# 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): September 25, 2018

# **ALDEYRA THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-36332 (Commission File No.) 20-1968197 (IRS Employer Identification No.)

131 Hartwell Avenue, Suite 320 Lexington, MA 02421 (Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 imes

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 8.01. Other Events.

On September 25, 2018, Aldeyra Therapeutics, Inc. (the "Company") issued a press release announcing the presentation of clinical results from the MESO-2 investigator-sponsored clinical trial of ADX-1612, a novel Heat Shock Protein 90 (HSP90) inhibitor, in combination with pemetrexed and cisplatin or carboplatin for the treatment of pleural malignant mesothelioma at the International Association for the Study of Lung Cancer Conference. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company is developing ADX-1612 pursuant to a License Agreement between the Company and Madrigal Pharmaceuticals, Inc. ("Madrigal"), entered into on December 26, 2016 (the "Agreement"). Pursuant to the Agreement, the Company obtained an exclusive, worldwide license from Madrigal under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HSP90 Inhibitors, including ADX-1612 (investigated in oncology under the name ganetespib) ("Agreement Products"). The Company has agreed to use its commercially reasonable efforts to develop Agreement Products.

In consideration for the rights licensed under the Agreement, the Company paid Madrigal an upfront license fee of \$250,000 and is obligated to make future regulatory and development and sales-dependent milestone payments to Madrigal of less than \$340 million in the aggregate (over 80% of such amount being tied to the Company's achievement of increasingly greater annual worldwide net sales milestones), as well as royalty payments to Madrigal at a rate which, as a percentage of net sales, is in the high single digits for products containing ADX-1612 and mid-single digits for any other HSP90 Inhibitor product. The Company is also obligated under the Agreement to pay Madrigal a percentage of certain sublicense revenue that the Company receives in connection with the Company entering into any sublicensing arrangements with any third parties, at a percentage rate which tiers downward from the mid-twenties to low-single digits based on the development stage of the product at the time of the sublicense.

The Agreement will remain in effect until all payment obligations under the Agreement expire. The Company may terminate the Agreement in its entirety or on an Agreement Product-by-Agreement Product basis with timely notice to Madrigal. Either party may terminate the Agreement for uncured material breach by the other party or upon certain insolvency or bankruptcy proceedings involving the other party, both with timely notice to the other party. In addition, Madrigal has the right to terminate the Agreement if the Company, its affiliates, or sublicensees interferes with, challenges the validity or enforceability of, opposes the extension of or grant of a supplementary protection certificate with respect to any of the Company's licensed patents under the Agreement. In the event of an early termination of the Agreement, all rights licensed and developed by the Company under the Agreement may revert back to Madrigal. Each party has agreed to indemnify the other party for certain third party claims arising under the Agreement.

The foregoing description of the Agreement is qualified in its entirety by reference to the Agreement. In connection with the announcement of clinical results from the MESO-2 investigator-sponsored clinical trial of ADX-1612, a copy of the Agreement is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference. The Company intends to submit a Freedom of Information Act confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the Agreement. The omitted material will be included in the request for confidential treatment.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Aldeyra Therapeutics, Inc. dated September 25, 2018.
99.2*	License Agreement, dated as of December 26, 2016, by and between Aldeyra Therapeutics, Inc. and Madrigal Pharmaceuticals, Inc.

\* Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. An application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. This exhibit has been filed separately with the Securities and Exchange Commission without redactions in connection with Aldeyra Therapeutics, Inc.'s confidential treatment request.

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

# ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed

Name: Joshua Reed Title: Chief Financial Officer

Dated: September 25, 2018



#### Aldeyra Therapeutics Announces Positive Mesothelioma Investigator-Sponsored Clinical Trial Results Presented at The International Association for The Study of Lung Cancer 19<sup>th</sup> World Conference on Lung Cancer

#### 61% Partial Response Rate of ADX-1612 in Combination with Platinum Therapy

LEXINGTON, Mass., September 25, 2018 (PRNewswire) — Aldeyra Therapeutics, Inc. (Aldeyra) (NASDAQ: ALDX), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced positive top-line results from the MESO-2 investigator-sponsored Phase 1/2 clinical trial of ADX-1612 (ganetespib) in patients with pleural malignant mesothelioma. ADX-1612, when combined with standard pemetrexed and platinum therapy, resulted in partial response rates that exceeded historical standard of care. ADX-1612 is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone that controls the folding and activation of client proteins involved in DNA repair and cell division. Results will be announced at a presentation at the International Association for the Study of Lung Cancer (ASLC) 19th World Conference on Lung Cancer (Abstract #11921) on September 25, 2018.

"The MESO-2 results are highly encouraging. Addition of ADX-1612 to pemetrexed and either cisplatin or carboplatin achieved an overall response rate of 61%, the highest seen to date for addition of a novel agent to front-line chemotherapy" said Professor Dean Fennell MD PhD, Chief Investigator of the Cancer Research UK MESO-2 clinical trial. "Hsp90 inhibition could represent a new advance for the treatment of mesothelioma."

The MESO-2 investigator-sponsored dose escalation clinical trial was designed to assess the safety, tolerability, and efficacy of ADX-1612 in combination with standard pemetrexed and platinum therapy, using either cisplatin or carboplatin. Twenty-seven patients with pleural malignant mesothelioma were enrolled at a single site in the UK and divided into one of three cohorts receiving 100, 150, or 200mg/m<sup>2</sup> of ADX-1612 on days 1 and 15 every 21 days. Of 23 evaluable patients, 22 patients (96%) manifested stable disease or clinical response, and one patient (4%) with non-epithelial histology progressed, as measured by via RECIST (Response Evaluation Criteria in Solid Tumors) criteria. The overall response rate was 61%, relative to historical standard of care response rates of 20 to 40%. The response rate in patients with epithelial histology was 76%. In seven patients, reduction of tumor burden was greater than 50%. One patient remained progression-free after 37 months. ADX-1612 was observed to be well-

tolerated, and dose-limiting toxicity was observed in three patients, all of whom were enrolled in the highest dose group.

"Malignant mesothelioma has no known cure, a poor prognosis, and a treatment landscape that has not changed in over a decade," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on the strength of the MESO-2 investigator-sponsored trial results relative to the unmet medical need in mesothelioma, we look forward to meeting with regulatory authorities to discuss these results."

#### About ADX-1612

ADX-1612 (ganetespib) is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone that controls the folding and activation of client proteins involved in DNA repair and cell division. Aldeyra is developing ADX-1612 for the treatment of lymphoproliferative immune diseases and cancers in combination with DNA-damaging agents.

#### About Mesothelioma

Malignant pleural mesothelioma is a rare, aggressive cancer that develops in the pleura, a thin layer of tissue surrounding the lungs. Approximately 3,000 people are diagnosed each year in the United States. Response rates to chemotherapy are generally less than 40%, and five-year survival rates are less than 20%.

#### About Aldeyra Therapeutics

Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. The company is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

#### Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's strategy, future operations, future, prospects, plans, and objectives and Aldeyra's plans and expectations for ADX-1612, including plans to initiate further clinical testing. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development

timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, the ability to obtain and maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldevra's product candidates; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory regulatory regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, both of which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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LICENSE AGREEMENT

# BETWEEN

# ALDEYRA THERAPEUTICS, INC.

AND

MADRIGAL PHARMACEUTICALS, INC.

#### LICENSE AGREEMENT

This LICENSE AGREEMENT (this "**Agreement**") is entered into as of December 26, 2016 (the "**Effective Date**") by and between Aldeyra Therapeutics, Inc., a Delaware corporation ("**Aldeyra**"), and Madrigal Pharmaceuticals, Inc., a Delaware corporation ("**Madrigal**"). Aldeyra and Madrigal each may be referred to herein individually as a "**Party**" or collectively as the "**Parties**."

#### RECITALS

WHEREAS, Madrigal possesses certain Patents, Know-How and expertise with respect to HSP90 Inhibitors (each as defined below);

WHEREAS, Aldeyra possesses expertise in developing and commercializing products that treat diseases related to endogenous aldehydes; and

**WHEREAS**, Aldeyra desires to obtain an exclusive, worldwide license under the Madrigal Technology (as defined below) to develop and commercialize HSP90 Inhibitors (as defined below), on the terms described in this Agreement.

#### AGREEMENT

**NOW, THEREFORE**, in consideration of the respective covenants, representations, warranties and agreements set forth herein, the Parties hereto agree as follows:

#### ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the following capitalized terms shall have the specified meanings.

- 1.1 **Affiliate.** Affiliate means, as of any point in time and for so long as such relationship continues to exist with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another Person if it (a) owns or controls more than 50% of the equity securities of the subject Person entitled to vote in the election of directors (or, in the case of a Person that is not a corporation, for the election of the corresponding managing authority), or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).
- 1.2 **Agreement Product.** Agreement Product means any product that contains an HSP90 Inhibitor where the manufacture, use or sale of such product would, but for the licenses granted in this Agreement, infringe a Valid Claim of a Licensed Patent in the jurisdiction where such product is manufactured, used or sold.

