

**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): March 15, 2024

FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-32295

(Commission File Number)

British Columbia, Canada

(State or other jurisdiction of
incorporation)

20-0442384

(I.R.S. Employer Identification No.)

**PO Box 13628, 68 TW Alexander Drive,
Research Triangle Park, NC**
(Address of principal executive offices)

27709
(Zip Code)

Registrant's telephone number, including area code: (919) 636-4530

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common shares, no par value	FENC	Nasdaq Capital Market

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement.

On March 15, 2024, Fennec Pharmaceuticals, Inc., a Delaware corporation (“Fennec”) and wholly owned subsidiary of Fennec Pharmaceuticals Inc. (the “Company”), entered into a License and Supply Agreement (the “Agreement”) with Norgine Pharma UK Limited (“Norgine”), pursuant to which Norgine is granted an exclusive license to commercialize the Company’s product PEDMARQSI[®] (known as PEDMARK[®] in the United States) for all human indications in the European Economic Area, Switzerland, the United Kingdom, Australia and New Zealand (collectively, the “Territory”).

Pursuant to the terms of the Agreement, Fennec shall receive the following payments from Norgine: (i) an upfront payment in the amount of €40 million, which was paid to Fennec on March 15, 2024, (ii) up to €210 million upon the achievement of certain regulatory and commercial milestones, and (iii) tiered royalty payments based on net sales of PEDMARQSI[®] in the Territory, which royalty payment range from mid-teen percent to mid-twenty percent based on the aggregate net sales of PEDMARQSI[®] in the Territory. The tiered royalty payments are subject to material reduction if an alternative or generic version of PEDMARQSI[®] becomes available in any respective country or jurisdiction within the Territory.

Subject to customary rights of each party to earlier terminate the Agreement, the term of the Agreement continues for the longer of: (i) March 15, 2034, or (ii) with respect to any particular country in the Territory, (a) the expiration of regulatory market exclusivity for PEDMARQSI[®] in such country, or (b) the last-to-expire of all patents for PEDMARQSI[®] in such country. The term of the Agreement shall be automatically renewed for additional three-year periods unless either party provides the other party written notice of its intent not to renew the Agreement at least one year prior to the applicable termination date of the Agreement.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to, and should be read in conjunction with, the full text of the Agreement, a copy of which is filed as Exhibit 10.1 hereto and is incorporated herein by reference. The Agreement and the foregoing description of the Agreement have been included to provide investors and shareholders with information regarding the terms of the Agreement. They are not intended to provide any other factual information about the Company, Fennec, or Norgine. The representations, warranties, and covenants contained in the Agreement were made only as of specified dates for the purposes of the Agreement, were solely for the benefit of the parties to the Agreement, and may be subject to qualifications and limitations agreed upon by such parties. In particular, in reviewing the representations, warranties, and covenants contained in the Agreement, it is important to bear in mind that such representations, warranties, and covenants were negotiated with the principal purpose of allocating risk between the parties to the Agreement, rather than establishing matters as fact. Such representations, warranties, and covenants may also be subject to a contractual standard of materiality or interpretation different from those generally applicable to reports and other documents filed with the U.S. Securities and Exchange Commission (“SEC”). Investors and shareholders should not rely on such representations, warranties, and covenants as characterizations of the actual state of facts or circumstances described therein. Rather, investors and shareholders should look to disclosures contained in the Company’s reports under the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

Item 8.01 Other Events.

On March 18, 2024, the Company issued a press release announcing the Agreement. A copy of the press release is filed as Exhibit 99.1 hereto.

The information contained in this Item 8.01, including Exhibit 99.1 filed herewith, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Exchange Act, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless such subsequent filing specifically references this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

[10.1*](#) [License and Supply Agreement, dated March 15, 2024, between Fenec Pharmaceuticals, Inc. and Norgine Pharma UK Limited.](#)

[99.1](#) [Press Release dated March 18, 2024.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

* In accordance with Item 601(b)(10)(iv) of Regulation S-K, certain provisions and terms of this exhibit have been redacted. Fenec will provide an unredacted copy of the exhibit on a supplemental basis to the SEC or its staff upon request.

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.

Date: March 21, 2024

FENNEC PHARMACEUTICALS INC.

By: /s/ Robert Andrade

Robert Andrade

Chief Financial Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN REDACTED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. [*] INDICATES INFORMATION HAS BEEN REDACTED.**

EXECUTION VERSION

LICENSE AND SUPPLY AGREEMENT

THIS LICENSE AND SUPPLY AGREEMENT (the “Agreement”) is entered into as of 15 March, 2024 (the “Effective Date”) by and between **FENNEC PHARMACEUTICALS, INC.**, a company incorporated under the laws of Delaware with registered offices at 68 TW Alexander Drive, Research Triangle Park, NC 27709, USA (“Fennec”) and **NORGINE PHARMA UK LIMITED**, a company incorporated under the laws of England and Wales with registered offices at Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, United Kingdom (“Licensee”). Fennec and Licensee may be referred to herein individually as a “Party” and jointly as the “Parties”.

RECITALS

WHEREAS Fennec owns certain intellectual property rights, license rights, data and documentation on PEDMARQSI[®] (known as PEDMARK[®] in the United States), a sodium thiosulfate injection for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients aged 1 month to up to 18 years of age with localised, non-metastatic, solid tumors (such product, as supplied to Licensee under this Agreement, is referred to as the “Product”);

AND WHEREAS Fennec Pharmaceuticals (EU) Limited was granted (i) European Commission marketing authorization for the Product under a paediatric-use marketing authorization EMEA/H/C/005130 on May 26, 2023, and (ii) UK marketing authorization for the Product under marketing authorization PLGB 57848/0001 on October 11, 2023 (the “Existing MAs”);

AND WHEREAS Licensee desires to distribute, market and sell the Product in the Territory and Fennec is prepared to grant to Licensee exclusive license rights to import, market, and distribute in accordance with all the terms and conditions hereof.

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants of the Parties, it is hereby agreed as follows:

1. DEFINITIONS

In this Agreement, including all appendices hereto:

1.1 “Affiliate” means:

- (i) in respect of Fennec, any company which controls, is controlled by, or is under common control with, Fennec. A company shall be regarded as in control of another company for the purposes of this Agreement if it owns or directly or indirectly controls more than fifty percent (50%) of the voting share capital of the other company or, in the absence of the ownership of more than fifty percent (50%) of the voting share capital of the company, if it controls the composition of its board of directors or similar governance body under the applicable corporate law. A company shall be regarded as being under common control with Fennec for the purposes of this Agreement if the same person (or persons) owns or directly or indirectly controls (including through one or more intervening persons, companies or trusts) more than fifty percent (50%) of the voting share capital of both the first company and the other company or, in the absence of the ownership of more than fifty percent (50%) of the voting share capital of the companies, if the same person (or persons) controls (including through one or more intervening persons, companies or trusts) the composition of the board of directors or similar governance body under the applicable corporate law of both the first company and the other company; and

(ii) in respect of Licensee, a Norgine Group Company,

provided that, with respect to the grant of license rights by Fenec to Licensee under Section 2 and Section 10, “Affiliate” shall exclude any Third Party that becomes an Affiliate due to such Third Party’s acquisition of Licensee.

1.2 “Alternative Source” has the meaning given to such term in Section 4.8.1.

1.3 “Applicable Law” means all applicable provisions of any and all laws, regulations and standards determined by any governmental or regulatory authority, including common law, and any generally applicable industry or self-regulatory standards, codes of practice and guidelines or other applicable matters of a similar nature, including Compliance Laws, that are in force from time to time in the Territory during the term of this Agreement, whether the same are regional, national or international.

1.4 “Calendar Quarter” means, in each year during the term of this Agreement, each of the following periods, as applicable: (i) January 1 to March 31, inclusive; (ii) April 1 to June 30, inclusive; (iii) July 1 to September 30, inclusive; and (iv) October 1 to December 31, inclusive.

1.5 “Change of Control” means the happening of any of the following events: (i) any transaction pursuant to which (A) a Party goes out of existence or (B) any person, or any Affiliate of such person, or group of persons acting jointly or in concert (other than the Party, a subsidiary of that Party or an employee benefit plan of that Party (including any trustee of such plan acting as trustee)) hereafter acquires beneficial ownership of securities of such Party representing 50% or more of the aggregate voting power of all outstanding securities of such Party; (ii) the sale of all or substantially all of a Party’s assets to a person other than an Affiliate of such Party; (iii) the dissolution or liquidation of a Party except in connection with the distribution of assets of such Party to one or more persons which were Affiliates prior to such event; or (iv) the occurrence of a transaction requiring approval of the Party’s shareholders involving the acquisition of that Party by an entity through purchase of assets, by amalgamation, merger or otherwise.

- 1.6 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party with respect to the objective that is the subject of such efforts, reasonable, good faith efforts and resources to accomplish such objective that such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the commercialization and sale of the Product in the Territory by Licensee, such efforts shall be similar to those efforts and resources consistent with the usual practice of Licensee in pursuing the commercialization and sale of drug products owned by it or to which it otherwise has rights that are of similar market potential as the Product in the Territory.
- 1.7 “Competing Product” means any product other than the Product that contains sodium thiosulfate as an active ingredient that is either indicated for or used off label for the treatment of platinum ototoxicity and is administered by intravenous injection or infusion, excluding compounding of sodium thiosulfate solutions.
- 1.8 “Confidential Information” means all know-how and other proprietary information and data of a financial, commercial or technical nature which the disclosing Party or any of its Affiliates (the “Disclosing Party”) has supplied or otherwise made available to the other Party or any of its Affiliates (the “Recipient Party”), whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement. Notwithstanding the foregoing, the existence of, and the terms and conditions of, this Agreement shall be considered Confidential Information of each of Fenec and Licensee.
- 1.9 “Controlled” or “Controls”, when used in reference to intellectual property, shall mean the legal authority or right of a Party (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to the other Party, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party. This term may be used herein as a noun.
- 1.10 “EMA” means the European Medicines Agency and all divisions under its direct control or any successor organizations.
- 1.11 “Euro” or “€” means the currency by the countries in eurozone (being certain member states of the European Union); provided that if the Euro ceases to exist then the currency adopted by the Netherlands shall replace Euro in this Agreement.
- 1.12 “Existing CMO” has the meaning given to such term in Section 4.8.2.
- 1.13 “Existing MAs” has the meaning given to such term in the recitals.
- 1.14 “FDA” shall mean the United States Food and Drug Administration, and all divisions under its direct control or any successor organizations.
- 1.15 “Fenec Improvements” has the meaning given to such term in Section 2.1.1.

- 1.16 “Field” means the diagnosis, prevention or treatment of diseases and other conditions in all indications in humans.
- 1.17 “Force Majeure” means any cause preventing either Party from performing any or all of its obligations which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the Party so prevented or its suppliers or subcontractors including without limitation strikes, lock-outs or other industrial disputes (whether involving the workforce of the Party so prevented or of any other Party), act of God, war, riot, civil commotion, malicious damage, pandemic, compliance with any Applicable Law coming into effect after the date hereof, accident, breakdown of plant or machinery, fire, flood, or storm.
- 1.18 “Generic Product” means, with respect to the Product, (a) any product that contains sodium thiosulfate as an active ingredient that is either indicated for or used off label for the treatment of platinum ototoxicity and is administered by intravenous injection or infusion (but excluding compounding of sodium thiosulfate solutions), that is sold by a Third Party under a regulatory approval granted by a Relevant Regulatory Authority to a Third Party, which Third Party has not obtained the right to market or sell such product from Licensee (including as a sublicensee, subcontractor, or distributor of Licensee or any of its Affiliates), and (b) is approved in reliance, in whole or in part, on the prior approval (or on data supporting safety or efficacy data submitted in support of the prior approval) of the Product as determined by the applicable Relevant Regulatory Authority, including without limitation any product authorized for sale (i) in the E.U. 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 (ii) in any other country or jurisdiction pursuant to the equivalents of such provisions, including any amendments and successor statutes with respect to the subsections (i) through (ii).
- 1.19 “Good Distribution Practice” or “GDP” means the regulatory standards and principles and guidelines of good distribution practice as in force from time to time relating to the warehousing, storage and physical distribution of medicinal products established by the Relevant Regulatory Authority including, without limitation, the European Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01), as the same may be amended from time to time.
- 1.20 “Good Manufacturing Practice” or “GMP” means the regulatory standards and principles and guidelines of good manufacturing practice as in force from time to time relating to the manufacturing of medicinal products established by the Relevant Regulatory Authority including, without limitation, the European Commission Directive (2003/94/EC).
- 1.21 “Latent Defect” means a defect that causes Product to fail to conform to the Specifications or to the warranties provided by Fenec hereunder, which defect is not reasonably discoverable upon inspection but is discovered at a later time.
- 1.22 “Local Agreements” has the meaning given to such term in Section 5.8 of this Agreement.

- 1.23 “Marketing Authorization/s” shall mean all approvals, licenses, registrations or authorizations of the competent Relevant Regulatory Authority in a country within the Territory, that are necessary for the marketing and sale of the Product in such country, including Pricing Approvals and Reimbursement Approvals in such country.
- 1.24 “MHRA” means the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, or any successor entity thereto.
- 1.25 “Minimum Purchase Quantity” has the meaning given to such term in Section 4.5.
- 1.26 “Net Sales” means the gross invoiced sales price of the Product billed by Licensee or its Affiliates or its or their sublicensees to Third Parties, less the following deductions, to the extent included in the gross invoiced sales price for the Product or otherwise directly paid or incurred by Licensee with respect to the sale of the Product: (i) normal and customary amounts actually repaid or credited by reason of defects, rejections, recalls or returns; (ii) tariffs, duties, excise, sales, value-added or other taxes (other than taxes based on income); (iii) outbound shipping, freight and insurance cost incurred to sell the Product; (iv) governmental and other rebates (or equivalents thereof) to national, state/provincial, local, and other governments, their agencies and purchases, and reimbursers, and normal and customary discounts and rebates allowed to trade customers and Third Party distributors, (v) commissions allowed or paid to Third Party distributors, brokers or agents other than sales personnel, sales representatives and sales agents employed or engaged by Licensee, its Affiliates or sublicensees, and (vi) reasonable provision for risk of write-offs for bad debt (provided that any amount subsequently recovered will be treated as Net Sales in the period during which it is paid).
- 1.27 “Norgine Group” means Spinnaker Topco Limited and any person directly or indirectly controlled by Spinnaker Topco Limited, where control means (a) the right to exercise the majority of voting rights and other governance rights in respect of that body corporate, or (b) the ownership of a majority of the issued shares and equity securities in that body corporate, but excludes the shareholders of Spinnaker Topco Limited, any subsidiary undertakings of such shareholders and any portfolio companies in which any shareholder of Spinnaker Topco Limited holds an investment or interest.
- 1.28 “Norgine Group Company” means any person who is a member of the Norgine Group.
- 1.29 “OHSU License” means the licence agreement between Oregon Health & Science University and Adherex, Inc. dated February 20, 2013 (as amended from time to time).
- 1.30 “Package” means to package and label the Product for its promotion, advertisement, distribution, marketing, offering and sale in the Territory, and “Packaging” has a corresponding meaning.
- 1.31 “Performance Plan” means the performance plan prepared by Licensee as updated from time to time, all as contemplated by Section 8.1 of this Agreement.
- 1.32 “Permitted Encumbrances” the liens granted under the security agreement dated as of the 1st day of August, 2022, by and among Fennec, Fennec Pharmaceuticals Inc., Oxiquant, Inc., Cadherin BioMedical Inc. and Petrichor Opportunities Fund I LP., as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time.

