UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For transition period from _____to_____

Commission file number 001-36332

ALDEYRA THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**20-1968197**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of Principal Executive Offices)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer a smaller reporting company or an emerging growth company. See the definitions of the "large accelerated filer," "accelerated filer," "non-accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller reporting company	☒
		Emerging Growth Company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2023, the last business day of the registrant's last completed second quarter, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was approximately $483,311,890, based on the closing price of the registrant's Common Stock, as reported by The Nasdaq Capital Market. Shares of Common Stock held by each executive officer, director and stockholders known by the registrant to be affiliated with such individuals based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 5, 2024 there were 58,895,768 shares of the registrant's Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the registrant's 2024 Annual Meeting of Stockholders, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Aldeyra Therapeutics, Inc.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2023
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements throughout this report are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "contemplates," "predict," "project," "target," "likely," "potential," "continue," "ongoing," "design," "might," "objective," "will," "would," "should," "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

- our plans to develop and commercialize reproxalap and any other product candidates, if approved;
- delay in or failure to obtain regulatory approval of reproxalap or any of our other product candidates, including as a result of the U.S. Food and Drug Administration (FDA) not accepting our regulatory filings or requiring additional clinical trials or data prior to review or approval of such filings;
- the likelihood and timing of the FDA's potential approval of a potential resubmission of the new drug application (NDA) for reproxalap;
- the adequacy of the data included in the potential resubmission of the NDA or the supplemental responses to the FDA;
- the likelihood and timing of the exercise of the exclusive option (the Option) by AbbVie Inc. (AbbVie) pursuant to the exclusive option agreement with AbbVie;
- the ability to maintain regulatory approval of reproxalap or any of our other our product candidates, if received, and the labeling for any approved products;
- uncertainty as to our ability to commercialize (alone or with others) and obtain reimbursement for reproxalap or any of our other product candidates following regulatory approval, if any;
- the size and growth of the potential markets and pricing for reproxalap or any of our other product candidates following regulatory approval, if any, and the ability to serve those markets;
- the rate and degree of market acceptance of any of reproxalap or any of our other product candidates following regulatory approval, if any;
- the timing of enrollment, commencement, and completion of our clinical trials;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving our product candidates;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- our expectations regarding our expenses and future revenue, the timing of future revenue, the sufficiency or use of our cash resources and needs for additional financing;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;

- our commercialization, marketing, and manufacturing capabilities and strategy;
- our ability to establish and maintain development and commercialization partnerships;
- our ability to successfully integrate acquisitions into our business;
- our expectations regarding federal, state and foreign regulatory requirements;
- political, economic, legal, social and health risks, public health measures, and war or other military actions, that may affect our business, results of operations and financial position, or the global economy;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain intellectual property protection for our product candidates; and
- the anticipated trends and challenges in our business and the market in which we operate.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission (SEC). Investors, the media, and others should note that we intend to announce material information to the public through filings with the SEC, the investor relations page on our website (https://ir.aldeyra.com), press releases, public conference calls, webcasts, and social media channels, including Facebook, and LinkedIn. The information disclosed by the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels. Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website. The contents of the websites provided above are not incorporated into this filing or in any other report or document we file with the SEC. These website addresses are intended to be inactive textual references only.

We encourage you to read the discussion and analysis of our financial condition and our financial statements contained in this annual report on Form 10-K. We also encourage you to read Item 1A of Part 1 of this annual report on Form 10-K, entitled “Risk Factors,” which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the SEC from time to time, including Forms 10-Q, 8-K and 10-K, which may supplement, modify, supersede or update those risk factors. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that our results will lead to the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

As used in this annual report on Form 10-K, the terms “Aldeyra,” “Registrant,” “the Company,” “we,” “us,” and “our” mean Aldeyra Therapeutics, Inc., together with its wholly-owned subsidiaries, unless the context indicates otherwise.

INDUSTRY AND MARKET DATA

We obtained the industry, market and certain other data used throughout this annual report on Form 10-K from our own internal estimates and research, as well as from industry and general publications, surveys and studies conducted by third parties. Internal estimates are derived from publicly-available information released by industry analysts and third-party sources, our internal research, and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and other data included in this annual report on Form 10-K are reliable and based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors". These and other factors could cause results to differ materially from those expressed in the estimates made by independent parties and by us.