- 1.3 Aldeyra. See first paragraph of this Agreement.
- 1.4 Aldeyra Indemnified Party. See Section 7.2.
- 1.5 **Applicable Law.** Applicable Law means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.
- 1.6 **Approval Application.** Approval Application means a New Drug Application filed with the FDA or the corresponding counterpart in jurisdictions other than the United States.
- 1.7 Breaching Party. See Section 8.3.3.
- 1.8 **Business Day.** Business Day means a Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in Philadelphia, Pennsylvania are authorized or obligated to close.
- 1.9 **Calendar Quarter.** Calendar Quarter means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.
- 1.10 **Calendar Year.** Calendar Year means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.
- 1.11 **Commercialize.** Commercialize or Commercializing means to market, promote, distribute, offer for sale, sell, have sold, import, export or otherwise commercialize a product, to conduct activities, other than Development and Manufacturing, in preparation for the foregoing activities, including obtaining Price Approval, and to conduct post-approval studies. When used as a noun, "Commercialization" means any and all activities involved in Commercializing.
- 1.12 **Commercially Reasonable Efforts.** Commercially Reasonable Efforts means with respect to the efforts to be expended by any Party with respect to any objective, commercially reasonable and good faith efforts to accomplish such objective.
  - 1.12.1 With respect to any objective relating to the Development, Manufacture or Commercialization of an Agreement Product by a Party, "Commercially Reasonable Efforts" means those efforts \*\*\*\*, taking into account all Relevant Factors in effect at the time such efforts are to be expended. It is expressly understood that, in certain circumstances, in light of all Relevant Factors, it may be consistent with the use of Commercially Reasonable Efforts for a Party to \*\*\*\*. Further, to the extent that the

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performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure shall be taken into account in determining whether the affected Party has used Commercially Reasonable Efforts to perform any such affected obligations.

- 1.12.2 **Relevant Factors** means all relevant factors that may affect \*\*\*\* and any other relevant scientific, technical, operational and commercial factors.
- 1.13 **Completion.** Completion means, with respect to any clinical trial, the date on which (a) the database(s) containing the applicable clinical trial data is determined to be complete and locked in order to permit the analysis of the primary and secondary endpoints of such clinical trial and (b) the final tables, listing and figures, together with any additional post-hoc analyses needed to support the interpretation of the results from such clinical trial have been compiled (ignoring for this purpose, any roll-over study conducted to collect additional data regarding the patients in such clinical trial after the collection of the data that will be used to evaluate the primary and secondary endpoints of the clinical trial).
- 1.14 **Confidential Information.** Confidential Information means any scientific, technical, trade or business information that is (a) given by one Party to the other and treated by the Disclosing Party as confidential or proprietary, or (b) developed by or on behalf of a Party under the terms of this Agreement. The Disclosing Party will, to the extent practical, use reasonable efforts to label or identify as confidential, at the time of

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disclosure, all Confidential Information that is disclosed by the Disclosing Party in writing or other tangible form. Notwithstanding anything to the contrary in the foregoing, all non-public information regarding either Party's business including all of its business and product plans, customer lists and all agreements between such Party and any Third Party, will be considered Confidential Information, whether or not labeled as confidential. The terms of this Agreement shall be Confidential Information of each Party.

- 1.15 **Controlled.** Control or Controlled means with respect to any intellectual property right, data or materials, possession of the right (whether by ownership, license or otherwise, other than pursuant to this Agreement) to grant a license, access or other right in, to or under such intellectual property right, data or materials.
- 1.16 **Covered**. Covered means, with respect to a Patent, a Valid Claim would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of a product; *provided*, *however*, that in determining whether a Valid Claim that is a claim of a pending application would be Infringed, it shall be treated as if issued as then currently being prosecuted.
- 1.17 **Development.** Development means, with respect to an Agreement Product, all pre-clinical, clinical and non-clinical research and development activities for such Agreement Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical trials (including pre-approval clinical trials), regulatory affairs, pharmacovigilance, clinical trial regulatory activities, obtaining and maintaining Regulatory Approval. When used as a verb, "Develop" or "Developing" means to engage in Development.
- 1.18 **Disclosing Party.** See Section 9.1.
- 1.19 Effective Date. See first paragraph of this Agreement.
- 1.20 Exploit. Exploit means to Develop, Manufacture, or Commercialize a product. Cognates of the word "Exploit" shall have correlative meanings.
- 1.21 FDA. FDA means the United States Food and Drug Administration, or any successor agency with similar responsibilities.
- 1.22 Field. Field means \*\*\*\*. Field does not include \*\*\*\*.
- 1.23 **First Commercial Sale.** First Commercial Sale means with respect to an Agreement Product, the first commercial sale in a country of such Agreement Product; provided that First Commercial Sale does not include \*\*\*\*

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- 1.24 **Force Majeure**. Force Majeure means a condition beyond the control of a Party, including an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, flood, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.
- 1.25 **Ganetespib**. Ganetespib means the non-geldanamycin resorcinol-containing triazolone compound with the chemical name 5-[2,4-dihydroxy-5-(1-methylethyl)phenyl]-4-(1-methyl-1H-indol-5-yl)-2,4-dihydro-3H- 1,2,4-triazol-3-one.
- 1.26 **Governmental Authority.** Governmental Authority means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.
- 1.27 **HSP90 Inhibitor.** HSP90 Inhibitor means a chemical substance (including, without limitation, Ganetespib) that inhibits the activity of Heat Shock Protein 90 (HSP90), together with any derivatives, fragments, isomers, isoforms and variants thereof and any salts, esters or formulations thereof.
- 1.28 **IND**. IND means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act and applicable regulations promulgated by the FDA, or (b) an equivalent application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of a pharmaceutical product in humans in a particular jurisdiction.
- 1.29 Indemnified Party. See Section 7.3.
- 1.30 Indemnifying Party. See Section 7.3.
- 1.31 **Infringed.** Infringed means any infringement as determined by Applicable Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe, provided however, that a judicial or administrative decision is not a pre-requisite to a Patent being Infringed for purposes of this Agreement.
- 1.32 Initiation. When used in reference to any clinical trial, Initiation of such clinical trial means dosing of the first patient in such clinical trial.
- 1.33 Insolvency Event. See Section 5.
- 1.34 **Inventory.** See Section 3.4.

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- 1.35 **Know-How.** Know-How means techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical material.
- 1.36 Liability. See Section 7.1.
- 1.37 Licensed Patents. Licensed Patents means any Patent included in the Madrigal Technology including, without limitation, those Patents listed in Schedule 1.35, attached hereto and incorporated herein by reference.
- 1.38 **Madrigal.** See first paragraph of this Agreement.
- 1.39 Madrigal Indemnified Party. See Section 7.1.
- 1.40 **Madrigal Technology.** Madrigal Technology means all Patents, Know-How and other intellectual property Controlled by Madrigal or its Affiliates during the term of the Agreement related to the Exploitation of HSP90 Inhibitors in the Field. Notwithstanding the foregoing, Madrigal Technology shall not include any Patents, Know-How or other intellectual property Controlled by \*\*\*\*, except for any Patents, Know-How or other intellectual property developed by \*\*\*\*.
- 1.41 **Manufacture.** Manufacture or Manufactured or Manufacturing means activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a product. When used as a verb, Manufacture means to engage in Manufacturing.
- 1.42 **Marketing Approval.** Marketing Approval means, with respect to any Agreement Product in a particular jurisdiction, all approvals, licenses, registrations or authorizations necessary for the Commercialization of such Agreement Product in such jurisdiction, other than Price Approval, including, with respect to the United States, approval of an Approval Application for such Agreement Product by the FDA, with respect to the European Union, approval of an Approval Application for such Agreement Product by the European Commission, and with respect to Japan, approval of an Approval Application for such Agreement Product by the Ministry of Health, Labour and Welfare.
- 1.43 **Net Sales.** Net Sales means the \*\*\*\* by Aldeyra, its Affiliates or Sublicensees (the "**Selling Party**") to Third Parties, less the following deductions from such gross amounts, to the extent such deductions are directly applicable or relatable to the sales of Agreement Products giving rise to \*\*\*\*:

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A qualifying amount may be deducted only once regardless of the number of the preceding categories that describe such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with the next quarterly report, provided that no such adjustment shall be made more than \*\*\*\* following the report of the associated Net Sales. Sales between or among Aldeyra, its Affiliates and Sublicensees will be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by Aldeyra or any such Affiliates or Sublicensees. An Agreement Product will not be deemed to be sold if \*\*\*\*

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If a sale, transfer or other disposition with respect to Agreement Products involves consideration other than cash or is not at arm's length, then the Net Sales from such sale, transfer or other disposition will be calculated on the average Net Sales price of the Agreement Product in arm's length sales for cash in the relevant country during the same Calendar Quarter as such sale, transfer or other disposition.