- 1.33 “Pharmacovigilance Agreement” has the meaning given to such term in Section 5.6.
- 1.34 “Pricing Approval” shall mean, with respect to a jurisdiction within the Territory which competent Relevant Regulatory Authority determine the pricing at which the Product should be sold, the approval, agreement, determination or decision by the applicable Relevant Regulatory Authorities establishing the pricing status for the Product in any jurisdiction within the Territory.
- 1.35 “Product” has the meaning given to such term in the recitals to this Agreement.
- 1.36 “Product Patents” has the meaning given to such term in Section 0 of this Agreement.
- 1.37 “Quality Agreement” has the meaning given to such term in Section 7.4 of this Agreement.
- 1.38 “Recall” means with respect to the Product, a “recall”, “correction” or “market” withdrawal, as those terms (or their equivalents) are defined by Applicable Law, as the same may be amended from time to time, and shall include any post-sale warning or mailing of information regarding such Product, including those warnings or mailings described by Applicable Law.
- 1.39 “Reimbursement Approval” shall mean with respect to a country of the Territory which competent Relevant Regulatory Authority determine the pricing at which the Product will be reimbursed, the approval, agreement, determination or decision by the applicable governmental authorities establishing the reimbursement status for the Product.
- 1.40 “Relevant Regulatory Authority” means, collectively, the European Commission, EMA, MHRA and any other and any other national, supranational, regional, provincial or local governmental or regulatory authority, agency, department, bureau, commission, council or other government entity having jurisdiction over the manufacture, importation, promotion, marketing, distribution or sale of the Products in the Territory.
- 1.41 “Specifications” means the specifications for the Product as set forth in the relevant file(s) of the Product as approved by the competent Relevant Regulatory Authorities in the Territory, with the additional requirement that the sulfate content of the sodium thiosulfate drug substance used to manufacture the Product is greater than 0.55% by weight.
- 1.42 “Subcommittee” has the meaning given to such term in Section 11.5.
- 1.43 “Territory” means, collectively, the European Economic Area as constituted as at the Effective Date (namely, Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden), Switzerland, the United Kingdom, Australia and New Zealand, together with any special territories of such countries.
- 1.44 “Third Party” means any person other than the Parties and their Affiliates.
- 1.45 “Third Party Claim” has the meaning given to such term in Section 18.3.1 of this Agreement.

- 1.46 “Trademark” means the trademark PEDMARQSI™ (as further set out in **Appendix D**) or any other trademarks owned or possessed by Fenec and used to identify the Product in the Territory.
- 1.47 “Working Days” means any day that is not a Saturday, Sunday or other day on which commercial banks are authorized or required to be closed, as the case may be, in New York, USA, London, England or Amsterdam, the Netherlands.

2. GRANT OF LICENSE; OBLIGATIONS

- 2.1 License. Fenec, for itself and its Affiliates, hereby grants to Licensee in accordance with the terms and conditions of this Agreement:
- 2.1.1 an exclusive (even as to and against Fenec and its Affiliates) license under the Product Patents and Marketing Authorizations; and
- 2.1.2 an exclusive, royalty-free, fully paid-up right and license to use any enhancements, improvements, information and data specifically relating to the Product that is developed by Fenec or its Affiliates (“Fenec Improvements”),
- to (i) import, export, promote, distribute, manufacture and/or have manufactured (in each case in accordance with Section 2.5 or Section 4.8), market, advertise, offer for sale, have sold and sell the Products in the Territory and within the Field, and (ii) support such investigator initiated studies in respect of the Product in the Territory as may be proposed by Licensee and agreed by Fenec (such agreement not to be unreasonably withheld, delayed or conditioned).
- 2.2 Licensee shall, and any of its Affiliates who are its sublicensees (if applicable) shall, be entitled to describe itself as Fenec’s “Authorized Licensee” (or similar) for the Product, but shall not be, or be considered as, Fenec’s agent for sales of the Product or as being entitled to bind Fenec in any way.
- 2.3 For the avoidance of doubt, no right or license to manufacture the Product is granted under this Agreement other than via an Alternative Source. Licensee shall not modify the Product without specific prior written permission from Fenec.
- 2.4 Licensee shall not, directly or indirectly, actively distribute, market and sell the Product outside the Territory, and Fenec shall not directly or indirectly, actively distribute, market and sell the Product in the Territory. Licensee shall promptly inform Fenec as to any request from a Third Party for Product coming from outside the Territory. Fenec shall promptly inform Licensee as to any request from a Third Party for Product coming from within the Territory.
- 2.5 Sublicensing and Subcontracting.

Sublicensing

- 2.5.1 Subject to Section 2.5.2 and Section 2.5.3, Licensee may grant sublicenses to its Affiliates and Third Parties without Fenec’s prior written consent, provided that (i) such sublicenses shall terminate no later than the earlier of the termination or expiry of this Agreement or the date on which such Affiliate ceases being an Affiliate, (ii) all sublicenses, and each sublicensee, shall be subject to the applicable terms and conditions of this Agreement, (iii) Licensee shall remain responsible and liable for all of the sublicensee’s compliance (and any failures to comply) with the applicable terms and conditions of this Agreement, (iv) no sublicense will diminish, reduce, or eliminate any obligation of Licensee under this Agreement; (v) Licensee shall provide advance written notice of any sublicense to a Third Party under this Section 2.5.1 and, for the avoidance of doubt, no advance notice is required in respect of any sublicense to an Affiliate under this Section 2.5.1.

2.5.2 Licensee shall not sublicense any of the licenses or rights granted to Licensee under this Agreement in respect of France, Germany, Italy or the United Kingdom to any Third Party without Fennec's express prior written consent, provided that such consent shall not be required for any sublicense in connection with an Alternative Source.

Subcontracting

2.5.3 Licensee (and its Affiliates and sublicensees) may subcontract any of its activities under this Agreement to a Third Party subcontractor; provided, that, in each case, any subcontract granted or entered into by Licensee (or its Affiliate or sublicensee) will not relieve Licensee (or such Affiliate or sublicensee, as applicable) from any of its obligations under this Agreement. Licensee will be responsible for the acts and omissions of its (and its Affiliate's or sublicensee's, as applicable) subcontractors in connection with their performance of any of its obligations or exercise of any of its rights hereunder. Any agreement with a subcontractor to perform activities on behalf of Licensee under this Agreement will be consistent with Licensee's obligations under this Agreement, including confidentiality which are no less stringent than those set forth in Article 9 (but of shorter duration if customary under the circumstances).

2.6 Licensee's Basic Obligations. Licensee shall take Commercially Reasonable Efforts to ensure that the Product sold in the Territory is sold in compliance with all Applicable Law, including without limitation in relation to Packaging and labelling and other regulatory and quality related matters. This shall include any repackaging/relabeling with Territory-specific packaging and tracking of Product inventory throughout the entirety of the supply chain as may be reasonably necessary.

2.7 Licenses to Fennec. Licensee, for itself and its Affiliates, hereby grants to Fennec and its Affiliates in accordance with the terms and conditions of this Agreement:

2.7.1 a royalty-free right and license during the terms of this Agreement to Licensee's trademarks set out in **Appendix E** for Fennec and its Affiliates as is necessary for Packaging the Products for sale in the Territory, provided that Fennec agrees, and shall cause its Affiliates, to conform to the customary industry standards for the protection of such trademarks and to such trademark usage guidelines as Licensee may furnish from time to time. For avoidance of doubt, Licensee and its Affiliates shall remain the owner of its trademarks; and

2.7.2 a royalty-free, fully paid up right and license to use any enhancements, improvements information and data specifically relating to the Product that is developed by Licensee or its Affiliates (“Licensee Improvements”), provided that the Licensee Improvements are used solely to import, export, promote, distribute, market, advertise, offer for sale, have sold and sell the Product by Fennec and its Affiliates outside the Territory and in the Field.

3. REPRESENTATIONS AND WARRANTIES

3.1 Licensee Representations and Warranties. Licensee represents, warrants and covenants to Fennec that:

- 3.1.1 it has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby;
- 3.1.2 neither the execution and delivery of this Agreement by it, nor its performance hereunder, conflicts with or will result in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, indenture, license, agreement or other instrument or obligation to which it is a party or by which it or any of its properties or assets may be bound; or to its best knowledge, violates any Applicable Law;
- 3.1.3 this Agreement is a legal, valid and binding agreement of Licensee, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors’ rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at law; and
- 3.1.4 it has not been debarred, is not subject to debarment, and will not use, in any capacity in connection with the obligations to be performed under this Agreement, any person who to its knowledge has been debarred pursuant to Section 306 of the *United States Food, Drug and Cosmetic Act* or similar Applicable Law in the Territory;
- 3.1.5 there is no suit, investigation, action or proceeding pending or, to its knowledge, threatened against Licensee before any court, governmental agency, or arbitration panel which may in any way materially adversely affect the performance of its obligations hereunder or transaction contemplated by this Agreement;
- 3.1.6 as of the Effective Date, neither it nor any of its Affiliates, either alone or together with any Third Party, is developing or commercializing a Competing Product; and
- 3.1.7 it will not make nor will it promise to make any payment in violation of the *U. S. Foreign Corrupt Practices Act* or similar Applicable Law in Territory.

3.2 Fennec Representation and Warranties. Fennec represents, warrants and covenants to Licensee that:

- 3.2.1 it has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby;
- 3.2.2 neither the execution and delivery of this Agreement by it, nor its performance hereunder, conflicts with or will result in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, indenture, license, agreement or other instrument or obligation to which it is a Party or by which it or any of its properties or assets may be bound; or to its best knowledge, violates any Applicable Law;
- 3.2.3 this Agreement is a legal, valid and binding agreement of Fennec, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing), regardless of whether considered in a proceeding in equity or at law;
- 3.2.4 it has not been debarred, is not subject to debarment, and will not use, in any capacity in connection with the obligations to be performed under this Agreement, any person who to its knowledge has been debarred pursuant to Section 306 of the *United States Food, Drug and Cosmetic Act* or similar Applicable Law in the Territory;
- 3.2.5 there is no suit, investigation, action or proceeding pending or, to its knowledge, threatened against Fennec before any court, governmental agency, or arbitration panel which may in any way materially adversely affect the performance of its obligations hereunder or transaction contemplated by this Agreement;
- 3.2.6 the Product has been developed in a diligent, professional manner and in full compliance with all Applicable Laws and Fennec has not been informed of any proceeding or similar action pending or threatened in writing seeking the revocation, suspension or amendment of either Existing MA for reasons related to safety or efficacy, nor has the EMA or the European Commission or MHRA requested or demanded in writing that Fennec discontinue any Marketing Authorization relating to the Product;
- 3.2.7 it has not and will not enter into any contract or any other transaction with any Third Party or Affiliate that conflicts with or derogates from its undertakings hereunder;
- 3.2.8 it will not make nor will it promise to make any payment in violation of the *U. S. Foreign Corrupt Practices Act* or similar Applicable Law in the Territory;
- 3.2.9 it has the right to grant to Licensee the licenses it purports to grant hereunder;
- 3.2.10 it is the owner of (i) the Product Patents, (ii) the Trademark, (iii) the Existing MAs, and (iv) all other intellectual property rights, license rights, data and documentation relating to the Product, in each case free from encumbrances, other than Permitted Encumbrances;

- 3.2.11 in respect of the Existing MAs, (i) each Existing MA is in the name of Fenec Pharmaceuticals (EU) Limited, (ii) the Existing MAs constitute all licenses, permits, approvals, qualifications, and governmental specifications, authorizations or requirements which Fenec or its Affiliates have in connection with the marketing and/or sale of the Product in the Territory, (iii) Fenec and/or its Affiliates have complied with all its material obligations under, and the terms and conditions of, the Existing MAs and all Applicable Laws in relation thereto, (iv) all fees due as at the Effective Date in respect of the Existing MAs have been paid, and (v) there are no (no have there been any) challenges, effective or threatened in writing to vary or revoke, either Existing MA and, to Fenec's knowledge, there are no subsisting events or circumstances which may reasonably be foreseen to adversely affect either Existing MA or cause any such challenge, variation or revocation;
- 3.2.12 (i) to its knowledge, it has not misappropriated or infringed, and covenants and agrees that it will not misappropriate or infringe, any intellectual property of a Third Party in connection with the Product or the performance of its respective obligations under this Agreement, (ii) neither it nor its Affiliates have received any written notice, or, to the knowledge of such Party, oral notice, of any claim that any patent or know-how (including any trade secret right) Controlled by a Third Party would be infringed, misappropriated or otherwise violated by the performance of the activities hereunder or by the commercialization of the Product in the Territory in accordance with this Agreement, (iii) to its knowledge, no patent or know-how Controlled by a Third Party is necessary for the commercialization of the Product in accordance with this Agreement;
- 3.2.13 the Product supplied to Licensee under this Agreement shall be manufactured in accordance with the Specifications and GMP;
- 3.2.14 neither Fenec, nor to its knowledge any contract manufacturing organization from which Fenec procures current supply of Product, has received any warning letters or other adverse findings relating to the manufacture of the Product or which could adversely impact the Product;
- 3.2.15 it has, and will have throughout the Initial Term and any Subsequent Term, the required expertise, permits and approvals to perform its obligations under the Agreement in a timely and professional manner;
- 3.2.16 Fenec Pharmaceuticals, Inc. is a US tax resident and beneficially owns the intellectual property rights licensed under this Agreement; and
- 3.2.17 Licensee is not a Sublicensee (as such term is defined in the OHSU License) under the OHSU License and none of the rights licensed to Licensee pursuant to this Agreement are sublicensed by Fenec under the OHSU License.
- 3.3 Survival of Representations and Warranties. All representations and warranties of Licensee and Fenec contained herein or made pursuant hereto (other than any representation or warranty expressed to be given as at the Effective Date) shall be ongoing during the Initial Term and any Subsequent Term. In the event of any breach of the representations and warranties set forth herein, the applicable Party shall notify the other Party of such breach in writing as soon as is reasonably practicable.

3.4 Data Room. Fennec shall leave the electronic data room named [***] and hosted by iDeals available to Licensee for a thirty (30) day period following the Effective Date to enable Licensee to download its contents. Such content is subject to Article 9 (Confidential Information).

4. SUPPLY, ESTIMATES, ORDERS & DELIVERY

4.1 Supply and Purchases of Product. Fennec hereby agrees to sell the Product to Licensee, or a designated Affiliate of Licensee, subject to the terms of this Agreement and Licensee hereby agrees to purchase all its requirements of the Product exclusively from Fennec, or a designated Affiliate of Fennec. Licensee and Fennec shall use Commercially Reasonable Efforts to enter into an amendment to this Agreement setting forth their additional duties and obligations relating to the manufacturing, supply and distribution of the Product under this Agreement within [***] days of the Effective Date.