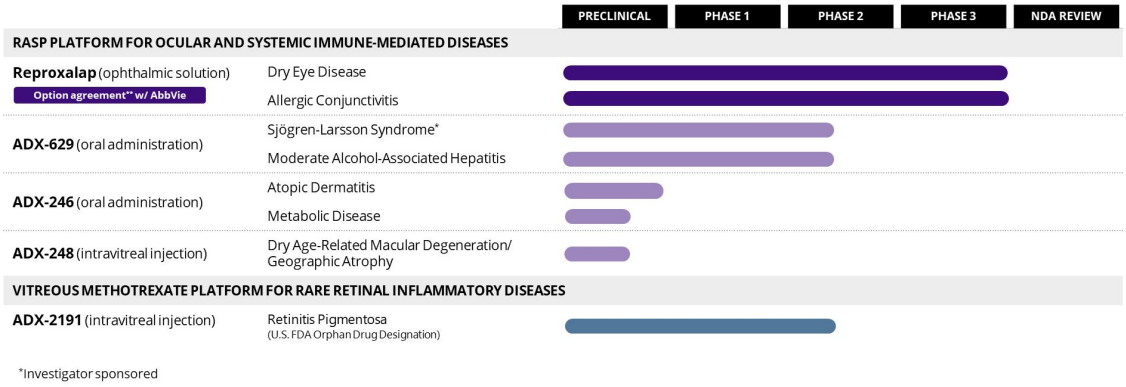
ITEM 1. *BUSINESS*

Overview

We are a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. We are developing a novel pharmaceutical platform targeting a class of toxic endogenous small molecules known as RASP (reactive aldehyde species) that are associated with many inflammatory, metabolic, and neurodegenerative diseases. Our RASP modulator product pipeline includes ADX-629, a novel orally administered RASP modulator in clinical development for moderate alcohol-associated hepatitis and Sjögren-Larsson Syndrome. Our preclinical RASP platform includes ADX-246, ADX-248, and other drug candidates in development for systemic inflammatory, metabolic and retinal diseases. The validity of the RASP platform is supported by reproxalap, our first-in-class product candidate in late-stage development for the treatment of dry eye disease. Reproxalap has demonstrated broad-based, rapid-onset activity and consistent safety across a number of Phase 2 and Phase 3 clinical trials. We have additional product candidates in development, including ADX-2191, which is in clinical development for the treatment of retinitis pigmentosa, a rare retinal disease characterized by inflammation and vision loss. ADX-2191 has received Orphan Drug Designation for the treatment of retinitis pigmentosa.

Our pipeline, as of the date of filing this annual report on Form 10-K is illustrated below.

Product Candidate Development Pipeline



On October 31, 2023 (the Option Agreement Effective Date), we entered into an exclusive option agreement (the Option Agreement) with AbbVie Inc. (AbbVie), pursuant to which we granted AbbVie an exclusive option (the Option) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with us to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by us in the field of ophthalmology relating to treating conditions of the ocular surface, and (d) a right to review data for any other compounds that are owned or otherwise controlled by us in the fields of ophthalmology and immunology before such data is shared with any other third party (the Collaboration Agreement). AbbVie has paid us a non-refundable payment of $1 million in consideration of the Option (the Option Payment).

On December 21, 2023, pursuant to the Option Agreement, AbbVie extended the period during which it may exercise the Option (the Exercise Period Extension) by paying us a non-refundable payment of $5 million (the Option Extension Fee). As a result of the Exercise Period Extension, AbbVie may exercise the Option by delivering written notice to us at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the date, if any, that we receive approval from the U.S. Food and Drug Administration of the NDA for reproxalap in dry eye disease (the FDA Decision) and (b) the date that is eighteen (18) months after the Option Agreement Effective Date. If the Collaboration Agreement is entered into, the Option Payment and the Option Extension Fee will be credited against the upfront cash payment payable by AbbVie.

Upon AbbVie's delivery of the agreement execution notice and the parties entering into the Collaboration Agreement, AbbVie would pay us a $100 million upfront cash payment, less the Option Payment and the Option Extension Fee. In addition, we would be eligible to receive up to approximately $300 million in regulatory and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA Decision is received prior to or after the execution of the Collaboration Agreement. In the United States, we would share profits and losses with AbbVie from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for us. Outside of the United States, we would be eligible to receive tiered royalties on net sales of reproxalap.

