, grant any rights or licenses or transfer any data or know-how to any third party that conflict with the RedHill's rights granted under this Agreement.

# 3. DATA AND PRODUCT TRANSFER

3.1 **Know-How**. Following the Effective Date in accordance with the schedule annexed hereto as **Annex C**, Apogee will (i) make reasonably available to RedHill the Licensed Know-How, and (ii) provide to RedHill either hard or electronic copies, with such medium determined at Apogee's discretion, of the Licensed Know-How, as shall be reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with the License granted under this Agreement. Following the Effective Date, Apogee will, at no cost to RedHill, provide RedHill with all additional information under its control relating to Products, including commercially reasonable assistance in replying to inquiries by RedHill in respect of the information and data provided and exercise of the License and otherwise in connection with the development of Products.

3.2 **Product**. Within [\*\*\*\*] Business Days following the Effective Date, Apogee will transfer to RedHill Ex Works Apogee's plant (Incoterms 2000), at no cost to RedHill other than reasonable transportation costs approved in advance by RedHill from such Ex Works point, no less than [\*\*\*\*] owned by or in the possession of Apogee. It is expressly agreed that, subject to the relevant provisions of this Agreement regarding RedHill's overall control and responsibility for all development activities, but notwithstanding the License granted hereunder, any remaining portion of [\*\*\*\*] (active ingredients and excipients in all forms, both expired and unexpired, as well as such finished product, both expired and unexpired) in the possession or control of Apogee at the Effective Date, may be used and are dedicated solely to Apogee's planned [\*\*\*\*], provided such [\*\*\*\*] are mutually agreed upon by the Parties, it being understood that RedHill will be the [\*\*\*\*]. It is further agreed that in the event Apogee and/or an [\*\*\*\*], RedHill agrees to use commercially reasonable efforts to manufacture and provide [\*\*\*\*]. For the avoidance of doubt, [\*\*\*\*].

3.3 Without derogating from any other obligations of Apogee under this Agreement, Apogee shall provide RedHill with timely ongoing quarterly reports regarding all studies, [\*\*\*\*] and other activities conducted by Apogee with ABC294640 and [\*\*\*\*].

3.4 **General Assistance**. Following the Effective Date and throughout the development process, to the extent reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with this Agreement, Apogee will provide RedHill with commercially reasonable general assistance, cooperation, guidance and the like, including making its employees reasonably available for consultation and in replying to inquiries by RedHill in respect of the Licensed Know-How provided and reasonable cooperation with RedHill and support of RedHill's submissions of Product for approval with any and all Regulatory Authorities.

3.5 **Technical Transfer Assistance.** To the extent reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with this Agreement, Apogee undertakes to provide reasonable assistance to RedHill in sharing technical information included within the Licensed Know-How to a contract manufacturing organization chosen by RedHill. For the avoidance of doubt, RedHill may share all such assistance with its Sublicensees.

3.6 **Consideration.** In consideration of the agreements of Apogee pursuant to Section 3.4 and Section 3.5, Apogee will be compensated according to a rate and expense reimbursement budget to be pre-approved (in writing) by RedHill.

## 4. DILIGENCE

4.1 **Authority; Obligations**. Following the Effective Date, RedHill shall have sole authority for the development, regulatory, manufacturing, licensing and commercialization of Products in the Field in the Territory. Notwithstanding the foregoing, RedHill will make a good faith, continuous and diligent effort using Commercially Reasonable Efforts to prepare, initiate and complete the clinical development of ABC294640 in accordance with relevant industry standards, obtain and maintain regulatory approvals necessary to commercialize ABC294640 for application for at least one indication in a jurisdiction chosen by RedHill in its sole discretion, and promptly after receipt of such regulatory approval in each applicable market, manufacture, market, promote and sell such Product in each such market as chosen by RedHill in its sole discretion, all in accordance with relevant industry standards (the "**Diligence Obligation**"), all subject to the termination provisions of this Agreement. For the avoidance of any doubt, the failure to meet the Diligence Obligation due to reasons that are beyond RedHill's control do not constitute a breach of the Diligence Obligation. Apogee's sole and exclusive remedy for a breach of the Diligence Obligation by RedHill shall be to terminate this Agreement as provided below.

4.2 **No Warranty**. For the avoidance of doubt, nothing contained in this Agreement shall be construed as a warranty by RedHill that any development or any commercialization to be carried out by it in connection with this Agreement will actually achieve its aims or any other results and RedHill makes no warranties whatsoever as to any results to be achieved in consequence of the carrying out of any such development. Furthermore, RedHill makes no representation to the effect that the commercialization of tany Product, or any part thereof, will succeed, or that it shall be able to sell Products in any quantity.

## 5. REPORTS

5.1 Until the end of all Royalty Terms, RedHill agrees as follows:

5.1.1 **Development Reports**. To keep Apogee informed with respect to activities and progress regarding the development, commercialization, sublicensing, and government approvals of Products. RedHill will provide written semi-annual development reports within [\*\*\*\*] days following the close of each six calendar-month period.