4.2 Forecasts. Prior to the Effective Date and no later than the tenth (10th) day of every month, Licensee shall provide to Fennec an eight (8) Calendar Quarter (twenty-four (24) months) rolling forecast of Licensee's estimated requirements of the Product for the Territory (such eight Calendar Quarter rolling forecast, the "Rolling Forecast"), which shall be reviewed annually and mutually agreed by the Parties in accordance with Section 11.3. The first Calendar Quarter of the Rolling Forecast submitted on a quarterly basis will be considered binding and hence will represent the ordering schedule for that Calendar Quarter. This ordering and forecasting procedure will apply on a rolling basis. The initial Calendar Quarter of the Rolling Forecast shall be the Calendar Quarter immediately following the Calendar Quarter that the forecast was delivered. Licensee shall exert all Commercially Reasonable Efforts to prepare each forecast as accurately as possible and shall update such forecasts to reflect actual and projected demand. Notwithstanding any contrary provision hereunder, Fennec shall not be deemed obliged to supply to Licensee quantity of Product higher than [***] of the first four Calendar Quarters demand within each submitted Rolling Forecast, however Fennec will act in good faith and use Commercially Reasonable Efforts to fulfil any such increased demand.

4.3 Orders and Invoicing. In accordance with Section 4.2 above, the first Calendar Quarter of each submitted Rolling Forecast shall be considered as firm orders. Licensee shall place firm orders for the Product required for the Territory specifying delivery date(s). Fennec shall procure the production of, and deliver to Licensee on the specified delivery date(s), the quantities of Product set forth in each such firm order. Following the date on which the relevant order of Product is available for collection, Fennec shall invoice Licensee. All sales and use taxes which Fennec is required by Applicable Law to collect from Licensee with respect to the supply of Product shall be paid by Licensee to Fennec unless Licensee provides a valid exemption to Fennec.

4.4 Delivery. Delivery of the Product to Licensee shall be FCA (Fennec's site at Almac Pharma Services Limited, Finnabair Industrial Estate, Dundalk, Co. Louth, Ireland A91 P9KD) (ICC Incoterms 2020). Licensee will, if requested by Fennec, arrange for export declarations on behalf of Fennec through Licensee's customs broker.

4.5 Minimum Purchase Quantity. With effect from the date on which Pricing Approval and Reimbursement Approval has been received by Licensee for the Product in each of France, Germany, Italy, Spain and the United Kingdom, on a calendar year basis, to be calculated on a pro-rata basis for any partial years where applicable, Licensee undertakes to order the following amounts of Product within the December Rolling Forecast for the immediate calendar year following such forecast delivered in accordance with Section 4.2 (hereinafter referred to as the “Minimum Purchase Quantity”):

- 4.5.1 [***] of the volume of Product set out in the first Calendar Quarter of the December Rolling Forecast for such calendar year;
- 4.5.2 [***] of the volume of Product set out in the second Calendar Quarter of the December Rolling Forecast for such calendar year;
- 4.5.3 [***] of the volume of Product set out in the third Calendar Quarter of the December Rolling Forecast for such calendar year; and
- 4.5.4 [***] of the volume of Product set out in the fourth Calendar Quarter of December Rolling Forecast for such calendar year.

If Licensee does not order the Minimum Purchase Quantity in any calendar year, then Licensee shall have the opportunity to remedy such default by paying to Fenec an amount equal to the deficiency, or placing orders of Product having an aggregate purchase price to Fenec hereunder equal to the deficiency, in either case, within [***] days from Fenec issuing written notice to Licensee of the foregoing. For clarity, any failure by Licensee to remedy such default in accordance with the foregoing after Fenec’s written notice shall constitute a material breach by Licensee for the purposes of Section 12.2. If, at any time, a Generic Product or Competing Product is launched in a country or other jurisdiction in the Territory, Licensee shall have the right to revise the applicable December Rolling Forecast by a reasonable amount of Product, and the Minimum Purchase Quantities set out above shall be deemed amended accordingly.

4.6 Sales Targets Discussion. The JSC’s October meeting each year (as referred to in Section 11.3) shall, at least in part, be devoted to discussing performance against the current year’s forecast and, based on the sales trends experienced and anticipated, the Parties shall in good faith discuss whether or not any of the sales targets in the Performance Plan should be amended for the next calendar year.

4.7 Shortages Allocation. Notwithstanding Section 4.3, if Fenec reasonably expects that it will be unable to deliver to Licensee quantities of Product in amounts sufficient to satisfy any firm order, Fenec shall promptly (and in all cases within [***] days of becoming aware of such expected shortage) notify Licensee of such expected shortage and the details relating thereto. In such instance Fenec shall, to the extent some but not complete production is practicable, use Commercially Reasonable Efforts to allocate available Product to itself, other distributors and Licensee on an even-handed basis in proportion to relative demand at the time.

4.8 Licensee Additional Manufacturing and Supply of Product and Manufacturing Technology Transfer.

- 4.8.1 Licensee may, at any time during the Initial Term or any Subsequent Term, procure an additional or replacement supplier of Product (or any part or component thereof, including active pharmaceutical ingredient) (an “Alternative Source”).
- 4.8.2 In the event that Licensee intends to procure an Alternative Source pursuant to Section 4.8.1, Licensee may request that Fennec provides assistance to Licensee with respect to the transfer of know-how relating to the Specifications and process for the manufacture of the Product from (i) the contract manufacturing organization that is supplying Product to Fennec at the relevant time (the “Existing CMO”), to (ii) Licensee or its designee (which designee may be an Affiliate of Licensee or any other contract manufacturing organization designated by Licensee) (a “Manufacturing Technology Transfer”). Upon such request, Fennec shall, and shall cause its Affiliates to, cooperate with Licensee and/or its designee(s), including without limitation (a) undertaking the following (to the extent such documents, information and/or access are within its possession or control), and (b) to the extent Fennec is not able or permitted to do so under sub-clause (a), using Commercially Reasonable Efforts to cause the Existing CMO to undertake the following, in each case in respect of any such Manufacturing Technology Transfer:
- (a) providing to Licensee or its designee copies of all technical documentation, specifications, procedures and know-how in its possession or control that are reasonably required for the manufacture of the Product;
 - (b) making available to Licensee and/or its designee(s) the services of such qualified and experienced scientists, production and quality assurance personnel, engineers, and quality checking personnel as may be necessary or reasonably required to support the Manufacturing Technology Transfer and the establishment of the manufacturing process for the Product. Such services may be provided either in person or remotely, and at such convenient times as the Parties and the Existing CMO may reasonably agree; and
 - (c) providing Licensee and/or its designee with reasonable access to the Existing CMO’s manufacturing site(s) to observe the manufacture of the Product at such times as the Parties and the Existing CMO may reasonably agree.
- 4.8.3 Licensee agrees to reimburse Fennec and the Existing CMO for its reasonable and documented direct out-of-pocket costs and expenses incurred in the provision of, or assistance with, the Manufacturing Technology Transfer, as applicable. No individual expense in excess of [***], or expenses in aggregate of [***], shall be incurred and sought to be reimbursed in connection with a Manufacturing Technology Transfer without Licensee’s prior agreement in writing.
- 4.8.4 In the event that Licensee establishes an Alternative Source, the Parties shall enter into good faith discussions to consider how such Alternative Source can be made available to Fennec. Where the Alternative Source is located outside the Territory, the scope of the license to manufacture under Section 2.1 shall be expanded automatically to permit the manufacture of the Product by the Alternative Source outside the Territory.

- 4.9 Changes to the Products. Any change to any of the constituents of any of the Product, source of constituents, Specifications, or manufacturing of the Product, change control management will be administered in accordance with the change control process set out in the Quality Agreement. If any such changes to the Product are:
- 4.9.1 required by Fennec (including changes made by any of its contract manufacturing organizations), Fennec shall bear the costs and expenses related to such change (including, without limitation, regulatory expenses and costs of wastage of Packaging); or
 - 4.9.2 required by Licensee or Applicable Law in the Territory, Licensee shall bear the costs and expenses related to such change (including, without limitation, regulatory expenses and costs of wastage of Packaging).
5. **GOVERNMENTAL APPROVALS, PHARMACOVIGILANCE, RECALL, LOCAL AGREEMENTS**
- 5.1 Marketing Authorization. Within [***] days after the Effective Date, Fennec shall, and shall cause its Affiliates to, file the necessary documentation to transfer the approved Existing MAs to Licensee's name. Following such transfer, Licensee shall be responsible for all costs incurred from the date of such transfer associated with the creation, filing, maintenance and amendments of all Marketing Authorization files respecting the Territory. Such registrations shall be under Licensee's name, but Licensee shall promptly transfer to Fennec or its designated Affiliate all Marketing Authorizations upon termination or expiry of this Agreement in accordance with Section 13.2. Licensee agrees that any regulatory submission in the Territory with a view to gaining any additional Marketing Authorization(s) shall be agreed by the JSC and thereafter shall be made by Licensee in accordance with the instructions given to the Licensee by Fennec to ensure consistency in any resultant local Marketing Authorization with other marketing authorizations held by Fennec in other countries outside the Territory. In connection with any such Marketing Authorization, Fennec shall, at its own cost, provide to Licensee an English language, US or European CTD format dossier with supporting documents respecting the Product and such other reasonable support as the Licensee may request.
- 5.2 Ownership of Marketing Authorization(s). While Licensee shall be the holder of the Marketing Authorization(s) on behalf of Fennec during the term of this Agreement, Fennec shall be the sole beneficial owner thereof. Fennec shall supply Licensee with all the relevant information and data necessary (i) to obtain and maintain any licenses and permissions necessary to supply, distribute, market and sell the Product in the Territory under one or more Marketing Authorizations, and/or (ii) in the event that Fennec intends to seek approval for one or more additional indications for the Product outside the Territory, to submit variations to the Relevant Regulatory Authority in respect of varying such Marketing Authorizations to include such additional indications, and in each case Licensee shall fully cooperate with Fennec in filing and maintaining such Marketing Authorizations. Licensee shall obtain any necessary approval by the Relevant Regulatory Authority of any educational and/or promotional material relating to the Product. If a Relevant Regulatory Authority requests information or documentation from Licensee that Licensee does not possess or control, Licensee may request such information or documentation from Fennec and Fennec shall promptly (and in any event within [***] Working Days) provide such information or documentation (to the extent in its or its Affiliates' possession or control) to Licensee.

- 5.3 Reimbursement Approval. Licensee shall be responsible for gaining a Reimbursement Approval and Pricing Approval for the Product from any Relevant Regulatory Authorities in those countries within the Territory in which Licensee elects to launch the Product. Licensee shall promptly inform Fennec of any request coming from or to be addressed to the Relevant Regulatory Authority in the Territory regarding pricing and/or reimbursement in respect of the Product, and, to the extent reasonably practicable, shall consult with Fennec prior to sending any response, information or documentation to such authorities.
- 5.4 Compliance. Licensee shall, in respect of each order for the Product, be responsible for: (a) complying with all Applicable Law relating to the import, distribution, sale and supply of the Product in the Territory and shall notify Fennec of any relevant changes in the Applicable Law in the Territory relating to the Packaging or labelling of the Product; and (b) obtaining any necessary import licences, certificates of origin or other requisite documents and paying all applicable customs and duties in respect of the importation of the Product into the Territory and the distribution and sale of the Product in the Territory.
- 5.5 Cooperation. Fennec shall fully cooperate with Licensee by providing reasonable assistance to Licensee in obtaining and maintaining the requisite documentation and governmental approvals mentioned above.
- 5.6 Pharmacovigilance. Licensee shall be responsible for all pharmacovigilance in respect of the Product in the Territory and will cooperate with Fennec as may be necessary with regard to safety matters concerning the Product at all times. Licensee shall immediately notify Fennec of any adverse reaction, side effect, injury, toxicity or sensitivity reaction, whether or not determined to be attributable to the Product. In order to establish the respective roles and responsibilities in managing the pharmacovigilance activities with regard to the Product in accordance with Applicable Law, the Parties shall use Commercially Reasonable Efforts to agree a specific pharmacovigilance agreement or Safety Data Exchange Agreement (SDEA) (hereinafter the “Pharmacovigilance Agreement”) within [***] days of the Effective Date and in any event prior to the marketing of any Product in the Territory. The standard operating procedures set forth therein shall be sufficient to permit each Party to comply with all Applicable Law and with its internal pharmacovigilance practices. Such standard operating procedures will be promptly updated if required by changes in Applicable Law. In the event of any conflict between the terms and conditions of this Agreement and the terms and conditions of the Pharmacovigilance Agreement with respect to the subject matters of the Pharmacovigilance Agreement, the terms and conditions of the Pharmacovigilance Agreement shall govern and control.
- 5.7 Recall. Licensee shall observe at all times the current regulations in the Territory in order to maintain an effective system for the Recall from market of the Product. In the event that any Relevant Regulatory Authority demands a Recall or takes similar action in connection with the Product sold, marketed or distributed by Licensee in the Territory, or Licensee becomes aware of any other facts or circumstances that suggest a Recall or voluntary withdrawal may be warranted, Licensee shall, within twenty-four (24) hours, advise Fennec by telephone or email and the Parties shall, acting reasonably, agree on an appropriate course of action. Fennec shall bear all costs of Recall or withdrawal except to the extent the Recall or withdrawal was caused by an act of negligence or default of Licensee, in which case Licensee shall bear all such expenses. Each Party acknowledges and agrees to reimburse any and all costs or charges in connection with the Recall or withdrawal paid by the other Party on its behalf. In any event of request of Recall of one or more Products, Licensee shall immediately take all appropriate steps as required by Applicable Law to comply with the Recall. In the event that any Relevant Regulatory Authority demands a Recall or takes similar action in connection with the Product sold, marketed or distributed by Fennec outside the Territory, or Fennec becomes aware of any other facts or circumstances that suggest a Recall or voluntary withdrawal may be warranted, Fennec shall, within twenty-four (24) hours, advise Licensee by telephone or email, and shall keep Licensee informed on a regular basis of the progress in planning and implementing any such Recall or withdrawal.

5.8 Local Agreements. Fennec shall, and shall cause its Affiliates to (as applicable), transfer and assign all of their rights, title and interest in and to the agreements disclosed by Fennec to Licensee prior to the Effective Date and listed in **Appendix A** (collectively, the “Local Agreements”), including all of Fennec’s and its Affiliates’ (as applicable) rights and obligations thereunder, in each case from and after the Effective Date and solely to the extent relating to the Territory. Fennec shall, and shall cause its Affiliates to (as applicable) transfer to Licensee all reports, analyses, materials and other documentation created or provided under or in connection with the Local Agreements prior to and including the Effective Date. As and from the Effective Date hereof, Licensee covenants and agrees that it will assume, discharge, perform and fulfil the obligations assigned to it under the Local Agreements to the extent relating to the Territory and to the extent consistent with the rights granted and obligations imposed under this Agreement. For the avoidance of doubt, the foregoing transfer, assignment and assumption applies prospectively only and does not release Fennec or its Affiliates (as applicable) from any responsibility or liability with respect to any of its obligations (including any payment obligations) under the Local Agreements (including for any services performed or deliveries of Product made by Fennec or its Affiliates, as applicable) prior to the Effective Date, all of which will be the responsibility of Fennec.