Solely for purposes of calculating Net Sales, if Aldeyra or its Affiliates or any permitted Sublicensee sells an Agreement Product in the form of a combination product containing an Agreement Product and one or more other therapeutically or prophylactically active ingredients (whether combined in a single formulation or package, as applicable, or formulated separately but packaged under a single label approved by a Regulatory Authority and sold together for a single price) (a "**Combination Agreement Product**"), Net Sales of such Combination Agreement Product for the purpose of determining the royalties due to Madrigal pursuant to this Agreement will be calculated by \*\*\*\*.

- 1.44 Non-Breaching Party. See Section 8.3.3.
- 1.45 **Party.** See first paragraph of this Agreement.
- 1.46 **Patent.** Patent means any issued patent or pending patent application in any country, jurisdiction or region (including inventor's certificates and utility models), including all

provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals and renewals and all patents granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing.

- 1.47 **Person.** Person means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.
- 1.48 **Phase 1 Clinical Trial.** Phase 1 Clinical Trial means any human clinical trial of an Agreement Product conducted to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness that would satisfy the requirements of 21 C.F.R. § 312.21(a), as amended from time to time, or the corresponding regulations in jurisdictions other than the United States.
- 1.49 **Phase 2 Clinical Trial.** Phase 2 Clinical Trial means any human clinical trial of an Agreement Product conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug that would satisfy the requirements of 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding regulations in jurisdictions other than the United States.
- 1.50 **Phase 2a Clinical Trial**. Phase 2a Clinical Trial means any human clinical trial of an Agreement Product conducted mainly to test the effectiveness of the drug for purposes of identifying the appropriate dose for a particular indication or indications that would satisfy the requirements of 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding regulations in jurisdictions other than the United States.
- 1.51 **Phase 3 Clinical Trial**. Phase 3 Clinical Trial means any human clinical trial of an Agreement Product conducted to gather additional information about effectiveness and safety of the drug that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling that would satisfy the requirements of 21 C.F.R. § 312.21(c), as amended from time to time, or the corresponding regulations in jurisdictions other than the United States.
- 1.52 **Price Approval.** Price Approval means, in any jurisdiction where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products as a condition of sale in such jurisdiction, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination.

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1.53 **Receiving Party.** See Section 9.1.

- 1.54 **Regulatory Approval.** Regulatory Approval means any technical, medical or scientific license, registration, authorization or and approval of any Regulatory Authority, necessary for the Development, Manufacture or Commercialization of a pharmaceutical product in a regulatory jurisdiction.
- 1.55 **Regulatory Authority.** Regulatory Authority means any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority involved in the granting of Regulatory Approvals or Price Approvals for pharmaceutical products in such country or countries.
- 1.56 **Residual Knowledge.** Residual Knowledge means knowledge, techniques, experience and Know-How that are (a) reflected in any Confidential Information Controlled by the Disclosing Party and (b) retained in the unaided memory of any authorized representative of the Receiving Party after having access to such Confidential Information. A Person's memory will be considered to be unaided if the Person has not intentionally memorized the Confidential Information for the purpose of retaining and subsequently using or disclosing it. In no event, however, will Residual Knowledge include any knowledge, techniques, experience and Know-How to the extent (at any time, for such time) within the scope of any valid patent claim Controlled by the Disclosing Party.
- 1.57 **Sublicense.** Sublicense means, directly or indirectly, to sublicense, grant any other right with respect to, or agree not to assert, any licensed right under the Madrigal Technology. When used as a noun, "Sublicense" means any agreement to Sublicense.
  - 1.57.1 **Sublicense Revenue**. Sublicense Revenue means remuneration received by Aldeyra or its Affiliates or any Sublicensee as a result of the grant of a Sublicense to a Sublicensee. Such remuneration includes any \*\*\*\*, provided, however, that, if Aldeyra or an Affiliate or any Sublicensee of Aldeyra receives a development, regulatory or approval milestone payment for the same milestone for which a milestone payment is paid by Aldeyra to Madrigal under Section 4.2 of this Agreement, Sublicense Revenue will include only \*\*\*\*. In addition, Sublicense Revenue excludes sums received by Aldeyra, its Affiliates or any Sublicensee: \*\*\*\*

\*\*\*\*. For clarity, any transaction that results in \*\*\*\* will not be considered a "Sublicense", and thus any remuneration received by Aldeyra as a result of such transaction is not considered Sublicense Revenue under this Agreement, provided that \*\*\*\*.

- 1.58 **Sublicensee.** Sublicensee means a Third Party, other than a distributor or Affiliate of Aldeyra, to whom Aldeyra (or a Sublicensee or Affiliate) sublicenses any of the rights granted to Aldeyra hereunder during the Term.
- 1.59 **Term.** See Section 8.1.
- 1.60 Third Party. Third Party means any Person other than Aldeyra, Madrigal or their respective Affiliates.
- 1.61 **Third Party Infringement.** See Section 5.3.1.
- 1.62 **Third Party License Payments**. Third Party License Payments means \*\*\*\* of all payments paid by Aldeyra, its Affiliates or any Sublicensee to a Third Party under a license agreement for intellectual property rights, other than the Madrigal Technology, which are necessary for the manufacture, use, sale or import of the Agreement Products.
- 1.63 Valid Claim. Valid Claim means a claim of any issued and unexpired patent or patent application within the Licensed Patents that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed; *provided, however*, that if a claim of a pending patent application within the Licensed Patents shall not have issued within \*\*\*\* after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until issued.

#### ARTICLE 2 LICENSE

2.1 **Exclusive License.** Subject to the terms and conditions of this Agreement, Madrigal grants to Aldeyra (and its Affiliates) an exclusive, worldwide, royalty-bearing, sublicenseable license, under the Madrigal Technology, to Exploit Agreement Products in the Field.

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2.2 **No Implied Licenses.** All rights in and with respect to any intellectual property Controlled by a Party that are not expressly licensed, granted or assigned to the other Party under this Agreement are retained by the first Party. Except as expressly provided in this Agreement, no Party shall be deemed by estoppel or implication to have granted the other Party any license or other right with respect to any intellectual property. Aldeyra shall not use the Madrigal Technology except for the Exploitation of Agreement Products.

#### ARTICLE 3 EXPLOITATION OF AGREEMENT PRODUCTS

- 3.1 **Overview of Development.** Aldeyra will be solely responsible for all Development of Agreement Products, subject to the diligence terms set forth in Sections 3.7 and 3.8 below, at Aldeyra's sole expense. On and after the Effective Date, Aldeyra shall bear all of the costs of carrying out activities related to the Exploitation of the Agreement Products other than any costs that were expended by Madrigal prior to the Effective Date and any costs related to the technology transfer outlined in Section 3.5 of this Agreement.
- 3.2 **Commercialization of Agreement Products.** Aldeyra will be solely responsible for the Commercialization of Agreement Products, at Aldeyra's sole expense.
- 3.3 **Plan, Report of Progress.** Aldeyra will provide a written forward-looking development plan and progress report \*\*\*\* to Madrigal by \*\*\*\*, as well as a brief summary presentation by \*\*\*\*, outlining Aldeyra's progress with the Development and Commercialization of Agreement Products to date.
- 3.4 **Manufacture and Supply of Agreement Products.** Madrigal hereby sells, conveys, assigns and transfers to Aldeyra all right, title and interest in and to all existing drug product, drug substance or other intermediary components of Ganetespib and any other HSP90 Inhibitor (the **"Inventory"**) on an "as-is" basis. Madrigal will transfer to Aldeyra to the location designated by Aldeyra using a carrier selected by and paid for by Madrigal EXW (Incoterms 2010) within 90 days of the Effective Date, (1) the Inventory and (2) copies of all existing agreements related to the supply chain for the manufacture of clinical trial materials. Madrigal shall enter into customary documents, including an appropriate bill of sale, if required, for the shipment of Inventory to Aldeyra. Prior to delivery of such Inventory to Aldeyra, Madrigal will store and handle all Inventory in the same manner and using the same degree of care in which such Inventory was stored and handled immediately prior to the Effective Date. All transfers of Inventory under this Section 3.4 will include the original certificates of analysis and other related documents for such Inventory.

For a period of six (6) months following the Effective Date, Madrigal will undertake Commercially Reasonable Efforts to provide access to previous Madrigal personnel for technical support for the Manufacturing of clinical trial material and IND filing, it being

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understood that such personnel are no longer employed by Madrigal and that Madrigal cannot obligate such personnel to work with Aldeyra. Madrigal hereby authorizes Aldeyra to directly engage any such personnel and shall waive any restrictions it may have with respect to such personnel in connection with the provision of such support to Aldeyra. Any expenses of utilizing such personnel shall be borne by Aldeyra.