5.1.2 **First Commercial Sale Report**. To report to Apogee the date of the First Commercial Sale of each Product in the first jurisdiction in which it occurs, together with the name of the country in which such First Commercial Sale occurred within [\*\*\*\*] Business Days following such First Commercial Sale.

5.1.3 **Royalty Reports**. With respect to each Royalty payment pursuant to Section 6.3, on a calendar quarterly basis within [\*\*\*\*] days following the end of each March, June, September and December, to deliver to Apogee written reports with respect to the period covered by the Royalty payment the amount of consideration received from Net Sales, Sublicense Sales Consideration, Sublicense Milestone Consideration, and Sublicense Sales Consideration received from Commercialization Partners, including the Recognized Deductions applicable in computing Net Sales and the deductions applicable in computing Sublicense Sales Consideration, Sublicense Milestone Consideration, and Sublicense Sales Consideration received from Commercialization Partners.

5.2 **Confidentiality of Reports.** Any and all information, data or reports supplied by RedHill pursuant to the provisions of this Section 5 shall be treated as RedHill's Confidential Information and subject to the confidentiality obligations set forth in Section 11 of this Agreement.

5.3 **Final Report**. If this Agreement is terminated for any reason during any Royalty Term, RedHill shall deliver a final report and associated Royalty payment to Apogee within [\*\*\*\*] days after such termination. Except as provided above, following termination, RedHill shall have no further reporting obligations under this Section 5.

# 6. FINANCIAL PROVISIONS

6.1 **Up-Front Payment**. Within [\*\*\*\*] Business Days after the Effective Date and against receipt of an appropriate invoice from Apogee, RedHill will pay Apogee a non-refundable, up-front, one-time cash license fee of One Million Five Hundred Thousand US Dollars (\$1,500,000).

6.2 **Milestone Payments**. RedHill will pay to Apogee the following one-time milestone payments (such payments are due only once in respect of each milestone event actually achieved and are not payable per Product, per indication, per generation or per country) after first achievement of each of the applicable milestones in respect of the first Product achieving such milestone, whether on the part of RedHill or an Affiliate, as follows:

6.2.1 [\*\*\*\*] days following *the earlier of* (i) [\*\*\*\*] and (ii) [\*\*\*\*] following the Effective Date: Two Million US Dollars (\$2,000,000).

- 6.2.2 Within [\*\*\*\*] days following [\*\*\*\*].
- 6.2.3 Within [\*\*\*\*] days following the [\*\*\*\*].
- 6.2.4 Within [\*\*\*\*] days following a [\*\*\*\*].

6.3 **Royalty Payments**. During the Royalty Terms, RedHill will pay Apogee royalties (each a "**Royalty**" and collectively, the "**Royalties**") as follows:

6.3.1	<u>Net Sales</u> .
6.3.1.1	A Royalty equal to [****] of the first [****].
6.3.1.2	A Royalty equal to [****] of [****].
6.3.2	Sublicense Sales Consideration.
6.3.2.1	A Royalty equal to [****] of the [****].
6.3.2.2	A Royalty equal to [****].

6.3.3 <u>Sublicense Milestone Consideration</u>. A royalty equal [\*\*\*\*] RedHill or an Affiliate.

6.3.4 <u>Commercialization Partner Sublicense Consideration</u>. Notwithstanding the terms of subsections 6.3.2 and 6.3.3 above, in the event that RedHill or an Affiliate grants a Sublicense to a Commercialization Partner during the [\*\*\*\*] months following the Effective Date, RedHill shall pay Apogee a Royalty equal to [\*\*\*\*] of all [\*\*\*\*] RedHill or an Affiliate [\*\*\*\*]. For the avoidance of doubt, all Sublicense Sales Consideration subject to this subsection 6.3.4 shall be included in calculating cumulative aggregate Sublicense Sales Consideration for the purposes of subsection 6.3.2 and 6.3.3 above.

6.4 **No Double Payment**. For the avoidance of doubt, Royalties shall be payable only once in respect of any sum received by RedHill; i.e., either (x) as a Royalty on Net Sales pursuant to Section 6.3.1, if the sum received by RedHill was in payment for a sale of Product by RedHill or its Affiliates; (y) as a Royalty on Sublicense Sales Consideration, pursuant to Section 6.3.2, if the sum received by RedHill was a royalty paid by a Sublicense to RedHill in respect of a sale of Product made by such Sublicensee; or (z) as a Royalty on Sublicense Milestone Consideration, pursuant to Section 6.3.3, if the sum received by RedHill was a Royalty paid by a Sublicense to RedHill as an upfront or milestone payment.

6.5 **Royalty Stacking**. RedHill may deduct from any Royalty due under this Agreement any royalties RedHill is required to pay to any third party pursuant to any agreement entered into by RedHill after the date hereof, and that is actually paid by RedHill to such party, in respect of the use of such third party's intellectual property rights that may reasonably be considered to be infringed by the manufacture, use or sale of a Product in its current formulation as of the date hereof.