6. FINANCIAL MATTERS

6.1 Fees and Other Payments

- 6.1.1 Up Front Fee. Licensee shall pay to Fennec on the Effective Date, as one-time, non-refundable, non-creditable fee, the amount set forth in **Appendix B** under the heading *Up Front Fee* in Euros (€) by wire transfer of immediately available funds into an account designated by Fennec.
- 6.1.2 Milestones Payments. Licensee shall also pay to Fennec the milestone payments, in each case after the achievement of the applicable milestone, as set forth in **Appendix B** under the heading *Milestone Payments*. Each milestone payment, once the applicable milestone has been achieved, are one-time only, non-refundable and non-creditable, and shall be paid in Euros (€) by wire transfer of immediately available funds into an account designated by Fennec within [***] days after the end of the Calendar Quarter during which the applicable milestone is achieved (which, for the avoidance of doubt, in respect of any sales milestone shall be the fourth (4th) Calendar Quarter in the applicable calendar year); *provided that*, the achievement of a higher sales milestone event shall trigger the milestone payment for such milestone event as well as for all lower milestone events in the event such lower milestone events had not been previously triggered and paid.

- 6.1.3 Transfer Price. The supply price to be paid by Licensee to Fenec for the Product supplied pursuant to this Agreement shall be as set forth in **Appendix B** (the “Transfer Price”). The Transfer Price for ordered Product shall be paid in Euros (€) by wire transfer to the bank account designated from time to time in writing by Fenec within [***] days from the end of the month in which Licensee receives the relevant invoice from Fenec.
- 6.1.4 Royalties. Licensee shall pay the royalties to Fenec on Net Sales of Product by the Licensee and its Affiliates at the applicable rates set forth in **Appendix B**. Royalties shall be paid in Euros (€) by wire transfer of immediately available funds into an account designated by Fenec within [***] days from the end of the month in which Licensee receives the relevant invoice from Fenec.
- 6.1.5 Royalty Reduction.
- (a) If in any country or other jurisdiction in the Territory during the Initial Term or a Subsequent Term, a Generic Product or a Competing Product is launched in such country or other jurisdiction prior to the third anniversary of the Effective Date, and following such launch the average Net Sales of Product in any subsequent two consecutive Calendar Quarters in that country or other jurisdiction are, in comparison to the average Net Sales of Product in the same two consecutive Calendar Quarters in that country or other jurisdiction, reduced by (i) [***] from the applicable rate(s) set forth in **Appendix B**, and/or (ii) [***] from the applicable rate(s) set forth in **Appendix B**. A worked example is set out in **Appendix B**.
 - (b) If in any country or other jurisdiction in the Territory during the Initial Term or a Subsequent Term, a Generic Product or a Competing Product is launched in such country or other jurisdiction on or after the third anniversary of the Effective Date, and following such launch the Net Sales of Product in a subsequent Calendar Quarter in that country or other jurisdiction are, in comparison to the Net Sales of Product in the previous Calendar Quarter in that country or other jurisdiction, reduced by (i) [***] from the applicable rate(s) set forth in **Appendix B**, and/or (ii) [***] from the applicable rate(s) set forth in **Appendix B**.

- 6.1.6 Sales Taxes. Licensee shall be solely responsible for the collection and payment of all taxes payable in connection with its sale of the Products in the Territory and the performance of its services as contemplated herein.
- 6.2 Reporting. Licensee shall send within [***] days after the end of each Calendar Quarter, a written report detailing Net Sales of the Product in unit and amounts in Euros (€) for such Calendar Quarter, if any (each, a "Quarterly Report"). Licensee shall also keep Fennec reasonably informed of any material developments in market conditions, competitive products, and other factors reasonably likely to affect the distribution and/or sale of the Product in the Territory.
- 6.3 Payment Method; Currency Conversion. All payments under this Agreement shall be made in Euros (€) by wire transfer or other means acceptable to Fennec, as specified by Fennec. Payments due under this Agreement that are calculated based on amounts received by Licensee or its Affiliates in currencies other than Euros (€) will be converted into the Euros (€) equivalent, applying the average daily closing rate of exchange as officially published on www.fxtop.com for the applicable calendar quarter to which the payment relates, in accordance with then current accounting standards of Licensee or its Affiliate, as applicable.
- 6.4 Late Payments. Interest at the rate of [***] above the then-current 3 month ECB Euribor rate, compounded monthly (or such lesser rate then permissible under Applicable Law) shall be payable on any overdue amounts. Such interest shall accrue from the due date of payment until payment is made. The foregoing interest shall be due from Licensee without any special notice and shall be in addition to any other remedies that Fennec may have pursuant to this Agreement.
- 6.5 Withholding Tax. Licensee will make all payments to Fennec under this Agreement without deduction or withholding for taxes ("Withholding Tax") except to the extent that any such deduction or withholding is required by Applicable Law in effect in the relevant country in the Territory at the time of payment. Any Withholding Tax required to be withheld on amounts payable by Licensee under this Agreement will be timely paid by Licensee on behalf of Fennec to the appropriate governmental authority in the relevant country in the Territory, and Licensee will furnish Fennec with the corresponding proof of payment of such Withholding Tax, as may be required in order to enable Fennec to request reimbursement or deduction of the withheld amount, or to otherwise comply with its duties. If Licensee is required to withhold any Withholding Tax on amounts payable by Licensee to Fennec, Licensee will use Commercially Reasonable Efforts to recover such Withholding Tax and if recovered, shall timely remit such amounts to Fennec.

6.6 Reports and Records; Audit by Fennec. Licensee shall keep (and shall cause its Affiliates to keep) accurate books and records of Net Sales of Product in accordance with its then-current internal accounting policies. Licensee shall keep (and shall cause its Affiliates to keep) such books and records for not less than three (3) years following the calendar year to which they pertain. Once per calendar year, Fennec will have the option to engage (at its own expense, except as otherwise provided below) an independent internationally-recognized certified public accountant, appointed by Fennec and reasonably acceptable to Licensee, to examine in confidence (such terms of confidentiality being no less stringent than those set forth in Article 9 (but of shorter duration if customary under the circumstances)) the books and records of Licensee as may be necessary to determine, with respect to any of the preceding three (3) calendar years, the correctness or completeness of any report or payment required to be made under this Agreement; provided however, that the books and records for any particular calendar year will only be subject to one audit. Licensee shall make its books and records available for inspection by the auditor during regular business hours at such place or places where such books and records are customarily kept, upon receipt of reasonable advance notice from Fennec (being not less than one (1) month's advance written notice). The books and records shall be reviewed solely to verify the accuracy of payments made by Licensee. Fennec shall use Commercially Reasonable Efforts to ensure that any such audit is conducted in a manner that minimises disruption and inconvenience to Licensee. The report of such accountant will be limited to a certificate verifying any report made or payment submitted by Licensee during such period or identifying any over-payment or under-payment made by Licensee, accompanied by an explanation of the basis for its determination of such over-payment or under-payment, and shall be provided to Licensee at the same time as it is provided to Fennec and Licensee shall have [***] days to respond to such report with its comments and representations on the report's findings. In addition, if the accountant is unable to verify the correctness of any such payment, the accountant's report may include information relating to why such payment is unverifiable. If the audit reveals any underpayment by Licensee to Fennec, then Licensee will pay any undisputed underpayment to Fennec within [***] days after Licensee's receipt of the audit report and, if such underpayment by Licensee is more than [***] of the reported amount, Licensee shall bear the accountant's reasonable and actually incurred costs of carrying out the audit. If the audit reveals any overpayment by Licensee to Fennec, then Fennec will reimburse any such undisputed overpayment to Licensee within [***] days after Licensee's receipt of the audit report. The result of the audit and the audit report shall be final and subject to the confidentiality obligations under Article 9.

7. PERFORMANCE BY FENNEC

7.1 Supply. Fennec shall supply or have supplied the Product in conformity with the Specifications and Good Manufacturing Practices, together with such documentation as required under the Quality Agreement. Fennec shall not be responsible for any damages or losses suffered by Licensee resulting from the storage, testing, use or sale of the Product by Licensee after delivery. Licensee shall inform Fennec of any claim relating to quantitative deficiencies in any delivery of Product which Licensee considers to have been caused prior to delivery within [***] Working Days following actual receipt of any such delivery. Any claim for a quantitative deficiency which is not made within such period shall be deemed to have been waived by Licensee. In the event Fennec determines there is a quantitative deficiency from the applicable order, the Parties shall investigate such deficiency and, if such deficiency occurred prior to delivery to Licensee, Licensee shall only be obligated to pay for actual quantities delivered; provided, however, that Fennec shall have the option, subject to prior agreement of Licensee, of rectifying any such deficiency that occurred prior to delivery by promptly delivering the appropriate quantities (with no additional shipment costs for Licensee) of Product to Licensee, in which case Licensee shall be obligated to pay for any such quantities pursuant to the terms and conditions of this Agreement. Any such quantitative deficiencies (whether or not subsequently delivered by Fennec) shall be deducted from the applicable Minimum Purchase Quantity required to be purchased by Licensee under Section 4.5. Fennec shall, at all times, maintain, at its own cost, inventory equivalent to a [***] supply of Product based on the Rolling Forecast, at its European releasing site (Almac Pharma Services Limited, Finnabair Industrial Estate, Dundalk, Co. Louth, Ireland A91 P9KD) and shall manage such inventory on a FEFO (first expiry, first out) basis.

- 7.2 Acceptance/Rejection of Product. Licensee shall notify Fennec or its designee of any rejection of Product and of the basis under this Agreement for such rejection, including any testing or inspection results, within [***] Working Days after delivery of such Product to Licensee, or, in the case of Latent Defects, within [***] Working Days after Licensee having first taken notice of the Latent Defect (in each case, a “Rejection Notice”). Failure to notify Fennec or to identify the basis under this Agreement for rejection within such period shall constitute acceptance of such Product. Following delivery of a Rejection Notice, the Parties shall conduct good faith discussions with the aim of resolving any dispute as to whether a Product is defective. If the Parties are unable to reach such a resolution, then samples or batch records, as appropriate, from the batch which is in dispute will promptly be submitted for testing and evaluation to an independent Third Party (including a testing laboratory) as shall be agreed to in writing by both Parties acting reasonably. The determination of such Third Party as to whether such Product meets the Specifications will be final and binding. The cost of the testing and evaluation by the Third Party shall be borne by Fennec if the Third Party determines that the Product in question does not meet the Specifications as a result of a cause occurring prior to delivery and by Licensee if the Third Party determines that the Product in question meets the Specifications or do not meet the Specifications as a result of a cause occurring after delivery. If any sampled Product is found by the Third Party or is agreed by Fennec not to conform to the Specifications as a result of a cause occurring prior to delivery, Licensee shall not be required to pay for such Product, and Fennec shall as soon as possible, if so requested by Licensee, replace such defective Product at no additional cost to Licensee and have such defective Product destroyed, at Fennec’s expense, in accordance with Applicable Law in the jurisdiction in which destruction occurs. Any such defective Product (whether or not subsequently re-delivered by Fennec) shall be deducted from the applicable Minimum Purchase Quantity required to be purchased by Licensee under Section 4.5.
- 7.3 Quality Agreement. Either Fennec, Licensee (if required) and the manufacturer/s of the Product will have separately signed quality agreements setting forth the respective duties and obligations relating to the manufacturing and supply of the Product (“CMO Quality Agreement(s)”) or, if Licensee is not party to the CMO Quality Agreements, Fennec shall supply a copy of the CMO Quality Agreement(s) to Licensee as soon as reasonably possible following the Effective Date or its/their execution, as applicable, and Fennec and Licensee shall enter into a quality agreement setting forth their respective duties and obligations relating to the manufacturing, supply and distribution of the Product under this Agreement (the “Quality Agreement”), such Quality Agreement to be in place before any commercial launch of the Product in the Territory. In the event of any conflict between the terms and conditions of this Agreement and the terms and conditions of the Quality Agreement with respect to the subject matters of the Quality Agreement, the terms and conditions of the Quality Agreement shall govern and control.
- 7.4 Brand Strategy and Materials. Fennec shall share with Licensee, on an ad-hoc basis upon Licensee’s reasonable request, global brand strategy and materials as are relevant to the marketing and sale of the Product in the Territory. Notwithstanding the foregoing, Licensee shall have sole responsibility for the Product marketing materials used in the Territory and may adapt, develop and produce its own marketing materials in accordance with Applicable Law in the Territory and internal marketing policies of Licensee (and shall own all copyright therein), provided that Licensee shall indicate in all marketing materials that Licensee is acting on its own account as licensee of Fennec, by including the following statement: “Product under license from Fennec Pharmaceuticals Inc. PEDMARQSI is a registered trade mark of the Fennec group of companies, licensed to the Norgine group of companies”. If necessary, Licensee may translate such materials into other languages at Licensee’s expense, provided that Licensee shall be solely responsible for ensuring that all such translations are accurate.

7.5 Compliance.

In addition to the definitions set out in Section 1, the following definitions shall apply:

“Anti-Corruption Laws” means all laws, regulations or orders relating to bribery or corruption, including, without limitation, (i) the U.S. Foreign Corrupt Practices Act 1977 (as amended), (ii) the UK Bribery Act 2010, and (iii) any national and international laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

“Anti-Facilitation of Tax Evasion Laws” means all applicable laws, regulations or orders designed or intended to prohibit, prevent, or restrict the facilitation of tax evasion, including, without limitation, the UK Criminal Finances Act 2017.

“Anti-Money Laundering Laws” means all applicable laws, regulations or orders relating to money laundering, terrorist financing or the proceeds of criminal activity, including, without limitation, (i) the European Union Anti-Money Laundering Directives and any related legislation implemented by member states of the European Union, (ii) the UK Proceeds of Crime Act 2002, and (iii) the U.S Bank Secrecy Act and USA PATRIOT Act.

“Anti-Trust Laws” means all applicable laws governing the conduct of any person in relation to restrictive or other anti-competitive agreements or practices (including cartels, pricing, resale pricing, market sharing, bid rigging, terms of trading, purchase or supply and joint ventures), abuse of dominant or monopoly market positions (whether held individually or collectively) and the control of acquisitions or mergers.

“Compliance Laws” means Anti-Corruption Laws, Anti-Facilitation of Tax Evasion Laws, Anti-Money Laundering Laws, Anti-Trust Laws, Data Protection Laws, Economic Sanctions Laws, Export Control Laws and Modern Slavery and Human Trafficking Laws.

“Data Protection Laws” means (i) Regulation (EU) 2016/679; EU Directives 2002/58/E and 2009/136/EC (each as implemented into the national law of EU Member States); (ii) Regulation (EU) 2016/679, as its forms part of the laws of England and Wales, Scotland and Northern Ireland by virtue of the Data Protection Act 2018, as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019; or (iii) other equivalent laws and regulations in other jurisdictions, each as amended, consolidated or repeated from time to time.