For a period of six (6) months following the Effective Date, Madrigal shall use Commercially Reasonable Efforts to assist Aldeyra in assuming (or if assumption is not possible, then otherwise obtaining the benefit of) any existing vendor agreement(s) for the Manufacture of any Agreement Product or component thereof.

Aldeyra will be solely responsible for all future Manufacturing of Agreement Products needed for Development and Commercialization of Agreement Products.

# 3.5 Technology Transfer and Data Sharing.

- 3.5.1 Madrigal will provide to Aldeyra such Know-How which is readily available to Madrigal as Aldeyra may reasonably request in order to practice the Madrigal Technology or to otherwise Exploit Agreement Products in accordance with a mutually acceptable set of activities (including, in response to any questions from a Regulatory Authority, Know-How related to HSP90 Inhibitors). Notwithstanding the above, Madrigal will transfer to Aldeyra all known files and data relating to Ganetespib and other HSP90 Inhibitors which have been synthesized by or on behalf of Madrigal and all other known supporting documents related to the same, including without limitation all safety reports and any adverse event reports from clinical trials conducted by Madrigal or from those clinical trials listed on Schedule 3.6.
- 3.5.2 Such transfer will include all Know-How Controlled by Madrigal regarding the prior development of HSP90 Inhibitors that Aldeyra may reasonably request for use in connection with Development of the Agreement Products. Madrigal will undertake Commercially Reasonable Efforts to make its current and former employees that have generated Know-How with respect to HSP90 Inhibitors available for Aldeyra to consult with in connection with the transfer of such Know-How.
- 3.5.3 After the completion of the technology transfer, Madrigal shall provide Aldeyra access to any Know-How in the Madrigal Technology that Aldeyra may reasonably request in order to practice the Madrigal Technology or to otherwise Exploit Agreement Products to the extent any such Know-How has not been transferred (e.g., access to laboratory notebooks).
- 3.5.4 Each Party shall designate in writing a senior level employee of such Party that will act as the primary contact with respect to the technology transfer and such employee shall responsible for coordinating efforts with respect to the technology transfer.

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#### 3.6 **Regulatory Filings and Approvals; Clinical Trials.**

- 3.6.1 <u>Registration Strategy for Agreement Products</u>. Aldeyra will have sole responsibility for developing a registration strategy for each Agreement Product and for coordinating all regulatory matters with respect to Agreement Products.
- 3.6.2 <u>Clinical Trials</u>. After the Effective Date, Madrigal shall continue to be responsible for the medical monitoring, and reporting to Regulatory Authorities for the clinical trials in the oncology field which are listed in Schedule 3.6. Madrigal shall (i) continue to manage the Regulatory Approvals for such clinical trials, and (ii) continue to manage the clinical operations for such trials to their conclusion, per the existing protocols and without new patient enrolment, through its existing consultants engaged for such purpose. Aldeyra shall reimburse Madrigal its actual costs associated with management of such trials up to \*\*\*\*.
- 3.6.3 <u>Filings and Approvals</u>. Aldeyra will file, in its own name, all applications for any form of Regulatory Approval for all Agreement Products. Aldeyra shall have the sole responsibility for communicating with any Regulatory Authority regarding any applications for any form of Regulatory Approval for all Agreement Products. Madrigal shall permit Aldeyra to cross-reference any prior applications for any form of Regulatory Approval for any Agreement Products made by Madrigal, if any.
- 3.6.4 <u>Inspections</u>. Madrigal shall cooperate in good faith with respect to the conduct of any inspection by any Regulatory Authority of any site or facility of Madrigal or any Third Party contract vendor who was engaged by Madrigal for the Development of the Agreement Products including Third Party contract manufacturers.
- 3.7 **Diligence.** Aldeyra will use Commercially Reasonable Efforts to Develop Agreement Products.
- 3.8 **Effect of Sublicensing on Diligence.** Sublicensing will not relieve Aldeyra of its diligence obligations under this Agreement. However, activity by Sublicensee(s) and under any Sublicense will count toward satisfaction of Aldeyra's diligence obligations.

#### ARTICLE 4 FINANCIAL PROVISIONS

4.1 **Initial Payments.** Aldeyra shall pay to Madrigal an upfront license fee of \$250,000 within five (5) days after the Effective Date.

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# 4.2 Milestone Payments.

4.2.1 <u>Agreement Product with Ganetespib</u>. Aldeyra shall pay Madrigal the milestone payments set forth in this <u>Section 4.2.1</u> upon the achievement of such milestone for an Agreement Product containing Ganetespib:

	Milestone	Payment	Number of Payments
1.	Upon Aldeyra's election to move forward with human clinical trials for any indication based on results of the preclinical plan (as described in Schedule 8.2)	****	One time only
2.	If required for filing of Approval Application in U.S., Initiation of first Phase 3 Clinical Trial	****	One time only for first indication
3.	If required for filing of Approval Application in EU, Initiation of first Phase 3 Clinical Trial	****	One time for the first indication and one time for the second indication
4.	If required for filing of Approval Application in Japan, Initiation of first Phase 3 Clinical Trial	****	One time for the first indication and one time for the second indication
5.	If Phase 2 or Phase 2a Clinical Trial is sufficient for Approval Application in U.S., Submission of Approval Application in U.S.	****	One time for the first indication and one time for the second indication
6.	If Phase 2 or Phase 2a Clinical Trial is sufficient for Approval Application in EU, Submission of Approval Application in EU	****	One time for the first indication and one time for the second indication
7.	If Phase 2 or Phase 2a Clinical Trial is sufficient for Approval Application in Japan, Submission of Approval Application in Japan	****	One time for the first indication and one time for the second indication
8.	Marketing Approval in U.S. for first indication	****	One time for the first indication

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	Milestone	Payment	Number of Payments
9.	Marketing Approval in EU for first indication	****	One time for the first indication
10.	Marketing Approval in Japan for first indication	****	One time for the first indication
11.	Marketing Approval in U.S. for second indication	****	One time for the second indication
12.	Marketing Approval in EU for second indication	****	One time for the second indication
13.	Marketing Approval in Japan for second indication	****	One time for the second indication
14.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
15.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
16.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
17.	Annual Worldwide Net Sales* equal or exceed ****	****	One time

\*Annual Worldwide Net Sales means worldwide Net Sales for all Agreement Products containing Ganetespib in any four consecutive Calendar Quarters. If more than one unpaid milestone is achieved in the period, the milestone payment associated with the highest amount of Annual Worldwide Net Sales will be paid in full and any other previously unpaid milestone associated with a lower amount of Annual Worldwide Net Sales will be paid at \*\*\*\*. For example, if Annual Worldwide Net Sales equal \$300 million in four consecutive Calendar Quarters, Aldeyra will pay Madrigal the \*\*\*\* milestone payment, and if the \*\*\*\* milestone payment criteria had not earlier been met, Aldeyra will pay Madrigal an \*\*\*\*. In the event that any Annual Worldwide Net Sales threshold is met in three or fewer consecutive Calendar Quarters, the associated payment shall be due after the end of such shorter period, in accordance with Section 4.4.

4.2.2 <u>Agreement Product with HSP90 Inhibitor other than Ganetespib</u>. Aldeyra shall pay Madrigal the milestone payments set forth in this <u>Section 4.2.2</u> upon the achievement of such milestone for an Agreement Product not containing Ganetespib:

	Milestone	<b>Payment</b>	Number of Payments
1.	Marketing Approval in U.S. for first indication	****	One time for the first indication
2.	Marketing Approval in EU for first indication	****	One time for the first indication
3.	Marketing Approval in Japan for first indication	****	One time for the first indication
4.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
5.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
6.	Annual Worldwide Net Sales* equal or exceed ****	****	One time
7.	Annual Worldwide Net Sales* equal or exceed ****	****	One time

\*Annual Worldwide Net Sales means worldwide Net Sales for all Agreement Products not containing Ganetespib in any four consecutive Calendar Quarters. If more than one unpaid milestone is achieved in the period, the milestone payment associated with the highest amount of Annual Worldwide Net Sales will be paid in full and any other previously unpaid milestone associated with a lower amount of Annual Worldwide Net Sales will be paid at \*\*\*\*. For example, if Annual Worldwide Net Sales equal \$300 million in four consecutive Calendar Quarters, Aldeyra will only pay Madrigal the \*\*\*\* milestone payment, and if the \*\*\*\* milestone payment criteria had not earlier been met, Alderya will pay Madrigal an additional \*\*\*\*. In the event that any Annual Worldwide Net Sales threshold is met in three or fewer consecutive Calendar Quarters, the associated payment shall be due after the end of such shorter period, in accordance with Section 4.4.