6.6 **Due Dates for Payment; Late Payments.** All payments due pursuant to the provisions of Section 6.3 shall be due and payable to Apogee on a calendar quarterly basis within [\*\*\*\*] days following the end of the applicable quarter. All payments will be made against receipt of an appropriate invoice from Apogee for same; provided that RedHill notifies Apogee in writing of the occurrence of the event requiring payment. In the event such payment may require approval of any governmental authority, RedHill undertakes to file for approval promptly following the Effective Date and to effectuate prompt payment following receipt of the necessary approval. In addition to any other remedies available to Apogee, any failure by RedHill to make a payment within [\*\*\*\*] days after the date when due shall obligate RedHill to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Apogee at a rate per annum equal to [\*\*\*\*] per month, or the highest rate allowed by applicable law, whichever is lower.

6.7 **Payment Method**. Any amounts due to Apogee under this Agreement will be paid in U.S. dollars, by wire transfer in immediately available funds to the most recent account designated in writing at least [\*\*\*\*] days in advance by Apogee.

6.8 **Currency; Foreign Payments.** If any currency conversion will be required in connection with the calculation of any payment hereunder, such conversion will be made by using the exchange rate for the purchase of U.S. dollars as published in *The Wall Street Journal*, Eastern Edition, on the date of the payment. If at any time legal restrictions prevent the prompt remittance of any payments in any jurisdiction, RedHill may notify Apogee and make such payments by depositing the amount thereof in local currency in a bank account or other depository in such country in the name of Apogee or its designee, and RedHill will have no further obligations under this Agreement with respect thereto.

6.9 **Taxes.** RedHill may deduct from amounts it is required to pay Apogee pursuant to this Agreement an amount equal to that required by applicable law to be withheld by RedHill for or due on account of any taxes (including VAT to the extent applicable, but other than taxes imposed on or measured by net income of RedHill) or similar governmental charge imposed by any jurisdiction based on such payments to Apogee ("**Withholding Taxes**") and such payment shall be deemed as payment to Apogee in accordance with this Agreement. RedHill will provide Apogee a certificate evidencing payment of any Withholding Taxes.

6.10 **Continuing Right**. Following the expiration of the Royalty Term in any country, RedHill shall be entitled to continue to exploit the License in the Field in such country with respect to Products without having to pay Royalties or make any other payment to Apogee in respect of such activities.



### 7. RECORDS RETENTION AND AUDIT

7.1 **Record Retention**. Until the expiry of the Royalty Terms, RedHill will maintain (and will ensure that its Affiliates maintain) complete and accurate books, records and accounts that fairly reflect Net Sales and Sublicense Consideration in the relevant jurisdiction, in sufficient detail to confirm the accuracy of Royalty payments made hereunder, which books, records and accounts will be retained for [\*\*\*\*] years after the end of the period to which such books, records and accounts pertain. For the avoidance of doubt, RedHill has no (a) duty of trust or other fiduciary relationship with Apogee regarding the maintenance of the records or the calculation and reporting of royalties or (b) obligations to maintain any records except in accordance with its own document retention policy.

7.2 Audit. Apogee will have the right, at its own cost, to have an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to RedHill and who agrees to be bound by a customary undertaking of confidentiality at least as restrictive as those in this Agreement, have access during RedHill's normal business hours, and upon reasonable prior written notice, to RedHill's records as may be reasonably necessary to verify the accuracy of RedHill's Royalty Reports, for any period ending not more than [\*\*\*\*] months prior to the date of such request; *provided, however*, that Apogee will not have the right to conduct more than one such audit in any calendar year or more than one such audit covering any given time period. The accounting firm shall not in any way be compensated (in whole or in part) contingent on the outcome of the audit. The accounting firm will disclose to Apogee only the results of its audit and not any other information. Any such audit shall not unreasonably interfere with the business of RedHill. Apogee shall provide to RedHill a copy of the audit report within [\*\*\*\*] following the final payment under this Agreement. The costs of the audit are the responsibility of Apogee provided that in the event that there is a shortfall of more than [\*\*\*\*] in the payment due, and provided such [\*\*\*\*] or more shortfall is resolved if applicable in accordance with section 7.3, the audit costs and all related travel costs up to a maximum cap of [\*\*\*\*] will be covered by RedHill within [\*\*\*\*] days of billing.

7.3 **Payment of Additional Amounts**. If the audit report shows that payments made by RedHill are in excess of the required payment, Apogee shall pay RedHill the excess amount within [\*\*\*\*] days after the date it provides the copy of the audit report to RedHill. If the audit report shows that additional payments are owed by RedHill under this Agreement, RedHill shall, at its own cost, have an additional [\*\*\*\*] to conduct an additional (second) audit to verify Apogee's audit results, and, assuming the two audits reconcile, RedHill shall make such additional payments within [\*\*\*\*] days after the date on which such second accounting firm's written report is delivered to RedHill. If the results of the two audits do not reconcile, the Parties shall, unless otherwise agreed, appoint a third independent auditor, who – on basis of the audit results achieved by the first two auditors and such additional investigations and reviews, which the third auditor may find to be required – shall conduct a third and final audit the result of which shall be applied by the Parties. The Parties shall equally share the costs of for the third audit to be conducted, unless the third audit substantially confirms the results of either party's individual audit in which case the audit costs and all related travel costs of such audit shall be paid by the other party hereto up to a maximum cap of [\*\*\*\*].