“Economic Sanctions Laws” means applicable economic or financial sanctions, restrictive measures, trade embargoes or Export Control Laws imposed, administered or enforced from time to time by any sanctions authority.

“Export Control Law” means all applicable laws, regulations or orders relating to the export or re-export of goods, technology, software, technical data, or services, including those administered by (i) the U.S. Department of Commerce, including the Export Administration Regulations, (ii) the U.S. Department of the Treasury, (iii) the U.S. Department of State; (iv) the Export Control Joint Unit of the United Kingdom; and (v) the European Union or any member state thereof.

“Modern Slavery and Human Trafficking Law” means all applicable anti-slavery or human trafficking laws, statutes, regulations and codes from time to time in force, including laws, statutes and regulations relating to immigration, recruitment, forced labour, child labour, working hours, minimum pay and work place including, without limitation, the UK Modern Slavery Act 2015.

7.5.1 General. Fenec shall, and shall procure that its Affiliates shall:

- (a) perform its obligations under this Agreement in accordance with Applicable Laws and comply at all times with all Compliance Laws and any codes of conduct of any applicable regulatory authority or trade association, and professional industry standards;
- (b) not do, or omit to do, any act that may cause or lead Licensee or any of its Affiliates to be in breach of any Compliance Laws or other requirements set out in this Section 7.5;
- (c) maintain and enforce adequate policies designed to ensure compliance by Fenec and its Affiliates with all Compliance Laws and other requirements set out in this Section 7.5;
- (d) promptly notify Licensee if it becomes aware of, or the subject of, an investigation, inquiry, enforcement proceeding or prosecution which relates to, any actual or alleged breach of any Compliance Laws or other requirements set out in this Section 7.5, giving full details (to the maximum extent possible) of the breach and any action taken or proposed to be taken by Fenec and/or any of its Affiliates as a result;
- (e) promptly co-operate with Licensee and/or any regulator and/or prosecutor in any investigation relating to any actual or alleged breach of any Compliance Laws or other requirements set out in this Section 7.5 by Fenec or any of its Affiliates; and
- (f) at least once a year, certify to Licensee in writing, by executing a compliance certificate as provided and/or amended by Licensee from time to time, its compliance and the compliance of its Affiliates with all applicable Compliance Laws. Fenec shall provide such compliance certificate together with such supporting evidence of compliance as Licensee may reasonably request.

7.5.2 Anti-Bribery and Corruption. Fenec and its Affiliates have not and will not make, directly or indirectly, in connection with this Agreement and/or in connection with any other business transaction related to the Norgine Group, a payment or gift of, or an offer, promise, or authorisation to give money or anything of value to any government official or other person or entity while knowing or having reason to believe that some portion or all of the payment or thing of value will be offered, given, or promised, directly or indirectly, to a government official or another person or entity for the purpose of:

- (a) influencing any act or decision of such government official or such person or entity in their official capacity, including a decision to do or omit to do any act in violation of their lawful duties or proper performance of functions; or
- (b) inducing such government official or such person or entity to use their influence or position with any government entity or other person or entity to influence any act or decision; or
- (c) in order to obtain or retain business for, direct business to, or secure an improper advantage for the Norgine Group.

7.5.3 Representations and Warranties. Fenec represents and warrants that:

- (a) it and its Affiliates are familiar with and understand the requirements and prohibitions of applicable Compliance Laws, and have had and will continue to have appropriate training regarding Compliance Laws;
- (b) it and its Affiliates are not conducting any business directly or indirectly in any territory in breach of Compliance Laws (including the Economic Sanctions Laws restricting trade in Russia, Belarus, Cuba, Iran, Syria, North Korea, Crimea of Ukraine, Donetsk Peoples Republic, Luhansk Peoples Republic);
- (c) neither it nor any of its Affiliates has at any time prior to the date of this Agreement committed a breach, is in breach of, or is subject to any investigation, inquiry, enforcement proceeding or prosecution which relates to an actual or alleged breach of applicable Compliance Laws;
- (d) it has conducted and will continue to conduct appropriate due diligence on its consultants, subcontractors, service providers and any other of its own counterparties to ensure their compliance with all Compliance Laws; and
- (e) in connection with this Agreement, no improper financial or other advantage has been, will be or is agreed to be given to any person (whether working for or engaged by any member of the Norgine Group or any Third Party) by or on behalf of Fenec or any of its Affiliates.

7.5.4 Record Keeping and Audit. Fennec shall keep (at its normal place of business) detailed, accurate and up-to-date records and books of account showing in reasonable detail all expenditures incurred and payments made or received in relation to this Agreement and the steps taken by Fennec to comply with Compliance Laws and other requirements set out in this Section 7.5. Fennec shall ensure that such records and books of account are sufficient to enable Licensee to verify Fennec's and its Affiliates' compliance with this Section 7.5. Fennec shall within [***] Working Days of receipt of written request from Licensee permit Licensee and its Third Party representatives (subject to customary confidentiality undertakings), on reasonable notice during normal business hours, but without notice in case of any reasonably suspected breach of this Section 7.5, to access and take copies of Fennec's records and meet relevant Fennec's personnel, in order to audit Fennec's and its Affiliates' compliance with their obligations under this Section 7.5. Licensee shall use Commercially Reasonable Efforts to ensure that any such audit is conducted in a manner that minimises disruption and inconvenience to Fennec. Fennec shall give all reasonable assistance to Licensee and its representatives in relation to the conduct of such audit. Each Party shall bear its own costs and expenses related to any such audit unless Fennec is in material breach of any of its obligations under this Agreement, in which case Fennec shall pay to Licensee the reasonable costs and expenses of such audit. Such audit rights shall continue for one (1) year after termination of this Agreement.

7.5.5 Data Protection. At the time of signing this Agreement, the Parties agree that no personal or sensitive personal data (including but not limited to data concerning health, meaning personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about the data subject's health status) will be processed in connection with the Agreement. If, after the signing of this Agreement, either Party anticipates that personal or sensitive personal data will be processed, the Parties will enter into a data processing agreement or "Standard Contractual Clauses" (SCCs) as appropriate under applicable Data Protection Laws, using Licensee's template.

8. PERFORMANCE BY LICENSEE

8.1 Performance. Following transfer of the Marketing Authorization to Licensee, Licensee shall itself, or through its Affiliates, sublicensees or other Third Parties (in each case as permitted under this Agreement), use Commercially Reasonable Efforts to commercialize the Product in the Territory in accordance with the Performance Plan. Licensee agrees to manage at Licensee's expense the registration, distribution and/or sale of the Product throughout the Territory in accordance with the Performance Plan. Such Performance Plan shall be updated from time to time by Licensee. Licensee shall provide a copy of the initial Performance Plan to Fennec within [***] days of the Effective Date, and thereafter a copy of the Performance Plan for each calendar year by no later than September 30th of the prior year.

8.2 Product Packaging. Licensee shall provide Fennec with necessary Product Packaging information (including local artwork, codes for serialization and barcoding of the Product so that Fennec can provide Licensee finished Product in local packaging) to ensure the Packaging of the Product is in compliance with all Applicable Law in the Territory and rules and regulations of all Relevant Regulatory Authorities in the Territory.

- 8.3 Handling of Product. Licensee undertakes that the Product shall be handled and stored in accordance with the Applicable Laws, GDP, and any relevant information provided by Fenec. Licensee shall permit a qualified technical specialist from Fenec with reasonable prior notice, during normal business hours, to visit and observe the facilities for the storage and handling of Product in accordance the Specifications and Fenec's written instructions.
- 8.4 No Changes. Other than to comply with Applicable Law, Licensee undertakes not to make or cause any changes to the Specifications, therapeutic indications, Packaging, labelling, package insert or shipping container or sizes of the Product that is delivered to Licensee or its Affiliates without previously acquiring Fenec's written consent, such consent not to be unreasonably withheld, delayed or conditioned.
- 8.5 Compliance. Licensee shall distribute, market and/or sell the Product in the Territory under the Marketing Authorizations and fulfil its obligation hereunder in accordance with: (i) all Applicable Law in the Territory; (ii) Fenec's Code of Business Ethics as provided in writing to Licensee, including the anti-bribery and corruption policies therein (and Licensee shall complete and return all necessary diligence questionnaires as provided by Fenec in connection therewith).
- 8.6 Non-Conflict. During the term of this Agreement, Licensee will not (directly or indirectly through any Affiliate) commercialize a Competing Product in the Field.

9. CONFIDENTIAL INFORMATION

- 9.1 Confidentiality. Subject to the other provisions of this Article 9, all Confidential Information disclosed by a Disclosing Party under this Agreement will be maintained in confidence and otherwise safeguarded by the Recipient Party. The Recipient Party may only use the Confidential Information for the purposes of this Agreement and pursuant to the rights granted to the Recipient Party under this Agreement. Subject to the other provisions of this Article 9, each Party and its Affiliates shall hold as confidential such Confidential Information of the other Party or its Affiliates in the same manner and with the same protection as such Recipient Party maintains its own confidential information but in no event with less than a reasonable degree of care.
- 9.2 Exceptions. The obligations under this Article 9 shall not apply to any information to the extent that such information:
- 9.2.1 is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Recipient Party;
 - 9.2.2 was known to, or was otherwise in the possession of, the Recipient Party prior to the time of disclosure by the Disclosing Party, as demonstrated by competent evidence;

- 9.2.3 is disclosed to the Recipient Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party; or
- 9.2.4 is independently developed by or on behalf of the Recipient Party, as evidenced by its written records, without reference to the Confidential Information disclosed by the Disclosing Party under this Agreement.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Recipient Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Recipient Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Recipient Party unless the combination and its principles are in the public domain or in the possession of the Recipient Party.

9.3 Authorized Disclosures.

- 9.3.1 In addition to disclosures permitted under Section 9.2, Licensee may disclose Confidential Information belonging to Fennec or its Affiliates to the extent such disclosure is necessary in the following instances: (i) filing or prosecuting and maintaining patents (including the Product Patents) as permitted by this Agreement; (ii) in connection with regulatory filings for the Product; (iii) prosecuting or defending litigation as permitted by this Agreement; (iv) complying with applicable court orders or governmental regulations; or (v) to the extent otherwise necessary or appropriate in connection with exercising the license and other rights granted to it hereunder.
- 9.3.2 In addition, Licensee and its Affiliates and their respective sublicensees may disclose Confidential Information of Fennec or its Affiliates to Third Parties as may be reasonably necessary or useful in connection with the commercialization of the Product as contemplated by this Agreement, including in connection with subcontracting transactions.
- 9.3.3 In addition, a Recipient Party may disclose Confidential Information of the Disclosing Party (including the existence of this Agreement) to its (i) employees, agents, contractors, consultants, and advisers, (ii) *bona fide* prospective or actual underwriters, lenders or acquirers, and (iii) its Affiliates and sublicensee, in each case provided that such persons are bound to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.
- 9.3.4 In the event the Recipient Party is required to disclose Confidential Information of the Disclosing Party (including this Agreement or any provision of it) by law or pursuant to the rules of any recognized stock exchange (including, without limitation or in connection with *bona fide* legal process, such disclosure shall not be a breach of this Agreement; provided, that the Recipient Party: (i) informs the Disclosing Party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; (iii) at the Disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure; and (iv) consults with the Disclosing Party on the provisions of this Agreement, together with the Schedules or other attachments attached hereto, to be redacted in any filings made by Fennec or Licensee with the Securities and Exchange Commission or any other regulatory body or as otherwise required by Applicable Law.

9.4 Press Release. Subject to applicable law, neither Party may issue a press release or announcement in respect of this Agreement or the transactions contemplated by it without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed). The Parties acknowledge that it is the intention of each Party to issue a press release following the execution of this Agreement. Following the publication of such press release (whether by one Party or jointly), subject to applicable law, neither Party will issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned, or delayed), except that a Party may, once a press release or public announcement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or public announcement without the further approval of the other Party.

10. USE OF NAME & TRADEMARK; INTELLECTUAL PROPERTY

10.1 Ownership, License and Use of Trademark.

10.1.1 Licensee acknowledges that the Trademark is and shall be exclusively owned or Controlled by Fenec.

10.1.2 Fenec shall be responsible for, and shall diligently carry out and shall bear all costs (including attorneys' fees) for the preparation, filing, prosecution, maintenance, defence and extensions, if any, of the Trademark relating to the Product in the Territory throughout the term of this Agreement. Fenec shall, as soon as reasonably practicable following the Effective Date, register the Trademark in each country in the Territory. In the event that Licensee is unable to use the trademark PEDMARQSITM as a result of Applicable Law or any other regulatory reason, Fenec shall, as soon as reasonably practicable, provide a back-up trademark to Licensee for use in connection with the Product in the applicable countries in the Territory.

10.1.3 Fenec hereby grants to Licensee an exclusive (even as to and against Fenec) license to use (and to authorize others to use in accordance with this Agreement) the Trademark in the Territory for the term of this Agreement in connection with the import, export, promotion, distribution, manufacture (as required under Section 2.6 or in accordance with Section 4.8), marketing, advertising, offering for sale, selling the Product, or having the Product sold by or on behalf of the Licensee in any country in the Territory. Licensee may record the license granted to it under this Section at applicable trademark registries in the Territory.

- 10.1.4 Licensee will not use Fennec's name, the Trademark as part of Licensee's firm, corporate or business name, and shall not use the name of Fennec or the Trademark in any way except in relation to the Product purchased from, and marketed, distributed and sold under license from, Fennec or otherwise in accordance with this Agreement.
- 10.1.5 Licensee agrees to provide reasonable assistance to Fennec at Fennec's written request to defend and enforce Fennec's rights to the Trademark and its other intellectual property in respect of the Product in the Territory at Fennec's guidance and expense. Without limiting the foregoing, Licensee shall exercise reasonable vigilance to detect and shall report to Fennec any instances coming to Licensee's attention of infringement by any Third Party of the Trademark. Fennec shall use Commercially Reasonable Efforts to defend, pursue and remedy any such infringement. If Fennec decides not to defend, pursue and remedy any such infringement, or ceases to diligently pursue such action, Licensee will have the right, but not the obligation, using counsel of its choosing at its sole cost and expense, to institute such action against the applicable Third Party(ies).
- 10.2 Standards. Fennec shall notify Licensee in writing of the standards of quality and specifications that must be adopted by Licensee in the handling of the Product and Licensee undertakes to comply strictly with such standards and specifications subject to Applicable Laws in the Territory. Fennec shall give Licensee written notice of any modifications or changes to the standards of quality or Specifications and Licensee must use its best efforts to implement any such modification or change as soon as reasonably practicable, subject to Applicable Law in the Territory.
- 10.3 Similar/Confusing Marks. Licensee shall not use in its business in the Territory (or apply or obtain registration for) any trademark or corporate name or trading name identical with or confusingly similar to the Trademark. Licensee shall not do or omit to do anything that would diminish or impair the rights of Fennec or of the Product's licensor in respect of the Trademark.
- 10.4 Other Intellectual Property Matters.