- 4.3 **Effect of Sublicensing on Achievement of Milestones.** Achievement by any Sublicensee of any milestone will constitute achievement of such milestone by Aldeyra (if not already achieved by Aldeyra).
- 4.4 **Notice and Payment.** Aldeyra shall provide Madrigal with written notice upon the achievement of each of the milestone events set forth in Section 4.2, such notice to be provided, within \*\*\*\* after Aldeyra determines that such milestone or has been achieved. Aldeyra shall make the appropriate milestone payment concurrently with such notice.

# 4.5 Royalties.

4.5.1 <u>Royalty Rates</u>. Aldeyra shall pay Madrigal royalties based on the aggregate, worldwide Net Sales of each Agreement Product during a Calendar Quarter at the rates set forth in the table below. The obligation to pay royalties shall be imposed only once with respect to the same unit of an Agreement Product:

Agreement Product	<b>Royalty Rate</b>
Agreement Product containing Ganetespib	****
Agreement Product containing any other HSP90 Inhibitor	****

- 4.5.2 <u>Royalty Term</u>. Royalties on any Agreement Product will be payable, on an Agreement Product-by-Agreement Product and country-by-country basis, beginning on the date of First Commercial Sale of the Agreement Product and continuing until the later of (i) expiration of the last Valid Claim contained in the Licensed Patents Covering the Agreement Product in such country; or (ii) expiration of regulatory exclusivity in such country. To the extent required by Applicable Law in any country, the royalty rate following expiration of the last Valid Claim in such country, but during the remaining term of any regulatory exclusivity, shall be reduced to \*\*\*\* of the otherwise applicate royalty rate.
- 4.5.3 <u>Effect of Sublicensing on Royalties</u>. Net Sales of an Agreement Product by a Sublicensee will be subject to the same royalty obligations as Net Sales by Aldeyra. Net Sales by Sublicensee(s) will be aggregated with Net Sales by Aldeyra for the purpose of determining the level of annual Net Sales of the applicable Agreement Product so as to determine the applicable royalty payment.
- 4.5.4 <u>Royalty Adjustment for Third Party Royalties for Blocking IP</u>. Aldeyra will be permitted to deduct any Third Party License Payments from royalties payable to Madrigal with respect to Net Sales of any Agreement Product to which such Third Party License Payments are applicable, on a country-by-country basis, provided that the royalty rate payable to Madrigal during any royalty period shall not be lower than \*\*\*\* of the royalty rate that would have been otherwise applicable. Any Third Party License Payments that, if applied, would exceed the offset allowed herein in a given royalty period shall be rolled over and applied to reduce the royalties owed to Madrigal in succeeding royalty periods until such Third Party License Payments are depleted.
- 4.5.5 <u>Royalty Adjustment for Generic Entry</u>. If a generic equivalent of an Agreement Product is approved for marketing in any country, the royalty payable on Net

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Sales of such Agreement Product in such country will be reduced, effective on the date of market entry of the generic in that country, to \*\*\*\* of the amount otherwise payable on such Net Sales (without regard for the reduction in Section 4.5.2), and if any such generic drug or equivalents gain collectively greater than \*\*\*\* market share in such country based on unit sales as reported by IMS or similar source, no royalties would be payable in such country for so long as such market share is maintained.

4.5.6 <u>Royalty Reports</u>. During the Term, within \*\*\*\* after the end of each Calendar Quarter, Aldeyra shall deliver a report to Madrigal specifying on an Agreement Product-by-Agreement Product basis: (a) gross sales in the relevant Calendar Quarter, (b) Net Sales in the relevant Calendar Quarter, including a summary of deductions applied to determine Net Sales; (c) a summary of the then-current exchange rate methodology then in use by Aldeyra, (d) any adjustments under Sections 4.5.2, 4.5.4 and/or 4.5.5, and (e) royalties payable on such Net Sales. All royalty payments due for each Calendar Quarter shall be due and payable together with Aldeyra's delivery of the applicable report under this Section 4.5.6. All such reports will be considered Confidential Information of Aldeyra and will be maintained in confidence by Madrigal.

#### 4.5.7 <u>Sublicense Revenue</u>.

(a) Aldeyra shall pay to Madrigal a percentage of Sublicense Revenue received by Aldeyra from its Sublicensees according to the following schedule:

Percentage of the Sublicense Revenue to be payable to Madrigal	Events achieved by Aldeyra related to the timing of the issuance of each Sublicense by Aldeyra
****	Prior to filing of an IND
***	After filing an IND but prior to completion of the first clinical trial
***	After completion of first clinical trial

- (b) Aldeyra will pay any Sublicensing Revenue due to Madrigal within \*\*\*\* after the end of the Calendar Quarter in which Aldeyra receives such Sublicense Revenue from a Sublicensee.
- (c) Where any Sublicense is part of a broader transaction that involves the Sublicense, license or assignment of other intellectual property rights or assets Controlled by Aldeyra or licensed or otherwise Controlled by

Aldeyra from a Third Party in addition to the Madrigal Technology, Aldeyra will determine in good faith an appropriate relative apportionment between the value of the Madrigal Technology being sublicensed and the value of the other rights being sublicensed, licensed or assigned by Aldeyra that were Controlled by Aldeyra or obtained from such Third Party and the Sublicense Revenue required hereunder shall be based solely upon that portion of the total value that represents the value of the Sublicense of the Madrigal Technology. Upon request of Madrigal, Aldeyra shall provide the basis of, and supporting documentation for, such apportionment.

## 4.6 **Payment Method; Currency**.

- 4.6.1 All payments under this Agreement shall be paid in U.S. Dollars, by wire transfer to an account designated by Madrigal (which account Madrigal may update from time to time in writing).
- 4.6.2 If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. Dollars, then such amounts shall be converted to their U.S. Dollar equivalent using Aldeyra's then-current standard procedures and methodology, including its then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied.
- 4.7 Withholding Tax. Where any sum due to be paid to Madrigal hereunder is subject to any withholding or similar tax, Aldeyra shall pay such withholding or similar tax to the appropriate Government Authority and deduct the amount paid from the amount then due Madrigal, in a timely manner and promptly transmit to Madrigal an official tax certificate or other evidence of such withholding sufficient to enable Madrigal to claim such payment of taxes. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Aldeyra to Madrigal under this Agreement. Madrigal shall provide Aldeyra any tax forms that may be reasonably necessary in order for Aldeyra not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.
- 4.8 **Records, Audit.** During the Term and for \*\*\*\* thereafter, Aldeyra shall, and shall cause its Affiliates and Sublicensees to, keep and maintain accurate and complete records regarding Net Sales during the three preceding Calendar Years. Upon reasonable prior written notice from Madrigal, Aldeyra, its Sublicensees and Affiliates shall permit an independent certified public accounting firm, selected by Madrigal and reasonably

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acceptable to Aldeyra, to examine the relevant books and records of Aldeyra and its Sublicensees and Affiliates, as may be reasonably necessary to verify the reports submitted by Aldeyra in accordance with Section 4.5.6. An examination by Madrigal under this Section 4.8 shall occur not more than once in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than 36 months before the date of the request. No Calendar Year will be subject to audit under this Section 4.8 more than once. The accounting firm shall be provided access to such books and records at Aldeyra's or its Sublicensee's or Affiliate's facility or facilities where such books and records are normally kept and such examination shall be conducted during normal business hours. Aldeyra may require the accounting firm to sign a customary non-disclosure agreement before providing the accounting firm access to its facilities or records. Upon completion of the audit, the accounting firm shall provide both Madrigal and Aldeyra a written report disclosing whether the reports submitted by Aldeyra are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Madrigal. If the report or information submitted by Aldeyra results in an underpayment or overpayment, the Party owing such underpaid or overpaid amount shall promptly pay such amount to the other Party, and, if, as a result of such inaccurate report or information, such amount is an underpayment by Aldeyra of more than five percent of the amount that was owed, Aldeyra shall reimburse Madrigal for the reasonable expense incurred by Madrigal in connection with the audit.

4.9 **Late Payment.** Any payments or portions thereof due hereunder that are not paid when due, including any amounts payable based on an audit under Section 4.8, shall accrue interest from the date due until paid at an annual rate equal to \*\*\*\*.