7.4 **Sublicensee Audits.** To the extent RedHill or its Affiliates conducts any audit of a Sublicensee, RedHill or its Affiliate shall promptly provide the contents of such audit report to Apogee to the extent relevant to calculate any payments owing to Apogee under Section 6 of this Agreement. If an audit report shows that additional payments are owed by a Sublicensee to RedHill or its Affiliates, RedHill or its Affiliate shall pay all additional amounts owing to Apogee for such additional payments made by Sublicensee within [\*\*\*\*] days after RedHill or its Affiliates, Apogee shall refund to RedHill or such Affiliate all amounts paid to Apogee for such excess payments made by Sublicensee within [\*\*\*\*] days after RedHill or its Affiliates, Apogee shall refund to RedHill or such Affiliate all amounts paid to Apogee for such excess payments made by Sublicensee within [\*\*\*\*] days after RedHill or its Affiliates.

7.5 **Confidentiality**. Apogee will treat all information subject to review under this Section 7 in accordance with the confidentiality provisions of Section 11 below.

# 8. **REPRESENTATIONS AND WARRANTIES**

8.1 **By Both Parties**. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:

8.1.1 Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

8.2.2 Such Party has obtained all necessary consents, approvals and authorizations of all governmental authorities and other parties required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

8.2.3 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent not already obtained under, any contractual obligation or court or administrative order by which such Party is bound.

8.2 **By Apogee**. Apogee hereby further represents, warrants, and covenants to RedHill as of the Effective Date as follows:

8.2.1 The patents and patent applications identified on Annex A are all the patents and patent applications owned or controlled by Apogee or any of its Affiliates, or in which Apogee or any of its Affiliates has a licensable interest. Apogee undertakes that if there are any additional patents or related rights owned or controlled by Apogee or any of its Affiliates or in which Apogee or any of its Affiliates has a licensable interest. Apogee or any of its Affiliates has a licensable interest, Apogee or any of its Affiliates hereby grant a license to RedHill, its Affiliates, and any Sublicensee on the terms of the License hereunder.

8.2.2 Apogee has the sole legal and/or beneficial title to and ownership of the Patents and is the record owner of all patent applications and patents that comprise the Patents as is necessary to fulfill its obligations under this Agreement and to grant the License to RedHill pursuant to this Agreement, and the Licensed Intellectual Property and Technology is free and clear of any liens, encumbrances, claims or security interests of any kind (including prior license grants) that would interfere, or the exercise of which would interfere, with RedHill exercising the licenses or rights granted hereunder.

8.2.3 Apogee has not, and during the Term\_shall not, grant any rights to the Licensed Intellectual Property and Technology that conflict with the rights granted to RedHill hereunder, and no third party has any rights whatsoever (including the right to receive royalties or any other compensation) under the Licensed Intellectual Property and Technology to develop, use, sell, offer for sale or import any Product.

8.2.4 To Apogee's knowledge, the Licensed Know-How has not been misappropriated and is non-infringing. The exercise by RedHill of the License will not by itself infringe upon the patent or other intellectual property rights of any third party, and no actions, suits, claims, disputes, or proceedings concerning the Licensed Intellectual Property and Technology are currently pending or to Apogee's knowledge have been threatened. Furthermore, to Apogee's knowledge, there are no legal actions or proceedings by a third party (including employees or former employees of Apogee) contesting the ownership or validity of the Licensed Intellectual Property and Technology or ABC294640 or [\*\*\*\*] or any part thereof.

8.2.5 No additional licenses to any patents (including patents owned or controlled by third parties) or know-how are required to develop, manufacture, use or sell any Product.

8.2.6 Apogee has not brought or threatened any claim against any third party alleging infringement of any Patent, nor, to its knowledge, is any third party infringing or, to its knowledge, preparing or threatening to infringe any patent, or practicing any claim of any patent application, comprising a Patent.

8.2.7 Apogee has not received written notification of any interference, opposition, or reexamination proceedings against any of the Patents.

8.2.8 Apogee has complied with applicable regulations in submitting, prosecuting, and maintaining the Patents, in particular the duty of good faith and candor pursuant to U.S. patent law (including 37 C.F.R. 1.56) and analogous applicable foreign laws.

8.2.9 Apogee has no knowledge of any circumstances that would require a court to conclude that RedHill's current or planned commercialization of any Product, infringes or will infringe any valid patent rights of others as of the date hereof.

# 9. LIMITATION OF LIABILITY.

Except in the case of a fraud or willful misrepresentation, breach of confidentiality obligations and indemnification for payments to third parties under Section 13, in no event shall either Party be liable to the other or any of its Affiliates for any consequential, incidental, indirect, special, punitive or exemplary damages (including lost profits, business or goodwill) suffered or incurred by such other Party or its Affiliates, whether based upon a claim or action of contract, warranty, negligence or tort, or otherwise, arising out of or relating to this Agreement.