Prosecution and Maintenance of Patents in the Territory. Fennec shall own or Control (as applicable), be responsible for, and shall bear all costs (including attorneys' fees) for the preparation, filing, prosecution, maintenance, defence and extensions, if any, of all patents or patent applications relating to the Product, or administration or use of the Product, in the Territory during the term of this Agreement (collectively, the "Product Patents"). The Product Patents existing as at the Effective Date are set out in

- 10.4.1 **APPENDIX C.** Fennec shall consult with Licensee on all key decisions relating to the Product Patents in the Territory, including decisions relating to country validations, divisional filings, UPC strategy, defence, and shall give Licensee the opportunity to review and comment on any substantive communications relating to the Product Patents at patent offices in the Territory. Fennec shall consider in good faith Licensee's input and comments. Fennec shall provide to Licensee a written update on the status of the Product Patents in the Territory at least once per calendar year.

- 10.4.2 Enforcement. If either Fennec or Licensee has knowledge of any infringement or likely infringement of the Product Patents in the Territory, then the Party having such knowledge shall promptly inform the other Party in writing, and the Parties shall promptly consult with one another regarding the action to be taken. Unless the Parties otherwise mutually agree in writing, Fennec shall be responsible for and have the initial right, using counsel of its choice, to enforce such Product Patents or defend any declaratory action with respect thereto, at its sole expense, and Licensee shall give all reasonable assistance to Fennec in such action at Fennec's expense. If Fennec exercises such right, then Fennec shall control the strategy of such action and, provided that Fennec either receives Licensee's prior written consent or is required by Applicable Law, Fennec may use Licensee's name in connection with such action. If Fennec declines to commence such action, then Licensee shall have the right, but not the obligation, to commence such declined action with respect to such infringement within the Field in the Territory; provided that, prior to Licensee's commencement of any such declined action, Licensee shall reasonably consider Fennec's reasons for declining to commence the action. In the event that Licensee elects, in its sole discretion and at Licensee's sole expense, to commence such declined action, (i) Licensee shall reasonably consider Fennec's reasonable input with respect to such declined action; (ii) Fennec shall give all reasonable assistance to Licensee in such action; and (iii) Licensee may use Fennec's name in connection with such action. Licensee shall keep Fennec reasonably apprised of the progress of any such action commenced by Licensee.
- 10.4.3 Infringement of Third Party Patents. If Licensee, or any of its Affiliates, is sued by a Third Party for infringement of a Third Party's patent rights in the Territory because of the manufacture, use or sale of the Product in the Territory, Licensee shall promptly notify Fennec in writing of such suit, and the Parties shall consult each other to agree upon the course of action to be taken. Unless otherwise agreed in writing by the Parties, Fennec shall have the obligation to defend such suit in the Territory with counsel of its choice, solely at its own expense (including any amounts payable to any Third Party as a result of, or in connection with, any such action or suit, including without limitation damages, costs, license fees, royalty or other payments). Licensee shall have the right to be represented by advisory counsel of its own selection at its own expense, and Licensee shall reasonably cooperate in the defence of such suit and furnish to Fennec all pertinent evidence and reasonable assistance in Licensee's control.
- 10.4.4 Recoveries; Settlement. In the event that either Party recovers any amounts from any litigation or settlement under Section 10.4.2 or Section 10.4.3 or Section 10.1.5, such amounts shall first be applied to reimburse Fennec and Licensee for their respective actual out-of-pocket expenses, or equitable proportions thereof. Any remaining amount (i) attributable to loss of Net Sales of Product in the Territory, shall be retained by or paid to Licensee, and (ii) not attributable to loss of Net Sales of Product in the Territory, shall be retained by or paid to Fennec; provided, however, that any such remaining amount retained by or paid to Licensee under sub-clause (i) shall be deemed to be Product Net Sales hereunder and the payment to Fennec based on such Net Sales will be paid by Licensee. The Parties shall keep one another informed of their respective activities concerning, and the status of, any litigation or settlement thereof concerning a Product Patent or the Product; provided, however, that no settlement or consent judgment or other voluntary final disposition of any suit defended or action brought by a Party pursuant to this Section 10.4 may be entered into without the written consent of the other Party if such settlement would require the other Party to be subject to an injunction or to make a monetary payment or would otherwise adversely affect the other Party's rights under this Agreement.

10.4.5 Domain Names. Licensee shall be permitted to register and be the owner of domain names corresponding to or containing the Trademark.

11. JOINT STEERING COMMITTEE

11.1 Joint Steering Committee. Fenec and Licensee shall establish a joint steering committee (the “Joint Steering Committee” or “JSC”) to facilitate communication and discussion between the Parties regarding Licensee’s commercialization activities with respect to the Product in the Territory, and Fenec’s development and commercialization activities with respect to the Product outside the Territory. The Joint Steering Committee shall facilitate the assistance to be provided by Fenec to Licensee in order to achieve the mutually desired objective of speed, efficiency and coordination regarding Licensee’s activities hereunder. The Joint Steering Committee’s responsibilities shall include review and discussion and, if applicable, approval of, without limitation:

- 11.1.1 the Performance Plan and Licensee’s progress with respect to the Performance Plan’s activities and objectives, and the results and other outcomes of the development and commercialisation of the Product under the Performance Plan;
- 11.1.2 Licensee’s forecasts and anticipated forecasting in respect of the Product in the Territory;
- 11.1.3 any strategic or operational issues identified by Licensee in connection with the Product in the Territory in the Field by or on behalf of Licensee;
- 11.1.4 Fenec’s general progress, results and other outcomes of development of Product in the Field outside the Territory (including its strategy, market insights, and review of any additional clinical data generated in respect of the Product, such data to be shared in advance of the relevant JSC meeting);
- 11.1.5 any strategic or operational issues identified by Fenec in connection with manufacturing and supply of the Product or with Product development in the Field outside the Territory by or on behalf of Fenec. Each Party will cooperate in good faith with the other Party; and
- 11.1.6 more generally, any information, including of a financial nature, which may detrimentally impact the performance by either Party of its obligations under the Agreement.

Each Party shall respect and reasonably consider the other Party's view, opinion, advice, recommendation and suggestion. The JSC meetings will serve as a meeting of the Parties for information exchange purposes, as set forth herein. The Joint Steering Committee shall be co-chaired by a representative of each of Fennec and Licensee. The Parties will endeavor in good faith and in compliance with this Agreement to reach unanimous agreement with respect to all matters within the JSC's responsibility. Each Party's representatives on the JSC will collectively have one (1) vote on all matters before the JSC. Should the JSC not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, (a) the lead representative of Licensee shall have final decision-making authority on all matters relating to the Performance Plan, the commercialization of the Product in the Territory and Licensee's forecasts and anticipated forecasts, and (b) Fennec's lead representative shall have final decision-making authority on all matters relating to Fennec's intellectual property as contemplated by Section 10 of this Agreement.

- 11.2 Membership. The JSC shall be comprised of up to four (4) members, with up to two (2) members appointed by Fennec and up to two (2) members appointed by Licensee. Each Party shall at all times have an equal number of representatives on the JSC, and each Party shall appoint only senior personnel as its representatives on the JSC. Each Party may replace one or more of its JSC representatives at any time, with prior written notice to the other Party. With the consent of the JSC members, other representatives of Fennec or Licensee may attend JSC meetings as observers.
- 11.3 JSC Meetings. In the first year following the Effective Date, the JSC will meet monthly, and thereafter during the term of this Agreement, the JSC will meet at least quarterly. In each year, two JSC meetings (unless otherwise agreed by the Parties, one in March and one in October) shall where reasonably practicable be in person at places as agreed to by the Parties, and the remaining meetings in such year shall be held via tele-conference or video-conference. Each Party shall bear its own personnel and travel costs and expenses relating to JSC meetings. The co-chairs of the JSC shall chair JSC meetings and be responsible for preparing the meeting agendas and minutes on an alternating basis. At such meetings, Licensee and Fennec shall discuss and/or keep informed the Parties about the Product business aspects, including, but not limited to, supply chain, regulatory, commercial, medical, marketing and forecasting. At the in-person October meeting, Licensee and Fennec shall: (i) analyse and review, with respect to the Product, the market, performance and planning for the following twelve (12) months from a supply chain and commercial activity perspective, and (ii) review and discuss the subsequent year's Performance Plan. Meeting minutes including follow-up actions shall be prepared promptly following each JSC meeting and in any event within [***] Working Days.
- 11.4 Special JSC Meetings. If sales of the Product throughout the Territory in any calendar quarter fall below [***] of the levels stated in the then-current Performance Plan or in case of manufacturing or supply issues or delays in Product delivery by Fennec, Fennec or Licensee may call a special JSC meeting, at which the Parties shall discuss a corrective action plan addressing the issue. The Parties shall negotiate in good faith to agree the corrective action plan. Licensee or Fennec, depending on the issue, shall use Commercially Reasonable Efforts to comply with the agreed corrective action plan, and shall keep the other Party informed on its progress at subsequent JSC meetings until the Parties agree (acting reasonably) that the requirements of the corrective action plan have been met.

- 11.5 No Committee Amendments; Authority. Notwithstanding the creation of the JSC, each Party to this Agreement shall retain the rights, powers, and discretion granted to it hereunder, and the JSC shall not be delegated or vested with any such rights, powers, or discretion unless such delegation or vesting is expressly provided for herein or the Parties expressly so agree in writing. The JSC shall have no power to amend or modify this Agreement, which may be amended or modified only as provided in Section 19.4 of this Agreement, or take any decision in relation to the development or commercialization activities of either Party.
- 11.6 Subcommittees. From time to time, the JSC may establish and delegate duties to subcommittees (each, a “**Subcommittee**”) on an “as needed” basis to oversee particular projects or activities (e.g., development and/or manufacturing). Each Subcommittee will consist of a mutually agreed number of representatives from each Party, and will meet from time to time upon mutual agreement between representatives from each Party. The decision-making within a Subcommittee will be by consensus, with each Party’s representatives on the applicable Subcommittee collectively having one (1) vote on all matters brought before the Subcommittee. Each Subcommittee and its activities will be subject to the direction, review and approval of, and will report to, the JSC. In no event will the authority of the Subcommittee exceed that specified for the JSC in this Section 11. Any matter not resolved by a Subcommittee will be referred to the JSC for resolution. Unless otherwise mutually agreed by the Parties, each Subcommittee will disband upon completion of all the obligations designated by the JSC to such Subcommittee.
- 12. TERM AND TERMINATION**
- 12.1 Initial Term and Subsequent Terms. This Agreement shall be effective as of the Effective Date and continue on a country-by-country basis until the date that is the later of the tenth (10th) anniversary of the Effective Date or expiry of the regulatory market exclusivity for the Product or the last-to-expire Product Patent in such country (hereinafter the “Initial Term”), unless sooner terminated as provided herein. After such Initial Term, the Agreement shall be automatically renewed for additional three (3) year periods (each a “Subsequent Term”), unless either Party gives written notice to the other of termination at least one (1) year prior to the expiry of the Initial Term or Subsequent Term, as applicable, upon which this Agreement shall terminate and expire at the expiry of the Initial Term or then current Subsequent Term, as applicable.
- 12.2 Termination for Breach. Upon the occurrence of a material breach of this Agreement, the Party aggrieved by such breach is entitled to give to the other Party written notice thereof. If within [***] days from the defaulting Party’s receipt of such written notice, the defaulting Party has failed or refused to remedy such material breach, the aggrieved Party shall have the right to terminate this Agreement forthwith by giving written notice to the breaching Party to such effect; provided, however, that if such breach is capable of being cured but cannot be cured within such [***] day period and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable in the circumstances to cure such breach.

12.3 Insolvency/Bankruptcy. In the event that a Party be adjudicated insolvent, or file a petition in bankruptcy or for reorganisation, or if a Party should take advantage of an insolvency act, or effect an assignment for the benefit of creditors (other than for purposes of consolidation or voluntary restructuring), or any step, application, order, proceeding or appointment is taken or made by or in respect of a Party for a distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, or if that Party is unable to pay its debts or if any event occurs which, under the applicable law of any jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Section 12.3 then, the other Party may terminate this Agreement forthwith, and subject to Applicable Laws the rights herein granted shall not constitute an asset in reorganisation, bankruptcy or insolvency which may be assigned, or which may accrue, to any court or creditor-appointed referee, receiver or committee. In any event when a Party first becomes aware of the likely occurrence of any such insolvency event in regard to that Party, it shall, to the extent reasonably practicable, promptly notify the other Party in writing in sufficient time to give the other Party sufficient notice to protect its interests under this Agreement.

12.4 Rights in Bankruptcy.

12.4.1 The Parties agree that this Agreement constitutes an executory contract under Section 365 of the Code for the license of “intellectual property” as defined under Section 101 of the United States Bankruptcy Code, 11 U.S.C. (the “Code”) and constitutes a license of “intellectual property” for purposes of any similar Applicable Laws in any other country in the Territory. The Parties further agree that Licensee, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including Section 365(n) of the Code, and any similar Applicable Laws in any other country in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Fennec under the Code and any similar Applicable Laws in any other country in the Territory, Licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless and until the rejection of this Agreement by or on behalf of Fennec as provided in the Code, or (ii) if not delivered under clause (i) above, upon written request therefor by Licensee following (A) the rejection of this Agreement by or on behalf of Fennec upon written request therefor by Licensee, and (B) the timely election by Licensee to retain its rights pursuant to Section 365(n)(1)(B) of the Code.

12.4.2 All rights, powers and remedies of Licensee provided for in this Section 12.4 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including under the Code and any similar Applicable Laws in any other country in the Territory). In the event of an insolvency event described in Section 12.3 in relation to Fennec, Licensee, in addition to the rights, power and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including under the Code). The Parties agree that they intend the following Licensee rights to extend to the maximum extent permitted by Applicable Law, including for purposes of the Code: (i) the right of access to any and all intellectual property (including all embodiments thereof) and regardless if it is included in the definition of “intellectual property” as defined by the Code, of Fennec, or any Third Party with whom Fennec contracts to perform an obligation of Fennec under this Agreement which is necessary or reasonably useful for the import, export, promotion, distribution, manufacture, marketing, advertisement, offering for sale and/or sale of the Product in the Territory; (ii) the right to contract directly with any Third Party described in clause (i) to complete the contracted work, (iii) the right to cure any breach of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to Fennec under this Agreement, and/or (iv) the right to step-in to pay Fennec’s renewal fees and take all other steps as required to maintain the Product Patents the Trademark and the Marketing Authorizations in the Territory.

13. EFFECT OF TERMINATION

- 13.1 Accrued Rights. The termination of this Agreement for whatever reason shall not affect the respective rights and liabilities of Fennec and Licensee which have accrued prior to such termination.
- 13.2 Termination by Licensee for Cause or Force Majeure. Upon termination of this Agreement by Licensee pursuant to Sections 12.2, 12.3 or 19.2:
- 13.2.1 all licenses and rights granted by each Party under this Agreement shall terminate (subject to Section 13.4) and Sections 13.3.1 to 13.3.3 shall apply; unless
- 13.2.2 Licensee elects in the relevant termination notice to continue the licenses and rights granted hereunder, in which case:
- (a) the licenses and other rights granted by Fennec to Licensee under this Agreement, and any sublicenses granted by Licensee (including through multiple tiers), shall remain in effect in accordance with their respective terms;
 - (b) Licensee's obligations under Section 8.1 shall cease and have no further effect;
 - (c) the JSC shall disband; and
 - (d) Licensee shall continue to pay Fennec in accordance with Article 6; provided that the amount of any not-yet-paid milestone payments and royalty payments payable by Licensee shall be reduced by [***] with effect from the date on which Licensee serves the applicable termination notice.