# ARTICLE 5 INTELLECTUAL PROPERTY

- 5.1 **Ownership of Inventions General Provisions.** Each Party will retain sole ownership of any intellectual property rights Controlled by such Party as of the Effective Date, or created or acquired by such Party independently of this Agreement. Ownership of any intellectual property created pursuant to this Agreement will follow inventorship as determined under U.S. patent law.
- 5.2 **Management, Prosecution and Maintenance of Madrigal Technology.** Aldeyra will have the first right at its expense, but not the obligation, to file, prosecute and maintain the Licensed Patents. Madrigal shall reasonably cooperate with Aldeyra requests for data, affidavits, and other information and assistance to support filing, prosecution and maintenance of the Patents within the Licensed Patents. Aldeyra shall promptly upon receipt forward to Madrigal copies of any significant office actions, communications, and correspondence relating to the Licensed Patents. Madrigal shall have the right to comment on and to discuss prosecution and maintenance activities with Aldeyra, and Aldeyra shall consider the same in good faith. Aldeyra will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Licensed Patents, *provided, however*, that Aldeyra does not represent or warrant that any patent will issue

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or be granted based on patent applications contained in the Licensed Patents. Notwithstanding the foregoing, if Aldeyra determines that it no longer intends to file, prosecute or maintain any Licensed Patent, Aldeyra shall notify Madrigal at least \*\*\*\* prior to any applicable filing deadline. Madrigal shall have the right in its sole discretion (upon notice to Aldeyra) to file, prosecute or maintain such Licensed Patent at Madrigal's expense. In the event that Aldeyra does not elect to file, prosecute or maintain a Licensed Patent, then, if (a) Madrigal elects to do so, (b) a Patent issues (or remains issued), and (c) such Patent is the only Licensed Patent Covering an Agreement Product in a specific country, Aldeyra shall reimburse Madrigal for its out-of-pocket expenses related to the filing, prosecuting and maintaining of such Licensed Patent in such country.

#### 5.3 Enforcement of Madrigal Technology.

- 5.3.1 <u>Notice</u>. If Aldeyra or Madrigal becomes aware that any Madrigal Technology is being Infringed or misappropriated by a Third Party (collectively, a **"Third Party Infringement"**), Aldeyra or Madrigal, as the case may be, shall promptly notify the other Party thereof in writing, reasonably detailing the Third Party Infringement. Aldeyra will have the sole right, but not the obligation, to enforce any Madrigal Technology in the Field.
- 5.3.2 <u>Madrigal Role If Aldeyra Enforces</u>. Madrigal shall have the right to join such proceeding brought by Aldeyra pursuant to Section 5.3.1 at any time at its own expense. Madrigal shall join such proceeding if it is deemed to be a necessary party and may join such proceeding if otherwise requested by Aldeyra, in each case subject to Aldeyra bearing all of Madrigal's expenses and indemnifying Madrigal from any losses incurred as a result of Madrigal joining such action. Aldeyra shall not admit the invalidity or unenforceability of any Madrigal Technology without Madrigal's prior written consent. Aldeyra shall keep Madrigal reasonably informed prior to and during any such enforcement. Madrigal shall assist Aldeyra, upon request and at Aldeyra's expense, in taking any other reasonable actions to enforce the Madrigal Technology against such Third Party Infringement.
- 5.3.3 <u>Recoveries</u>. All monies recovered upon the final judgment or settlement of any action to enforce the Madrigal Technology shall be used first to reimburse the costs and expenses (including reasonable attorneys' fees and costs) of Madrigal and Aldeyra (pro rata if the recovery is less than the amount to be reimbursed). The remaining portion of any such recovery shall be treated as \*\*\*\*.
- 5.3.4 <u>No Liability for Unfavorable Outcome to Litigation</u>. Neither Party shall incur any liability to the other Party as a consequence of any litigation brought as provided above or any unfavorable decision resulting therefrom, including any decision holding any Patent invalid or unenforceable.

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- 5.4 **Defense of Claims Brought by Third Parties.** If a Third Party initiates a proceeding against either Party claiming that intellectual property Controlled by such Third Party is infringed by the Exploitation of any Agreement Product, each Party that is named as a defendant in such proceeding shall have the right to defend itself in such proceeding. The other Party shall reasonably assist the defending Party in defending such proceeding and cooperate in any such litigation at the request and expense of the defending Party. The defending Party shall provide the other Party with prompt written notice of the commencement of any such proceeding and shall keep the other Party apprised of the progress of such proceeding and shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party. If both Parties are named as defendants in any proceeding, both Parties may defend such proceeding and the Parties shall reasonably cooperate with respect to such defense.
- 5.5 **Patent Listing.** Aldeyra shall have the sole right, but not the obligation, to submit to all applicable Regulatory Authorities patent information pertaining to each applicable Agreement Product pursuant to 21 U.S.C. § 355(b)(1)(G) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction.
- 5.6 **Patent Term Extension.** The Parties shall cooperate with each other in obtaining patent term restoration in any country under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to the Agreement Product. Aldeyra shall determine which relevant Licensed Patents shall be extended (including, without limitation, by filing supplementary protection certificates and any other extensions that are now or in the future become available). In the event that Aldeyra determines not to pursue any such restoration or extension, it shall so inform Madrigal and discuss in good faith with Madrigal such decision. Following any discussion requested by Madrigal, it shall \*\*\*\*.
- 5.7 **Recording.** If Aldeyra deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority in one or more jurisdictions, Madrigal shall reasonably cooperate to execute and deliver to Aldeyra any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Aldeyra's reasonable judgment, to complete such registration or recordation. Aldeyra shall reimburse Madrigal for all reasonable out-of-pocket costs, including attorneys' fees, incurred by Madrigal in complying with the provisions of this Section 5.7.

## ARTICLE 6 REPRESENTATIONS AND WARRANTIES

6.1 **Representations and Warranties of Aldeyra.** Aldeyra hereby represents and warrants to Madrigal, as of the Effective Date, that:

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- 6.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- 6.1.2 it (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
- 6.1.3 this Agreement has been duly executed and delivered on behalf of Aldeyra and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof;
- 6.1.4 the execution, delivery and performance of this Agreement by Aldeyra shall not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and
- 6.1.5 Aldeyra has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement.
- 6.2 **Representations and Warranties of Madrigal.** Madrigal hereby represents and warrants to Aldeyra, as of the Effective Date, that:
  - 6.2.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
  - 6.2.2 it (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
  - 6.2.3 this Agreement has been duly executed and delivered on behalf of Madrigal, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof;
  - 6.2.4 the execution, delivery and performance of this Agreement by Madrigal shall not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

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- 6.2.5 Madrigal has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution and delivery of this Agreement;
- 6.2.6 To Madrigal's knowledge, Madrigal Controls all Patents, Know-How and other intellectual property included in the Madrigal Technology and the Madrigal Technology is free and clear of any liens, charges and encumbrances;
- 6.2.7 as of the Effective Date, neither any license granted by Madrigal to any Third Party, nor any license granted by any Third Party to Madrigal conflicts with the license grants to Aldeyra hereunder and Madrigal is entitled to grant all rights and licenses (or Sublicenses, as the case may be) under such Madrigal Technology as it purports to grant to Aldeyra under this Agreement;
- 6.2.8 Schedule 3.1 sets forth a true, correct and complete list of all investigator-sponsored clinical trial agreements in place between Madrigal and such Third Party investigators for the conduct of clinical trials of Ganetespib in the oncology field;
- 6.2.9 Schedule 1.35 sets forth a true, correct and complete list of all Licensed Patents as of the Effective Date that are exclusively or primarily related to HSP90 Inhibitors in the Field, all of which are Controlled by Madrigal;
- 6.2.10 to Madrigal's knowledge, no Third Party has challenged in writing the extent, validity or enforceability of any Licensed Patent (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);
- 6.2.11 Madrigal has complied with all Applicable Laws, including to the knowledge of Madrigal any disclosure requirements of the United States Patent and Trademark Office or any analogous foreign Governmental Authority, in connection with the prosecution and maintenance of the Licensed Patents and has timely paid all filing and renewal fees payable with respect to any such Licensed Patents, except where any failure to do so would not have a material adverse effect on the rights granted to Aldeyra taken as a whole;
- 6.2.12 Madrigal has obtained assignments from the inventors of all inventorship rights relating to the Madrigal Technology, and all such assignments of inventorship rights relating to such Madrigal Technology are valid and enforceable;
- 6.2.13 to Madrigal's knowledge, no Third Party has any right, title or interest in or to, or any license under, any of the Madrigal Technology in the Field;
- 6.2.14 to Madrigal's knowledge, Madrigal has taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value

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of all Know-How that forms part of the Madrigal Technology that constitutes a trade secret under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants and independent contractors to maintain the confidentiality of such Know-How) and, to Madrigal's knowledge, such Know-How has not been used, disclosed to or discovered by any Third Party except pursuant to confidentiality agreements and there has not been a breach by any party to such confidentiality agreements;

- 6.2.15 no Madrigal Technology is subject to any funding agreement with any government or governmental agency;
- 6.2.16 there are no judgments or settlements against or owed by Madrigal or, to its knowledge, pending or threatened in writing claims or litigation, in either case relating to the Madrigal Technology;
- 6.2.17 there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the best knowledge of Madrigal, threatened in writing against Madrigal in connection with the Madrigal Technology or relating to the transactions contemplated by this Agreement; and
- 6.2.18 Madrigal has not employed (and has not used a contractor or consultant that has employed) any Person debarred by the FDA (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in any capacity in connection with the Madrigal Technology and the Development of Agreement Products.
- 6.3 **Madrigal Covenants.** Madrigal hereby covenants to Aldeyra that, except as expressly permitted under this Agreement:
  - 6.3.1 Madrigal shall not enter into any new agreement or other obligation with any Third Party, or amend an existing agreement with a Third Party, in each case that restricts, limits or encumbers the rights granted to Aldeyra under this Agreement; and
  - 6.3.2 Madrigal shall not and shall cause its Affiliates not to (a) license, sell, assign or otherwise transfer to any Person any Madrigal Technology (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any Madrigal Technology, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness), in both cases in a manner which would impair the rights granted to Aldeyra herein.