#### 10. PATENTS

#### 10.1 **Patent Prosecution and Maintenance**

#### 10.1.1 **Prosecution of Patents**.

As between the parties, RedHill undertakes and shall have the first right, at its own expense, to prosecute and maintain the Patents using counsel of its choice, in the jurisdictions and to the extent that RedHill shall deem appropriate at its sole discretion. All such filings shall be for the benefit of Apogee and shall identify Apogee as the owner of the inventions described in the applications. RedHill will provide Apogee with copies of all relevant documentation and will keep Apogee apprised of status and respond to Apogee's inquiries in that regard so that Apogee will be informed of the continuing prosecution. In the event RedHill decides not to file, to abandon, or otherwise elects not to prosecute and maintain any Patents in any jurisdiction in the Territory, RedHill shall provide Apogee with written notice at least [\*\*\*\*] days prior to the date such abandonment would become effective or the next prosecution and maintenance deadline in the applicable jurisdiction, whichever is sooner, in order to allow Apogee's own expense. If Apogee elects to continue prosecution and maintenance, RedHill shall execute such documents and perform such acts as Apogee shall reasonably request for Apogee to perform such prosecution or maintenance.

10.1.2 **RedHill's Requests**. Apogee shall use reasonable efforts to amend any Patent application to include claims or any other changes reasonably requested by RedHill to protect any Product contemplated to be sold under this Agreement. Moreover, Apogee will reasonably cooperate in the preparation, filing, prosecution, and maintenance of the Patents, including, to the extent necessary for such activities, taking commercially reasonable efforts to do the following: (a) promptly executing all papers and instruments and requiring employees to execute such papers and instruments as reasonable and appropriate so as to enable RedHill to file, prosecute, and maintain the Patents in any country; (b) promptly informing RedHill of matters known to Apogee that could reasonably be expected to adversely affect the preparation, filing, prosecution, or maintenance of any Patents; and (c) providing reasonable access to relevant documents and other evidence, making its employees available at reasonable business hours. This Section 10.1.2 shall likewise apply to RedHill if Apogee assumes any of RedHill's activities pursuant to Section 10.1.1.

### 10.2 **Patent Enforcement**.

10.2.1 **Infringement Notice**. If Apogee or RedHill knows or suspects that any Patent is being infringed by a third party's activities, it will promptly notify the other Party in writing. In addition, if Apogee or RedHill knows or suspects that any Licensed Know-How is being misappropriated by a third party's activities, it will promptly notify the other Party in writing. Such notices shall specify in reasonable detail the nature of such actual or suspected infringement or misappropriation.

10.2.2 **RedHill Enforcement**. RedHill will have the sole, exclusive and first right, but not the obligation, to remove such infringement and/or misappropriation and to control all litigation to remove such infringement and/or misappropriation, all as RedHill shall deem appropriate in its sole discretion. RedHill will provide Apogee with copies of all relevant documentation so that Apogee will be informed of the continuing action and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if Apogee has not commented upon such documentation in a reasonable time for RedHill to sufficiently consider Apogee's comments prior to a deadline, or RedHill must act to preserve the action, RedHill will be free to act without consideration of Apogee's comments, if any. RedHill shall, subject to recovery under Section 10.2.5, be solely responsible for all costs and expenses of such litigation undertaken by RedHill. If RedHill does not commence an infringement or misappropriation action within [\*\*\*\*] days after learning of the infringement or misappropriation, Apogee may commence an action against such infringement or misappropriation pursuant to Section 10.2.3 below.

10.2.3 **Apogee Enforcement**. In the event Apogee does, at its discretion, undertake any infringement or misappropriation action, Apogee will provide RedHill with copies of all relevant documentation so that RedHill will be informed of the continuing action and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if RedHill has not commented upon such documentation in a reasonable time for Apogee to sufficiently consider RedHill's comments prior to a deadline, or Apogee must act to preserve the action, Apogee will be free to act without consideration of RedHill's comments, if any. Apogee shall, subject to recovery under Section 10.2.5, be solely responsible for all costs and expenses of such litigation undertaken by Apogee.

10.2.4 **Co-operation**. The Parties will provide reasonable assistance to each other, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the prosecuting Party to maintain the action.

10.2.5 **Recovery**. Any amounts recovered in connection with or as a result of any action contemplated by Sections 10.2.2 and 10.2.3, whether by settlement or judgment, will be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), and any remainder received by RedHill in excess of the reasonable costs and expenses in making such recovery will be treated as Net Sales and payments will be due in respect of same pursuant to this Agreement.

### 10.3 Patent License

In the event that either or both of Apogee or RedHill are sued by a third party alleging that the commercialization of a Product infringes upon any intellectual property rights of such third party, the Party being so sued shall immediately give the other Party notice of same and the Parties shall thereafter proceed as provided in Section 13.