13.3 Termination by Fenec for Cause or No Election to Continue by Licensee or Force Majeure. Upon termination of this Agreement by Fenec pursuant to Section 12.2, 12.3 or 19.2, the expiration of this Agreement, or if this Agreement terminates pursuant to Section 13.2.1, then the following shall apply:

13.3.1 Approvals and Authorizations; Trademarks. Following termination or expiration of this Agreement, Licensee shall return to Fenec (or to the company or person designated by Fenec) any regulatory filings, approvals and authorizations received for the Product, the complete documentation and any other informative material relating to scientific, technical and/or marketing data regarding the Product which it has received or generated during the period of validity of this Agreement, without exception, and without retaining any copies of such documentation and material as soon as reasonably practicable in accordance with Applicable Laws. Furthermore, following termination or expiration of this Agreement, subject to Section 13.3.3, (i) Licensee shall remove and cease to use the Trademark and any signs containing Fenec's name and assign to Fenec any domain names in respect of which Licensee is the registrant and which exclusively relate to the Product, and (ii) Fenec shall remove and cease to use Licensee's name and logo and have no further rights pursuant to Section 2.7.1. In case any authorizations or other approvals received for the Product cannot be returned to Fenec or its designee, Licensee shall promptly apply for their cancellation, upon Fenec's written request. The reasonable fees and disbursements payable to Third Parties that are actually incurred in connection with the assignments or cancellations, as applicable, contemplated by this Section 13.2 (collectively, "Transfer Costs") shall be paid at first instance by Licensee and shall be reimbursable by Fenec as follows, as applicable:

- (a) if this Agreement expires at the end of the Initial Term or any Subsequent Term in accordance with Section 12.1, then Fenec shall reimburse Licensee an amount equal to one-half of such Transfer Costs;
- (b) if this Agreement is terminated by Fenec in accordance with Section 12.2 or 12.3 of this Agreement, Licensee shall be solely and entirely responsible for and pay all Transfer Costs and Fenec shall not be required to reimburse any such Transfer Costs; or
- (c) if this Agreement is terminated by Licensee in accordance with Section 12.2 or 12.3 of this Agreement, Fenec shall reimburse Licensee for all Transfer Costs actually incurred by Licensee.

To the extent that such assigned regulatory filings and/or Marketing Authorizations are related to the Product, all such data, files, materials, information, filings and approvals shall thereafter be deemed to be Fenec's Confidential Information and subject to Article 9 of this Agreement. Licensee further agrees to execute and deliver such instruments and take such other actions as Fenec shall reasonably request in order to carry out this provision.

- 13.3.2 **Orders.** It is understood between the Parties that during the twelve (12) month period preceding the expiration of a Subsequent Term (as defined under Section 12.1 above) of this Agreement, Licensee shall not purchase stock of Product in an amount above and beyond the amount purchased during the previous twelve (12) month period (in terms of trend) plus [***]. For example, if this Agreement expires on March 31, 2034, then the amount of Product ordered by Licensee between March 31, 2033, and March 31, 2034, shall not be higher than the amount ordered during the twelve (12) month period immediately before March 31, 2033. The above provision is applicable, *mutatis mutandis*, in case this Agreement is terminated before the Initial Term as provided under Section 12.1 above. Fennec shall be entitled to reject any purchase order issued by Licensee during the six (6) months period before the expiration or termination date of this Agreement. In the event that this Agreement is terminated by Fennec pursuant to either Section 12.2 or 12.3, such termination shall operate as a cancellation, as of the date thereof, of all orders of Product which have not yet been produced by Fennec, and neither Party shall thereafter be under any obligation to the other Party with respect to orders so cancelled.
- 13.3.3 **Purchase of Stock.** In the event of any termination of this Agreement due to Licensee's material breach, or as otherwise agreed between the Parties in writing, either (i) Fennec shall repurchase the Products in Licensee's possession and control at the same price paid by Licensee or (ii) Licensee may continue to sell its existing inventories and any work-in-process of the Product until the earlier of (a) Licensee's completion of the transfer of all Marketing Authorizations for the Product, or (b) Fennec's directing Licensee to halt all sales of the Product by notice. If either such event occurs prior to the sale of all of Licensee's inventories and work-in-process of the Product, then Licensee shall sell to Fennec, and Fennec shall purchase, at Licensee's cost, any remaining Licensee inventory and work-in-process of the Product that are useable and saleable (provided that the presence of a Norgine label on any such inventory and/or work-in-progress shall not deem the Product not useable or not saleable) within a commercially reasonable period of time (such period not being longer than [***] days). All such Product shall be delivered to Fennec at an address nominated by Fennec and payment therefore shall be made by Fennec after deduction of any amount due and payable by Licensee to Fennec. If Fennec exercises this option, it shall be responsible for reasonable delivery costs.
- 13.4 **Survival.** Without limiting Section 13.1, and notwithstanding any other provision of this Agreement, the provisions of Articles 1, 9, 10, 13, 14, 15, 16, 17, 18 and 19, and Sections 5.6, 5.7, 6.2, 6.5, 6.6, 7.2 and 7.5.4 shall survive expiration or termination of this Agreement; provided that the provisions of Article 9 (Confidential Information) shall survive the termination or expiration of this Agreement for a period of five (5) years.

14. GOVERNING LAW

This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of State of New York without reference to conflicts of laws principles. To the extent that it may otherwise be applicable, the Parties hereby expressly agree to unconditionally waive and exclude from the operation of this Agreement the *United Nations Convention on Contracts for the International Sale of Goods*, as amended and as may be amended further from time to time. This Agreement has been negotiated and drafted by the Parties in the English language. Any translation into any other language shall not be an official version thereof. In the event any translation of this Agreement is prepared for convenience or for any other purpose, the provisions of the English version shall prevail.

15. DISPUTE RESOLUTION

- 15.1 **Negotiation.** The Parties shall attempt in good faith to resolve any and all disputes that arise between them promptly, voluntarily and amicably. Any dispute arising between the Parties relating to, arising out of, or in any way connected with this Agreement, or any term or condition hereof, or the performance by either Party of its obligations hereunder (a “Dispute”), whether before or after expiration or termination of this Agreement, which is not settled by the Parties within twenty (20) days after written notice of such Dispute is first given by one Party to the other Party in writing, will be referred to a senior executive designated by Fennec and a senior executive designated by Licensee who are authorized to settle such Dispute on behalf of their respective companies (“Senior Executives”). The Senior Executives will meet (or confer by telephone or video conference) promptly and no later than within ten (10) days after the end of the initial 20-day period referred to above, at a time and place mutually acceptable to both Senior Executives. If the Dispute has not been resolved by the Senior Executives within twenty (20) days after the end of the initial 10-day period referred to above (or such longer time period as may be mutually agreed upon by the Senior Executives), the Dispute will be resolved in accordance with the remainder of this [Article 15](#).
- 15.2 **Jurisdiction.** If a Dispute is not resolved in accordance with [Section 15.1](#), the Parties irrevocably agree that the courts of New York, New York, USA shall have exclusive jurisdiction to hear and decide any suit, action or proceedings, or to settle any disputes, which may arise out of or in any way relate to this Agreement or its formation and, for these purposes, each Party irrevocably submits to the jurisdiction of the courts of New York, New York, USA.
- 15.3 **Court Actions; Injunctive Relief.** Notwithstanding the above, to the full extent allowed by Applicable Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect the Parties’ rights or enforce the Parties’ obligations under this Agreement without the requirement to implement the negotiation process under [Section 15.1](#) above. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of patents or other proprietary or intellectual property rights. Each Party waives any right, and agrees not to apply to have any disputes under this Agreement tried or otherwise determined by a jury, except where required by Applicable Law.

16. ASSIGNMENT

This Agreement may not be transferred or assigned, either totally or in part, by either of the Parties hereto to any Third Party without the prior written consent of the other Party, except that either Party shall have the right to assign this Agreement (i) to one or more of its Affiliates, or (ii) to a successor to all or substantially all of its assets relating to the Product or Change of Control (and the relevant Party will notify the other Party in respect of any such event described under sub-clause (ii) as soon as reasonably practicable following such event). Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be null and void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

17. WAIVER

The waiver of and relief from any breach or non-fulfilment of any term and condition of this Agreement does not constitute a waiver of or relief from any other breach or non-fulfilment of that or any other term and condition.

18. LIABILITY, INDEMNITY AND INSURANCE

- 18.1 Fennec Indemnification Obligations. Subject to the provisions of this Article 18, Fennec shall indemnify, defend and hold Licensee and its owners, officers, directors, Affiliates, and employees (collectively, "Licensee Indemnified Parties") harmless from and against any and all losses arising out of or resulting from any Third Party Claims made or suits brought against Licensee Indemnified Parties ("Losses") which arise or result from (i) Fennec's material breach of any of its representations, warranties or covenants set forth in this Agreement, or any of its obligations hereunder; (ii) Fennec's manufacture, registration, handling, storage, use, transportation or sale (whether inside or outside the Territory) of any Product on or after the Effective Date, including, without limitation, any Third Party Claim for personal injury or death, to the extent such Third Party Claims arise from the period of time commencing on or after the Effective Date and to the extent such is not attributable to Licensee's breach of this Agreement or any Applicable Laws; (iii) Fennec's negligence or wilful misconduct with regard to the Products to the extent such is not attributable to Licensee's breach of this Agreement or any Applicable Laws, or (iv) any claim that the manufacture, import, export, promotion, distribution, marketing, advertising, offering for sale, or sale of Product in the Territory infringes any intellectual property rights of any Third Party. Licensee must promptly notify Fennec in writing of any such claim or threats of claims that it receives from a Third Party or (v) any other claim arising outside the Territory other than a claim in respect of which Licensee provides indemnification pursuant to Section 18.2.
- 18.2 Licensee's Indemnification Obligations. Licensee shall indemnify, defend and hold Fennec and its officers, directors, agents, Affiliates, and employees (collectively, "Fennec Indemnified Parties") harmless from and against any and all Losses arising out of or resulting from any Third Party Claims made or suits brought against Fennec Indemnified Parties which arise or result from (i) Licensee's material breach of any of its representations, warranties or covenants set forth in this Agreement, or any of its obligations hereunder; (ii) Licensee's marketing, distribution, or sale of any Product on or after the Effective Date, including, without limitation, any Third Party Claim for personal injury or death, to the extent such Third Party Claims arise from the period time commencing on or after the Effective Date and to the extent such is not attributable to Fennec's breach of this Agreement or any Applicable Law; or (iii) Licensee's negligence or wilful misconduct with regard to the Products to the extent such is not attributable to Fennec's breach of this Agreement or any Applicable Laws. Licensee shall have no obligation to indemnify the Fennec Indemnified Parties to the extent that the Losses arise out of or result from, directly or indirectly, matters for which Fennec is obligated to indemnify Licensee under Section 18.1. Fennec must promptly notify Licensee in writing of any such claim or threats of claims that it receives from a Third Party.

18.3 Indemnification Procedure.

- 18.3.1 For purposes of this Agreement, “Third Party Claim” means a claim asserted by a Third Party (in no event to include any Affiliate of either Party) against a Licensee Indemnified Party or Fennec Indemnified Party, as applicable (each, an “Indemnified Party”). In the event a Third Party Claim is asserted with respect to any matter for which an Indemnified Party is entitled to indemnification hereunder, then the Party entitled to seek indemnification in respect thereof (the “Indemnitee”) shall promptly notify in writing the Party obligated to indemnify the Indemnified Party thereof (the “Indemnitor”); provided, however, that no delay on the part of the Indemnitee in notifying the Indemnitor shall relieve the Indemnitor from any obligation hereunder unless (and then only to the extent that) the Indemnitor is prejudiced thereby. Such notice shall request indemnification and describe the potential Losses and Third Party Claim giving rise to the request for indemnification, and provide, to the extent known and in reasonable detail, relevant details thereof. If the Indemnitee fails to give the Indemnitor notice of its intention to defend any such Third Party Claim as provided in this Section 18.3.1, the Indemnitee shall have the right to assume the defense thereof with counsel of its choice, at the Indemnitor’s expense, and defend, settle or otherwise dispose of such Third Party Claim without the consent of the Indemnitor.
- 18.3.2 In the event the Indemnitor elects to assume the defense of a Third Party Claim, the Indemnitee of the Third Party Claim in question and any successor thereto shall permit Indemnitor’s counsel and independent auditors, to the extent relevant, reasonable access to its books and records and otherwise fully cooperate with the Indemnitor in connection with such Third Party Claim; provided, however, that (i) the Indemnitee shall have the right fully to participate in such defense at its own expense; (ii) the Indemnitor’s counsel and independent auditors shall not disclose any Confidential Information of the Indemnitee to the Indemnitor without the Indemnitee’s consent; (iii) access shall only be given to the books and records that are relevant to the Third Party Claim or Losses at issue. The defense by the Indemnitor of any such actions shall not be deemed a waiver by the Indemnitee of its right to assert a claim with respect to the responsibility of the Indemnitor with respect to the Third Party Claim or Losses in question. The Indemnitor shall not have the right to settle or compromise any Third Party Claim against the Indemnitee (that the Indemnitor has defended pursuant to this Section 18.3.2) without the consent of the Indemnitee which shall not be unreasonably withheld or delayed. No Indemnitee shall pay or voluntarily permit the determination of any Losses which is subject to any such Third Party Claim while the Indemnitor is negotiating the settlement thereof or contesting the matter, except with the prior written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed.
- 18.4 Limitations. Except as set forth in Section 18.1(iii), liability for breach of contract relating to the manufacturing or supply of the Product by Fennec or any of its Affiliates or subcontractors under this Agreement shall be limited to, at Fennec’s option: (i) replacement of Product or (ii) refund of the purchase price in respect of which a breach occurred. ALL OTHER LIABILITIES FOR SUCH BREACH OF CONTRACT, EXPRESS OR IMPLIED, CONTRACTUAL OR OTHERWISE, ARE EXCLUDED. FENNEC SHALL IN NO CIRCUMSTANCES BE LIABLE TO LICENSEE FOR ANY CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING ANY OTHER LOSS OF PROFIT, SUFFERED BY LICENSEE OR ANY CLAIM MADE AGAINST LICENSEE BY A THIRD PARTY AS A RESULT OF ANY DELAY IN, OR SUSPENSION OR CANCELLATION OF, DELIVERY FOR WHATEVER REASON. FURTHER, FENNEC SHALL NOT BE LIABLE FOR PRODUCT DEFECTS THAT HAVE BEEN CAUSED SOLELY BY ABNORMAL OR INCORRECT CONDITIONS OF USE, STORAGE PENDING USE, ACCIDENT, MISUSE OR NEGLIGENCE BY THE LICENSEE, ITS EMPLOYEES, SERVANTS AND AGENTS OR BY THE CARRIER AFTER ANY RELEVANT PRODUCT LEAVES FENNEC’S, ITS AFFILIATES’ OR SUBCONTRACTORS’ FACILITY. FENNEC MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE EXPRESSLY MADE HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY FENNEC.