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6.4 **Disclaimer.** Except as otherwise expressly set forth in this Agreement, NEITHER PARTY NOR ITS AFFILIATES MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Aldeyra and Madrigal understand that each Agreement Product is the subject of ongoing Development and that neither Party can assure the safety, usefulness or commercial or technical viability of any Agreement Product.

#### ARTICLE 7 INDEMNIFICATION; INSURANCE

7.1 **Indemnification by Aldeyra.** Aldeyra shall indemnify, defend and hold harmless Madrigal, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "**Madrigal Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the Madrigal Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

7.1.1 \*\*\*\*; or

7.1.2 \*\*\*\*.

- 7.2 **Indemnification by Madrigal.** Madrigal shall indemnify, defend and hold harmless Aldeyra, each of its Affiliates, Sublicensees, distributors and each of its and their respective employees, officers, directors and agents (each, a "**Aldeyra Indemnified Party**") from and against any and all Liabilities that the Aldeyra Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:
  - 7.2.1 \*\*\*\*;
  - 7.2.2 \*\*\*\*;

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7.2.3 \*\*\*\*: or

7.2.4 \*\*\*\*.

- 7.3 **Procedure.** Each Party shall notify the other Party in writing if it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 7, such Party (the "**Indemnified Party**") shall give prompt written notice of the indemnity claim to the other Party (the "**Indemnifying Party**") and provide a copy to the Indemnifying Party of any complaint, summons or other written or verbal notice that the Indemnifying Party receives in connection with any such claim. An Indemnified Party's failure to deliver written notice shall relieve the Indemnifying Party of liability to the Indemnified Party under this Article 7 only to the extent such delay is prejudicial to the Indemnified Party shall permit the Indemnifying Party to control any litigation relating to such claim and the disposition of such claim by negotiated settlement or otherwise and any failure to contest prior to assuming control shall be deemed to be an admission of the obligation to indemnify. The Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to such claim and shall not settle or otherwise resolve such claim without the Indemnified Party's prior written consent which shall not be withheld, delayed or conditioned unreasonably other than settlements only involving the payment of monetary awards for which the Indemnifying Party shall be fully-responsible. The Indemnified Party's sole cost and expense.
- 7.4 **Insurance.** Aldeyra shall maintain, at its cost, reasonable insurance against liability and other risks associated with its Exploitation of the rights granted hereunder, and shall furnish to Madrigal evidence of such insurance upon request. Notwithstanding the foregoing, Aldeyra may self-insure to the extent that it self-insures for its other similar activities.
- 7.5 Limitation on Damages. Except \*\*\*\*, in no event shall Madrigal be liable to Aldeyra, or any successor-in-interest, for amounts in excess of \*\*\*\*.

7.6 **LIMITATION OF CONSEQUENTIAL DAMAGES.** Except for (a) claims of a Third Party that are \*\*\*\*, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY \*\*\*\*, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

### ARTICLE 8 TERM AND TERMINATION

- 8.1 **Term.** The term of this Agreement (the "**Term**") shall begin on the Effective Date and shall expire, unless the Agreement is terminated earlier as provided below, on the last to expire of any payment obligation under this Agreement.
- 8.2 **Termination at Will by Aldeyra.** This Agreement may be terminated in its entirety or on an Agreement Product-by-Agreement Product basis at any time by Aldeyra \*\*\*\* notice to Madrigal, provided that no such termination shall be effective prior to Completion by Aldeyra of the preclinical plan described in Schedule 8.2.
- 8.3 Termination for Material Breach. Either Party shall have the right to terminate this agreement for the other Party's material breach.
  - 8.3.1 <u>Aldeyra's Right to Terminate</u>. If Aldeyra believes that Madrigal is in material breach of this Agreement, then Aldeyra may deliver notice of such material breach to Madrigal. If the breach is curable, Madrigal shall have \*\*\*\* (\*\*\*\* in the case of any default in a payment obligation) from the receipt of such notice to cure such breach. If either Madrigal fails to cure such breach within the applicable period or the breach is not subject to cure, Aldeyra in its sole discretion may terminate this Agreement by providing written notice to Madrigal.
  - 8.3.2 <u>Madrigal's Right to Terminate</u>. If Madrigal believes that Aldeyra is in material breach of this Agreement, then Madrigal may deliver notice of such material breach to Aldeyra. If the breach is curable, Aldeyra shall have \*\*\*\* (\*\*\*\* in the case of any default in a payment obligation) following receipt of such notice to cure such breach. If Aldeyra fails to cure such breach within the applicable period or the breach is not subject to cure, Madrigal in its sole discretion may terminate this Agreement by providing written notice to Aldeyra.

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#### CONFIDENTIAL TREATMENT REQUESTED

- 8.3.3 Disputes Regarding Material Breach. Notwithstanding the foregoing, if the Party that is in purported breach of this Agreement (the "Breaching Party") in this Section 8.3 disputes in good faith the existence, materiality, or failure to cure of any such breach, and provides notice to the other Party (the "Non-Breaching Party") of such dispute within the relevant cure period, the Non-Breaching Party shall not have the right to terminate this Agreement, unless and until the relevant dispute has been resolved. It is understood and acknowledged that during the pendency of such dispute, all the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.
- 8.4 **Patent Challenge.** Madrigal shall have the right to terminate this Agreement immediately upon written notice to Aldeyra if Aldeyra or any of its Affiliates or Sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of, or the grant of a supplementary protection certificate with respect to, any Licensed Patent.
- 8.5 **Termination for Insolvency.** If either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within \*\*\*\* of the filing thereof (each, an "**Insolvency Event**"), then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to insolvent Party.
  - 8.5.1 If Aldeyra terminates this Agreement pursuant to this Section 8.5, all rights and licenses now or hereafter granted by Madrigal to Aldeyra under or pursuant to this Agreement, with respect to the Madrigal Technology Patents are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Madrigal agrees that Aldeyra, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. If (x) a case under the U.S. Bankruptcy Code is commenced by or against Madrigal, (y) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (z) Aldeyra elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, Madrigal (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall not interfere with Aldeyra's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

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### 8.6 **Consequences of Expiration or Termination of the Agreement.**

- 8.6.1 <u>Expiration of Term</u>. If this Agreement expires, rather than being terminated early, the licenses shall be fully paid and irrevocable.
- 8.6.2 In General. On expiration or termination of this Agreement for any reason, the following terms shall apply:
  - (a) Termination or expiration of this Agreement for any reason shall be without prejudice to any rights or financial compensation that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.
  - (b) The following provisions of this Agreement shall survive the expiration or termination of this Agreement: Article 1 (to the extent relevant to other surviving provisions), Article 4 (to the extent of obligations accrued prior to expiration or termination), Section 5.1, Section 6.4, Article 7 (to the extent of Liabilities accruing prior to expiration or termination), Article 9, and Article 10.
- 8.6.3 <u>Termination</u>. If this Agreement is terminated before the expiration of the Term by a Party, then, in addition to the terms set forth in Section 8.6.2, the following terms shall apply:
  - the Parties shall return (or destroy, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party's Confidential Information. Notwithstanding the foregoing, the Parties shall be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes;
  - (b) except as set forth in Section 8.6.3(d), the applicable licenses granted by Madrigal to Aldeyra under this Agreement shall terminate, and Aldeyra and its Affiliates shall cease Exploiting Agreement Products (but only to the extent such Agreement Products were either (i) generated using the Madrigal Technology or (ii) Covered by a Licensed Patent) or otherwise use the Madrigal Technology;
  - (c) except as explicitly set forth in Section 8.6.2, Aldeyra shall have no further rights and Madrigal shall have no further obligations under the Agreement; and
  - (d) any granted Sublicenses will remain in full force and effect; provided that the Sublicensee is not then in breach of its sublicense agreement, and the Sublicensee agrees to be bound to Madrigal as a licensor under the terms

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and conditions of the sublicense agreement, provided that in no event shall Madrigal have obligations or liabilities under such sublicense agreement in excess of Madrigal's obligations or liabilities under this Agreement. Madrigal will enter into appropriate agreements or amendments to the sublicense agreement to substitute itself for Aldeyra as the licensor under such agreement.