Neither Party shall, without the consent of the other Party, which shall not be unreasonably delayed or withheld, enter into any settlement or compromise or consent to any judgment in respect of any claim related to rights licensed to RedHill under this Agreement, unless such settlement, compromise or consent includes an unconditional release of the other Party from all liability arising out of the claim and does not otherwise limit or impair the other Party's rights.

# 11. CONFIDENTIALITY

11.1 **Disclosure and Use Restriction**. The Parties agree that, during the Term of this Agreement and thereafter, each Party will (a) use the same degree of care to maintain the secrecy of the Confidential Information (as such term is defined below) of the other Party that it uses to maintain the secrecy of its Confidential Information of like kind, (b) use the Confidential Information only to accomplish the purpose of this Agreement, and (c) limit internal dissemination of the Confidential Information to its and its Sublicensees' and Affiliates' respective directors, officers, employees, consultants, representatives or agents, whose duties justify the need to know such information, and then only provided that such individuals are bound by obligations of confidentiality and non-use at least as equivalent in scope to those set forth in this Agreement.

11.2 **Confidential Information**. "**Confidential Information**" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, which may include data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how:

- (i) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party as evidenced by written records;
- (ii) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party as evidenced by written records;
- (iii) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party other than as a result of an act or omission by the receiving Party in breach of this Agreement;
- (iv) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the disclosing Party not to disclose such information or know-how to others; or
- (v) was independently discovered or developed by such receiving Party, as evidenced by their written records, without the use of Confidential Information belonging to the disclosing Party and prior to any subsequent disclosure by the receiving Party.

All Licensed Know-How shall be deemed to be Confidential Information of Apogee; provided that RedHill shall be entitled to disclose and use any Licensed Know-How in the exercise of its rights under this Agreement on the terms provided in Section 11.3, including clause (iv) thereof.

11.3 **Authorized Disclosure**. Notwithstanding the provisions of Section 11.1 above, a Party shall be entitled to disclose the Confidential Information of the other Party hereto to the extent that such disclosure is:

- (i) made in response to a valid order of a court of competent jurisdiction; *provided*, however, that such Party will first (to the extent practicably possible) have given notice to such other Party and given such other Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided further* that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- (ii) otherwise required by law or stock exchange rule; *provided, however*, that the disclosing Party will provide such other Party with notice of such disclosure in advance thereof to the extent practicably possible and to the extent permitted, will redact from such disclosure the other party's Confidential Information or designate the same as trade secret;
- (iii) made by such Party to Regulatory Authorities as necessary for the development or commercialization of a medicinal product, including any Product, in a country, as required in connection with any filing, application or request for Regulatory Approval or as required by applicable securities laws and regulations, subject to the limitations in Section 11.3(ii); or
- (iv) made by such Party in the course of submitting financial accounts to relevant authorities as per local statutory requirements or to existing or potential acquirers; existing or potential collaborators; investment bankers; existing or potential investors, merger candidates, partners, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or, bona fide strategic potential partners; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Agreement.

# 12. PRESS RELEASES

Press releases or other similar public communication by either Party relating to the terms of this Agreement (but not, for the avoidance of doubt, unless reference is made to the other Party or the terms of this Agreement, with respect to activities in exercise of its rights under this Agreement) must be approved in advance by the other Party, which approval will not be unreasonably withheld or delayed, except for those communications required by applicable law, regulation or securities exchange rule (including a public offering prospectus), disclosures of information for which consent has previously been obtained, and information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement each of which will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof. For the avoidance of doubt, the Parties may issue press releases regarding the fact that this Agreement has been signed and the nature of the Agreement so long as they do not describe the specific provisions hereof without approval from the other party.

# **13. INDEMNIFICATION**

13.1 **Indemnification of Apogee**. RedHill will defend and hold Apogee and its Affiliates, and each of their respective directors, officers, employees and agents ("**Apogee Parties**") harmless, from and against any and all liability, suits, investigations, claims or demands by a third party to the extent arising from or occurring as a result of or in connection with (a) the negligence or willful misconduct on the part of RedHill in performing any activity contemplated by this Agreement, (b) breach by RedHill of any representations, warranties, or covenants set forth in this Agreement, and/or (c) the development, testing, use, manufacturing, promotion, sale or other disposition of a Product; except to the extent the liability or loss arises from the (i) negligence or willful misconduct on the part of an Apogee Party; or (ii) breach by Apogee of any representations, warranties or covenants set forth in this Agreement. RedHill shall, in addition, indemnify Apogee against any losses, damages or liabilities from such claims (including reasonable attorneys' fees and expenses) by paying the amount of any judgment awarded against Apogee in connection with such claims.