EXCEPT IN THE CASE OF A BREACH OF ARTICLE 9, NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES, WHETHER FORESEEABLE OR NOT, THAT ARE IN ANY WAY RELATED TO THIS AGREEMENT.

18.5 Insurance. Each Party shall maintain general liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, provided in no event shall the general liability insurance amounts be less than two million dollars (\$2,000,000) per occurrence and four million dollars (\$4,000,000) in the aggregate limit of liability per year. The Parties shall provide written proof of such insurance to each other upon request.

19. MISCELLANEOUS

19.1 Communications. Any notice, information or written communication required by the terms of this Agreement, to be given to any of the Parties hereto, shall be given by registered letter prepaid first class post or equivalent, email, facsimile transmission or by personal courier delivery and properly addressed to the other Party's address below, or to the last address communicated by the Party using the same procedure:

To Fenec:

Fenec Pharmaceuticals, Inc.
PO Box 13628
68 TW Alexander Drive
Research Triangle Park, NC 27709
USA
Attention: [***]
Email: [***]

To Licensee:

Norgine Pharma UK Limited
Norgine House
Widewater Place
Moorhall Road
Harefield
Uxbridge UB9 6NS
United Kingdom
Attention: [***]
Email: [***]

With a copy to the Chief Legal Officer at legaldept@norgine.com

Any such notice, information or communication shall be effective as of the date when it duly arrives in the hands of the addressee.

- 19.2 **Force Majeure.** If either Party is prevented from performing any or all of its obligations under this Agreement due to a Force Majeure, then upon receipt of prompt notification from the affected Party, specifying the nature and extent of the circumstances giving rise to such Force Majeure, the other Party shall, for the period required by the Force Majeure cause, excuse the affected Party from performing the obligations under this agreement that have been affected by such Force Majeure. If a Force Majeure situation causes the delay of any shipment hereunder for more than [***] Working Days, said shipment may be cancelled by Licensee. Notwithstanding the foregoing, (i) the Parties agree that to the extent their respective obligations are not affected by the Force Majeure event, they will use reasonable endeavours to continue sales of the Product in the Territory, and (ii) if such a Force Majeure induced failure of performance by the affected Party continues for a period of more than [***] consecutive days and such failure frustrates or materially and adversely impacts achievement of the fundamental objectives of the Agreement, then the other Party may terminate this Agreement upon written notice to the affected Party.
- 19.3 **Severability.** In the event that any provisions of this Agreement are or become ineffective or if any omission is discovered, the validity of the remaining provisions shall not thereby be affected. In place of the ineffective provisions, or for the purpose of rectifying the omission, any invalid provision or omission shall be replaced by the nearest legally possible solution, which best reflects the Parties' intention, taking into consideration the spirit and object of this Agreement, had they considered the point.
- 19.4 **Headings.** The paragraph headings are for convenience only and shall not be deemed to affect in any way the language of the provisions to which they refer.

- 19.5 Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the Parties hereof with respect to its subject matter and supersedes all prior agreements, arrangements, dealings or writings between the Parties hereof. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto. Fenec shall cooperate with Licensee in obtaining all consents required in respect of such amendment in order to preserve Licensee's rights under its Non-Disturbance of License Agreement with Petrichor Opportunities Fund I LP dated 15 March 2024.
- 19.6 Relationship of the Parties. During the term hereof the relationship between Fenec and Licensee is that of vendor and vendee. Licensee, its agents and employees shall, under no circumstances, be deemed agents or representatives of Fenec. Neither Licensee nor Fenec shall have any right to enter into any contracts or commitments in the name of, or on behalf of, the other to bind the other in any respect whatsoever.
- 19.7 Benefit of Agreement. This Agreement enures to the benefit of and is binding upon the respective successors and permitted assigns of the Parties.
- 19.8 Official Language. The language of this Agreement and of any documents, papers or proceedings required by or under this Agreement, shall be English. Any Party requesting or requiring translations of such documents, papers or proceedings shall bear all costs and expenses of such translations.
- 19.9 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original but all of which, taken together, shall constitute one and the same instrument. Signatures delivered by portable document format (".pdf"), facsimile or DocuSign® (or similar electronic signature exchange platform) shall constitute original signatures. The Parties agree that the electronic signatures appearing on this Agreement are the same as handwritten signatures for the purposes of validity, enforceability and admissibility pursuant to the Electronic Signatures in Global and National Commerce (ESIGN) Act of 2000, and Uniform Electronic Transactions Act (UETA) model law, or similar applicable laws.

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorised representatives in duplicate, effective as of the Effective Date.

FENNEC PHARMACEUTICALS, INC.

NORGINE PHARMA UK LIMITED

/s Robert Andrade

/s Chris Bath

By: Robert Andrade

By: Chris Bath

Title: CFO

Title: CEO

Date: March 15, 2024

Date: March 15, 2024

**APPENDIX A
LOCAL AGREEMENTS**

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**APPENDIX B
FINANCIAL MATTERS**

Up Front Fee (€):

€40,000,000

Milestone Payments (€):

<i>Regulatory Milestones</i>		
<i>Regulatory Milestone</i>	<i>Regulatory Milestone Details</i>	<i>Milestone Payment</i>
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
<i>Sales Milestones</i>		
<i>Sales Milestone</i>	<i>Sales Milestone Details</i>	<i>Milestone Payment</i>
Sales Milestone 1	[***]	[***]
Sales Milestone 2	[***]	[***]
Sales Milestone 3	[***]	[***]
Sales Milestone 4	[***]	[***]
Sales Milestone 5	[***]	[***]
Sales Milestone 6	[***]	[***]

Transfer Price (€):

The Transfer Price shall be the sum of:

(i) the price that Fenec pays to the Existing CMO in respect of the Product as of the Effective Date, being [***];

plus

(ii) [***] of such amount;

plus

(iii) the applicable amount that Fennec pays to Almac in respect of the labelling and packaging of the Product; provided that such amount shall not exceed the amounts set out in the annex below.

Prior to the meeting of the JSC in either (i) October during the first year of the Initial Term (when the JSC is meeting monthly), or (ii) the final Calendar Quarter in any subsequent year (when the JSC is meeting quarterly), Fennec (a) may notify Licensee of any planned price increase, and (b) will notify Licensee of any planned price decrease, in each case communicated to it by the Existing CMO of an increase or decrease to limb (i) of the Transfer Price (such proposal to include sufficient details and supporting documentation in respect of the increase or decrease in costs of materials or fees, as made available to Fennec by the Existing CMO) that shall apply for Product ordered in the next calendar year, and the Parties shall discuss in good faith any such increase or decrease via the JSC; provided that, in the case of an increase, in no circumstances shall any such price increase be greater than [***] for such calendar year, unless otherwise agreed in writing by Licensee (such agreement not to be unreasonably withheld, delayed or conditioned).

Royalties (€):

<i>Portion of annual Net Sales of Product in the Territory in a calendar year</i>	<i>Royalty Rate</i>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Royalty Reduction Worked Example:

Overall Territory Sales (€m)		[***]	
Effective Royalty Rate	Rate	€m	
Up to [***]	[***]	[***]	
[***] - [***]	[***]	[***]	
[***] - [***]	[***]	[***]	
		[***]	
Effective royalty rate		[***]	
Assuming [***] has erosion impact			
[***] revenues	[***]		
Royalty reduction applicable	[***]		
Royalty rate in [***]	[***]		(i.e. reduction based on Territory effective royalty rate)
Royalty payable in [***] (€m)	[***]		
Royalty payable for rest of Territory			
Territory sales excluding [***]	[***]		
Effective royalty rate	[***]		
Royalty payable (€m)	[***]		

Annex: Labelling and Packaging Costs

[***]

APPENDIX C
PRODUCT PATENTS AS OF THE EFFECTIVE DATE

Docket Number	Country / Region	Title	Application Number	National Filing Date
21111-006AU1	AU - (Australia)	ANHYDROUS SODIUM THIOSULFATE AND FORMULATIONS THEREOF	2019299216	12/11/2020
21111-007AU1	AU - (Australia)	FORMULATIONS OF ANHYDROUS SODIUM THIOSULFATE	2019299217	12/11/2020
21111-007EP1	EP - (European Patent Convention)	FORMULATIONS OF ANHYDROUS SODIUM THIOSULFATE	19830950.2	1/26/2021

**APPENDIX D
TRADEMARK**

PEDMARQSI®

Country	Registration number	Registration date
European Union	018858616	August 26, 2023
United Kingdom	UK00003897436	June 30, 2023
Switzerland	799444	June 27, 2023
Norway	327467	July 4, 2023

**APPENDIX E
LICENSEE TRADEMARKS**

Trademark	International Registration No.	Country/Region	Registration Date	Renewal Date	Trademark Owner	Class
	1234879	European Union	13.11.2014 National Registration date: 15.12.2015	13.11.2024	Velinor A.G.	5



Fennec Pharmaceuticals and Norgine Enter into Exclusive Licensing Agreement to Commercialize PEDMARQSI in Europe, Australia, and New Zealand

Agreement pairs Norgine's commercial expertise and leading European footprint with PEDMARQSI, the first and only approved therapy in the European Union and U.K. for reducing the risk of cisplatin-induced hearing loss in pediatric patients with localized, non-metastatic solid tumors

Fennec will receive €40 million in upfront and up to €210 million in additional commercial and regulatory milestones, and tiered royalties up to the mid-twenties

Enhances Norgine's commitment to bringing transformative therapies to patients in Europe, U.K., Australia, and New Zealand who currently do not have access to a therapy to treat this life altering condition

Research Triangle Park, N.C. and Uxbridge, United Kingdom, March 18, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ: FENC; TSX: FRX), a commercial stage specialty pharmaceutical company, and Norgine, a leading European specialist pharmaceutical company, today announced an exclusive licensing agreement under which Norgine will commercialize *PEDMARQSI*[®] in Europe, Australia and New Zealand. *PEDMARQSI* is the first and only approved therapy in the EU and U.K. for the prevention of ototoxicity (hearing loss) induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic solid tumors.

Under the terms of the licensing agreement, Fennec will receive €40 million in upfront consideration and up to €210 million in additional commercial and regulatory milestone payments and double-digit tiered royalties on net sales of *PEDMARQSI* in the licensed territories up to the mid-twenties. Norgine will be responsible for all commercialization activities in the licensed territories and will hold all marketing authorizations in the licensed territories.

It is estimated that more than 5,000 pediatric patients annually are eligible for platinum-based chemotherapy in Europe. *PEDMARQSI* was granted EU marketing authorization by the European Commission in June 2023, and received UK approval from the MHRA in October 2023. Approvals were based on safety and efficacy data from two open-label, randomized Phase 3 trials, SIOPEL 6 (pivotal) and Clinical Oncology Group [COG] Protocol ACCL0431. The studies compared *PEDMARQSI* plus cisplatin-based regimens to cisplatin-based regimens alone for the reduction of cisplatin-induced hearing loss in pediatric patients. *PEDMARQSI* holds eight years plus two years of data and market protection in Europe based on its Pediatric Use Marketing Authorization. Approval in Switzerland, Australia and New Zealand will also be pursued.

The first study (SIOPEL-6) involved 114 children with hepatoblastoma (a cancer of the liver), with an average age of about 19 months. The results showed that 35% (20 out of 57) of children who received PEDMARQSI 6 hours after each dose of cisplatin developed hearing loss compared with 67% (35 out of 52) of children who only received cisplatin. The second study involved 125 children aged 1 month to 18 years with different types of cancer, including hepatoblastoma, neuroblastoma (a cancer of immature nerve cells) and tumours of the central nervous system. The study found that hearing loss was experienced by 29% (14 out of 49) of children who received PEDMARQSI after each cisplatin dose compared with 56% (31 out of 55) of those who received only cisplatin.

“We are delighted to partner with Norgine, who shares our belief in the potential of PEDMARQSI to mitigate the risk of permanent and irreversible hearing loss that can occur in pediatric patients treated with cisplatin. Further, this partnership is an important step in achieving our mission of expanding PEDMARQSI to patients across the globe who are at risk of suffering from cisplatin-induced ototoxicity,” said Rosty Raykov, Chief Executive Officer of Fennec Pharmaceuticals. “From a deal perspective, the terms provided us many important benefits, including an upfront payment further solidifying our balance sheet, attractive economic terms providing meaningful participation in the ex-US success of PEDMARQSI and an experienced partner to successfully launch PEDMARQSI in the licensed territory.”

Chris Bath, Chief Executive Officer of Norgine, said “We are thrilled to announce our partnership with Fennec, to bring this vital medicine to pediatric patients who are being treated with cisplatin, across Europe and ANZ. We look forward to working with the Fennec team and launching PEDMARQSI in our territories in the coming months, establishing it as the standard of care in this critical patient population with high unmet need. This important milestone for our company builds on our 30-year track record of creating partnerships of enduring value and further underscores Norgine’s position as the specialty pharma partner of choice across Europe and ANZ.”

Moelis & Company LLC acted as financial advisor, and LaBarge Weinstein LLP acted as legal advisor to Fennec. Arnold & Porter acted as legal advisor to Norgine.

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK[®] and PEDMARQSI[®] to reduce the risk of platinum-induced ototoxicity in pediatric patients. PEDMARK received FDA approval in September 2022 and European Commission Marketing Authorization in June 2023 for PEDMARQSI. Further, PEDMARQSI received U.K. approval in October 2023. PEDMARK has received Orphan Drug Exclusivity in the U.S. for seven years of market protection and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. For more information, please visit www.fennecpharma.com.

About Norgine

Norgine is a leading European specialist pharmaceutical company that has been bringing transformative medicines to patients for over a century. Commitment to transforming people’s lives drives everything Norgine does with fully integrated infrastructure and exceptional partnership approach enabling creative solutions to bring life-changing medicines to patients that they may not otherwise be able to access. Norgine is proud to have helped more than 25 million patients annually around the world and generated over €500 million in net product sales in 2023.

Norgine has a direct presence in 18 European countries, as well as Australia and New Zealand and has a strong global network of partnerships in non-Norgine markets. Norgine possesses a flexible and fully integrated pharmaceutical business, with manufacturing (Hengoed, Wales and Dreux, France), third party supply networks and significant product development capabilities, in addition to sales and marketing infrastructure.

NORGINE and the sail logo are trademarks of the Norgine group of companies.

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK[®] and PEDMARQSI[®], the market opportunity for and market impact of PEDMARK and PEDMARQSI, its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company’s business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company’s patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company’s products will not be as large as expected, the Company’s products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company may not meet its future capital requirements in different countries and municipalities, and other risks detailed from time to time in the Company’s filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2022. Fenec disclaims any obligation to update these forward-looking statements except as required by law.

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

PEDMARK[®], PEDMARQSI[®] and Fenec[®] are registered trademarks of Fenec Pharmaceuticals Inc.

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