#### ARTICLE 9 CONFIDENTIALITY

- 9.1 **Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for \*\*\*\* thereafter, each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder shall: (a) keep the Disclosing Party's Confidential Information confidential; (b) not publish, or allow to be published, and shall not otherwise disclose, or permit the disclosure of, the Disclosing Party's Confidential Information in any manner not expressly authorized pursuant to the terms of this Agreement; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly authorized pursuant to the terms of this Agreement. Without limiting the generality of the foregoing, to the extent that Aldeyra provides to Madrigal any Confidential Information owned by any Third Party, Madrigal shall handle such Confidential Information in accordance with the terms and conditions of this Article 9 applicable to a Receiving Party.
- 9.2 **Authorized Disclosure.** Notwithstanding the foregoing provisions of Section 9.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to:
  - 9.2.1 file or prosecute patent applications as contemplated by this Agreement;
  - 9.2.2 prosecute or defend litigation;
  - 9.2.3 exercise its rights and perform its obligations hereunder;
  - 9.2.4 subject to the remainder of this Section 9.2, to its advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein (which may include professional ethical obligations); or
  - 9.2.5 comply with Applicable Law.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this Section 9.2, the Disclosing Party shall to the extent possible give reasonable advance written notice of such disclosure to the other Party and take reasonable measures to ensure confidential

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treatment of such information. In addition to the foregoing, Aldeyra may disclose Madrigal's Confidential Information to Third Parties in connection with the actual or potential Exploitation of Agreement Products; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein.

Notwithstanding anything to the contrary contained herein, in no event may Madrigal disclose Aldeyra's Confidential Information to any Third Party (including any of Madrigal's investors, collaborators or licensees) engaged in the Exploitation of an HSP90 Inhibitor for any indication which is being Exploited by Aldeyra.

- 9.3 **SEC Filings and Other Disclosures.** Either Party may disclose the terms of this Agreement to the extent required to comply with Applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country; *provided*, that such Party shall submit to the other Party its proposed disclosure at least ten (10) days prior to disclosure, with redactions if applicable, and reasonably consider the comments of the other Party regarding confidential treatment sought for such disclosure.
- 9.4 **Residual Knowledge Exception.** Notwithstanding any provision of this Agreement to the contrary, Confidential Information shall not include Residual Knowledge. Any use made by the Receiving Party of Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

### 9.5 **Public Announcements**.

9.5.1 <u>Public Announcements</u>. Each Party understands that this Agreement is likely to be of significant interest to investors, analysts and others and, therefore, that either Party has the right to make announcements of events or developments with respect to this Agreement that are material to such Party. The Parties agree that any such announcement will not contain Confidential Information of the other Party or, if disclosure of Confidential information is required by law or regulation or the rules of the U.S. Securities and Exchange Commission, any stock exchange or listing entity, will make reasonable efforts to minimize such disclosure and obtain confidential treatment for any such information that is disclosed to a Governmental Authority. Each Party agrees to provide the other Party with a copy of any public announcement as soon as reasonably practicable prior to its scheduled release. Except in the case of extraordinary circumstances, each Party will provide the other with an advance copy of any announcement regarding this Agreement, provided that such right of review and recommendation will only apply for the first time that specific information is disclosed and will not apply to the subsequent disclosure of substantially similar information that has been previously disclosed.

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- 9.5.2 <u>No Use of Names</u>. Except as otherwise required by Applicable Law, neither Party shall disclose or use the name or other identifying marks of the other Party in any advertisement, press release or other publicity inconsistent with such public announcements, without that Party's prior written approval.
- 9.6 **Publications.** During the Term, Aldeyra shall make all determinations in its sole discretion regarding any proposed academic, scientific and medical publication or public presentation related to any Agreement Product or any activities conducted pursuant to this Agreement.

### ARTICLE 10 MISCELLANEOUS

- 10.1 **Assignment.** Neither this Agreement nor any interest hereunder shall be assignable by either Party without the prior written consent of the other Party, except as follows: (a) a Party may, subject to the terms of this Agreement, assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets or sale of stock or ownership interest; and (b) either Party may assign its rights and obligations under this Agreement to any of its Affiliates; *provided* that such Party shall remain liable for all of its rights and obligations under this Agreement. The assigning or transferring Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 10.1. This Agreement shall be binding upon the successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 10.1 shall be void.
- 10.2 **Force Majeure.** Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party uses Commercially Reasonable Efforts to remove the condition.
- 10.3 **Representation by Legal Counsel.** Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party that drafted such terms and provisions.
- 10.4 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or emailed PDF (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or sent by nationally-recognized overnight courier, addressed as follows:

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If to Aldeyra:

Aldeyra Therapeutics, Inc. 131 Hartwell Avenue, Suite 320 Lexington, MA 02421 Attn: Chief Executive Officer

with a copy to:

Faber Daeufer & Itrato PC 890 Winter Street Suite 315 Waltham, MA 02451 Attn: Joseph Faber

If to Madrigal:

Madrigal Pharmaceuticals 200 Barr Harbor Drive, Suite 400 West Conshohocken, PA 19428 Attn: Chief Executive Officer

with a copy to:

Stradling Yocca Carlson & Rauth, P.C. 660 Newport Center Drive, Suite 1600 Newport Beach, CA 92660 Attn: Michael Lawhead

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile or email PDF on a Business Day (or if delivered or sent on a non-business day, then on the next Business Day); or (b) on receipt if sent by overnight courier.

- 10.5 **Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each of Aldeyra and Madrigal.
- 10.6 **Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.
- 10.7 **Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this

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Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause of portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as shall most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

- 10.8 **Descriptive Headings.** The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 10.9 **Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries that may be imposed upon or related to Madrigal or Aldeyra from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.
- 10.10 **Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term or after the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties, out of or in relation to or in connection with this Agreement, including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Chief Executive Officers (or his or her senior executive non-counsel designee) of each Party. If the matter is not resolved within \*\*\*\* following the request for discussions, either Party may then invoke the provisions of Section 10.11.
- 10.11 **Arbitration.** Any dispute, controversy or claim arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement that is not resolved pursuant to Section 10.10, shall be settled by binding arbitration administered by the American Arbitration Association pursuant to its Commercial Arbitration Rules (the "AAA Rules") then in effect, except as otherwise provided herein. The arbitration shall be governed by the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the **"Federal Arbitration Act"**), to the exclusion of any inconsistent state laws. The arbitration shall be conducted by three arbitrators, who shall be selected in accordance with the AAA Rules. The United States Federal Rules of Civil Procedure shall govern discovery and the rules of evidence for the arbitration. The arbitration will be conducted in Boston, Massachusetts, if initiated by

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Madrigal, and in Philadelphia, Pennsylvania, if initiated by Aldeyra, and the Parties consent to the personal jurisdiction of the United States federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. Any situation not expressly covered by this Agreement shall be decided in accordance with the AAA Rules.

- 10.12 **Governing Law.** This Agreement, and all claims arising under or in connection therewith, shall be governed by and interpreted in accordance with the substantive laws of The Commonwealth of Pennsylvania, without regard to conflict of law principles thereof, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued.
- 10.13 **Entire Agreement.** This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof, including that certain Confidentiality Agreement between Aldeyra and Madrigal dated April 18, 2016, which is hereby superseded and replaced in its entirety as of the Effective Date, and any Confidential Information disclosed by the Parties under such agreement shall be treated in accordance with the provisions of Article 9.
- 10.14 **Independent Contractors.** Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.
- 10.15 **Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation," (c) the word "shall" shall be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" shall

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mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), and (l) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."

- 10.16 **No Third Party Rights or Obligations.** No provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligations in any Person not a Party to this Agreement except for the provisions of Article 7 (Indemnification) (with respect to which the persons to which Article 7 (Indemnification) applies shall be Third Party beneficiaries for Article 7 (Indemnification) only in accordance with the terms and conditions of Article 7 (Indemnification)).
- 10.17 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 10.18 **Counterparts.** This Agreement may be executed in two counterparts, each of which shall be an original and both of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile or digital transmission (.pdf), each of which shall be binding when received by the applicable Party.
- 10.19 **Affiliates.** Aldeyra may perform any activities authorized under this Agreement itself or through any of its Affiliates. Aldeyra will be responsible for compliance by its Affiliates with this Agreement and will be responsible for all acts and omissions of such Affiliates as if committed or omitted by Aldeyra.

### CONFIDENTIAL TREATMENT REQUESTED

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

# ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady

Todd C. Brady C.E.O.

### MADRIGAL PHARMACEUTICALS, INC.

By: /s/ Paul A Friedman

Paul A. Friedman C.E.O.

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### **Licensed Patents**

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## Regulatory Approvals and On-Going Investigator-Sponsored Clinical Trials

<u>Trial Name</u> ****	Primary Investigator ****	Countries ****	Sites ****	Number active patients on study drug ****
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Schedule 8.2

Preclinical Assessment Plan