13.2 **Indemnification of RedHill**. Apogee will defend and hold RedHill, its Affiliates, and their respective directors, officers, employees and agents ("**RedHill Parties**"), harmless, from and against any and all liability, suits, investigations, claims or demands by a third party to the extent arising from or occurring as a result of or in connection with (a) negligence or willful misconduct on the part of Apogee; or (b) breach by Apogee of any representations, warranties, or covenants set forth in this Agreement, except to the extent the liability or loss arises from or occurs as a result of or in connection with (i) negligence or willful misconduct on the part of a RedHill Party; (ii) breach by RedHill of any representations, warranties, or covenants set forth in this Agreement. Apogee shall, in addition, indemnify RedHill against any losses, damages or liabilities from such claims (including reasonable attorneys' fees and expenses) by paying the amount of any judgment awarded against RedHill in connection with such claims.

13.3 Conditions to Indemnity. Each Party's agreement to indemnify and hold the other harmless is conditioned upon the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within [\*\*\*\*] days after the indemnified Party has knowledge of such claim, demand or action, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand and not making any admission or otherwise adversely affecting the indemnifying party's interest, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation of and defense of any such claim or demand; and (iv) the indemnifying Party not compromising or settling such claim or demand without the indemnified Party's prior written consent (such consent shall not be unreasonably withheld or unduly provided), unless avoiding such settlement prejudices the position of the indemnifying party and/or its insurers or unless such settlement includes as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified Party a complete release from all liability in respect of such claim or litigation; provided that, if the Party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (i), the indemnifying Party shall only be relieved of its indemnification obligation to the extent it is prejudiced by such failure and provided further that the indemnified Party is not obligated to notify the indemnifying Party of claims, demands and/or actions made directly against the indemnifying Party only. Notwithstanding the foregoing, if in the reasonable judgment of the indemnified party, such suit or claim involves an issue or matter which could have a materially adverse effect on the business, operations or assets of the indemnified party, the indemnified party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof, but in no event shall any such waiver be construed as a waiver of any indemnification rights such indemnified party may have at law or in equity.

#### 14. TERM AND TERMINATION

14.1 **Term**. Unless earlier terminated in accordance with the provisions of this Article 14, the term of this Agreement (the "**Term**") will become effective on the Effective Date and will continue in full force and effect until terminated in accordance with the terms hereof.

#### 14.2 **Termination**.

14.2.1 **Termination for Breach**. Subject to the limitations set forth in Sections 6.10 and 14.2.3, failure by a Party to comply with any of its material obligations contained herein will entitle the Party not in default to give to the defaulting Party notice specifying the nature of the material breach, requiring the defaulting Party to make good or otherwise cure such material breach, and stating its intention to invoke the provisions of Section 14.3 if such material breach is not cured. If such material breach is not capable of cure or if such material breach is capable of cure and is not cured within (a) within [\*\*\*\*] days of the date payment is due for late payments pursuant to Section 6.6, or (b) [\*\*\*\*] days after the receipt of such notice (or, if such material breach is capable of cure but cannot be cured within such [\*\*\*\*]-day period, if the defaulting Party does not commence actions to cure such material breach within such period and thereafter diligently continue such actions to achieve full compliance as soon thereafter as is reasonably possible, but such material breach is not cured with an additional [\*\*\*\*]-day period), the Party not in default will be entitled, without limiting any of its other rights conferred on it by this Agreement (except as expressly set forth herein), to terminate this Agreement by providing written notice to the breaching Party.

14.2.2 **Voluntary Termination**. Subject to Section 14.3.4 below, RedHill shall be entitled, in its sole discretion, to terminate this Agreement at any time on [\*\*\*\*] days written notice to Apogee, without the need to pay Apogee any compensation in respect of such termination,. In addition, subject to the limitations set forth in Section 6.10, Apogee shall be entitled, in its sole discretion, to terminate this Agreement in the event of a Bankruptcy Event with respect to RedHill.

14.2.3 Limited Rights of Termination. For the avoidance of doubt, it is hereby expressly agreed that outside the scope of Sections 14.2.1 and 15.12 Apogee shall have no right to terminate this Agreement. For the avoidance of doubt, Apogee shall not be entitled to terminate this Agreement for any reason whatsoever once all Royalty Terms have expired.

#### 14.3 **Consequences of Termination**

14.3.1 License. Upon early termination of this Agreement, all rights granted to RedHill under Section 2.1 will terminate; provided that RedHill shall have a period of [\*\*\*\*] days after the date of termination to sell-off Product, subject to Royalties on such sales being duly paid to Apogee.

14.3.2 **Continuation following Apogee's Bankruptcy**. The Parties agree that in the event that Apogee becomes insolvent or makes a filing under bankruptcy or similar laws in any jurisdiction, RedHill shall have the protection afforded to the licensee under the United States Bankruptcy Code, including the protections set forth in 11 U.S.C §365(n) or its equivalent in any other jurisdiction which allows the licensee, upon rejection of the license agreement by the debtor-licensor or its representative, the option to either retain the licensee's rights in the intellectual property under the existing contract while continuing to pay royalties, or to treat the executory contract as terminated.



14.3.3 **Return of Information and Materials**. Upon termination of this Agreement, each Party will promptly return to the other all Confidential Information of the other Party (except one copy of which may be retained for archival and compliance purposes).

14.3.4 **Accrued Rights**. Termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

14.3.5 **Survival**. This Section 14.3 and Sections 6, 7, 8, 9, 11, 13 and 15 of this Agreement will survive expiration or termination of this Agreement for any reason.

## 15. MISCELLANEOUS

15.1 **Assignment**. Without the prior written consent of the other Party hereto, neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that (i) either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party to any Affiliate, or to any third party successor in interest with which it has merged or consolidated, or to which it has transferred all or substantial part of its assets or stock to which this Agreement relates. Any purported assignment or transfer in violation of this Section 15.1 will be void *ab initio* and of no force or effect.

15.2 **Severability.** Should any term or provision of this Agreement be or become invalid or unenforceable or should this Agreement contain an omission, the validity or enforceability of the remaining terms or provisions shall not be affected. In such case, subject to the next following sentence, the Parties shall immediately commence to negotiate in good faith in order to replace the invalid or unenforceable term or provision by such other valid or enforceable term or provision which comes as close as possible to the original intent and effect of the invalid or unenforceable term or provision, or respectively, to fill the omission by inserting such term or provision which the Parties would have reasonably agreed to, if they had considered the omission at the date hereof. In the event that any term or provision as aforesaid is invalid, void or unenforceable by reason of its scope, duration or area of applicability or some similar limitation as aforesaid, then the court making such determination shall have the power to reduce the scope, duration, area or applicability of the term or provision so that they shall be enforceable to the maximum scope, duration, area or applicability permitted by applicable law which shall not exceed those specified in this Agreement or to replace such term or provision with a term or provision that comes closest to expressing the intention of the invalid or unenforceable term or provision.

15.3 **Governing Law.** This Agreement will be governed by and construed in accordance with the laws of England and Wales, without reference to any rules of conflicts of laws and the courts of London, England shall have exclusive jurisdiction of disputes regarding this Agreement and the Parties hereby submit to the jurisdiction of such courts.

15.4 **Notices.** All notices or other communications that are required or permitted hereunder will be in writing and delivered personally with acknowledgement of receipt, sent by electronic mail (provided receipt is acknowledged), facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier as provided herein), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Apogee, to:

Apogee Biotechnology Corp. 1214 Research Blvd. Suite 2014 Hershey Center for Applied Research Hummelstown, PA 17036, U.S.A Fax: + 1 717 531 4758

If to RedHill, to:

RedHill Biopharma Ltd. 21 Ha'arba'a Street Tel-Aviv 64739 Israel Fax: +972 (3) 541 3144

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 communication will be deemed to have been given (i) when delivered, if personally delivered, (ii) on the Business Day (on the receiving end) after dispatch, if sent by nationally-recognized overnight courier (third Business Day if sent internationally), (iii) on the third Business Day following the date of mailing, if sent by mail (fifth Business Day if sent internationally) and (iv) on the First Business day (on the receiving end) after being sent by facsimile or by if sent by electronic mail followed by facsimile. It is understood and agreed that this Section 15.4 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

15.5 Entire Agreement; Modifications. This Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby, including the Non-Binding Term Sheet between the Parties dated December 31, 2014. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.6 **Relationship of the Parties**. It is expressly agreed that the Parties will be independent contractors of one another and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party. The relationship between the Parties will not constitute a partnership, joint venture, agency or employer-employee relationship for financial, tax, legal or other purposes.

15.7 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. Any such waiver will not be deemed a waiver of any other right or breach hereunder.

15.8 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

15.9 **No Third Party Beneficiaries.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other parties.

15.10 **Expenses**. Except as expressly provided herein, each Party shall each bear its own legal, accounting and other expenses in connection with this Agreement and the transactions contemplated hereby.

15.11 **Further Assurances.** Each Party will 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 to carry out the provisions and purposes of this Agreement.

15.12 **Force Majeure**. Neither party shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof but only to the extent that such delay or non-performance is occasioned by a cause beyond the reasonable control and without fault or negligence of such party, including earthquake, fire, flood, explosion, discontinuity in the supply of power, court order or governmental interference, act of God, strike or other labor trouble, act of war or terrorism and provided that such party will inform the other party as soon as is reasonably practicable and that it will entirely perform its obligations immediately after the relevant cause has ceased its effect. If any such force majeure event continues for a continuous period of 12 months, the Party whose performance is not prevented by such event may terminate this Agreement with immediate effect by providing the other Party with written notice. This Section 14.15 shall not apply to any obligation of a party to make a payment hereunder.

**IN WITNESS WHEREOF,** the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

#### Apogee Biotechnology Corp.

Signature: <u>/s/ Charles D. Smith</u> Name: Charles D. Smith Title: President and CEO March 30, 2015

#### **RedHill Biopharma Ltd.**

Signature: <u>/s/ Dror Ben-Asher</u> Name: Dror Ben-Asher Title: CEO March 30, 2015

Signature: <u>/s/ Ori Shilo</u> Name: Ori Shilo Title: Deputy CEO, Finance and Operations March 30, 2015

ANNEX A
PATENTS
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