All of our development plans and timelines are subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, funding, and other factors that could delay the initiation, completion, or reporting of clinical trials. Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. The timing of ongoing clinical trials depends, in part, on the availability of clinical research facilities and staffing, and the ability to recruit patients.

As we continue to execute on our strategy of expanding our product candidate pipeline, we may license or acquire new immune-modulating approaches with novel therapeutic potential. In January 2019, we acquired Helio Vision, Inc. and thereby obtained rights to ADX-2191.

We have no products approved for sale in the United States or elsewhere. We will not receive any revenue from sales of our product candidates that we develop until we obtain regulatory approval. We intend to commercialize our products, if approved for sale, directly or through collaborations. Although we may receive commercial and license revenue in the future, we have to date primarily funded our operations through the sale of our common stock, convertible preferred stock, convertible promissory notes, warrants, and borrowings under debt facilities. We will need to raise additional capital in the form of debt or equity or through partnerships to fund additional development of our product candidates, and we may in-license, acquire, or invest in complementary businesses or products. In addition, contingent on capital resources, we may augment, diminish, or otherwise modify the clinical development plan described herein.

Since our incorporation, we have devoted substantially all of our resources to the preclinical and clinical development of our product candidates. If we do obtain marketing approval for reproxalap or any other product candidate that we develop, we intend to partner with other companies for commercialization, though there can be no guarantee that such partnership will be available. Our ability to generate revenues, if any, largely depends upon our ability, alone or with others, to complete development of and obtain regulatory approvals for our product candidates, and to successfully manufacture, market, and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter, and depend on a number of factors, including risks related to our business and industry, risks relating to intellectual property and other legal matters, risks related to our common stock, and other risks that are detailed in the section of this annual report on Form 10-K entitled "Risk Factors".

The Science Supporting Our Product Candidates

RASP: Mediators of Disease

In response to infection, injury, endogenous and exogenous chemical triggers, heat, and other stimuli, RASP (reactive aldehyde species) are generated through a variety of metabolic processes, including alcohol oxidation, enzymatic and non-enzymatic lipid oxidation, and polyamine and sphingosine metabolism. RASP appear to effect inflammation signaling via covalent binding to thiol (sulfur-containing) and amine (nitrogen-containing) residues on proteins, including receptors and enzymes. RASP-protein adducts directly influence the function of proteins, leading

to activation of intracellular inflammatory factors, including NF-κB, an important mediator in the inflammatory response, and inflammasomes. In addition, RASP adducts bind to Scavenger Receptor A, which also initiates pro-inflammatory signaling and leads to the formation of antibodies against the adducted protein, at least in part explaining the presence of host-directed antibodies in autoimmune diseases such as rheumatoid arthritis. Levels of RASP are generally observed to be elevated in ocular and systemic inflammatory disease, including the diseases represented in our RASP modulator pipeline, and thus represent therapeutic targets for immune modulation. RASP are also associated with metabolic and neurodegenerative diseases, and, in addition to upregulating inflammation, lead to DNA damage, accumulation of metabolic aggregates, and other pathologic outcomes.

Because of the inherent toxicity of RASP, most, if not all, living organisms contain enzymes, such as aldehyde reductases and aldehyde dehydrogenases, that convert RASP into non-toxic molecules. Genetic mutations in the RASP-metabolizing enzymes cause disease. In Sjögren-Larsson Syndrome, for example, mutations in fatty aldehyde dehydrogenase are responsible for skin, neurological, and retinal disease.

Aside from the potentiation of inflammation, there is no generally accepted biological role of high levels of RASP. Some physiologic molecules have RASP forms, including retinaldehyde (a form of Vitamin A) and pyridoxal and pyridoxal phosphate (forms of Vitamin B6), but the activity of physiological RASP is highly restricted by chaperone and other proteins that prevent reaction with other molecules, including our RASP modulators. Thus, pharmacotherapeutic RASP modulation is expected not to adversely affect normal physiologic processes. Consistent with the lack of accessibility of physiologic RASP, our most advanced RASP modulator, reproxalap, which has been administered as an ophthalmic solution to approximately 2,300 patients across a number of completed clinical trials for up to 12 months, has been observed to be generally well tolerated and has not been associated with any serious adverse events. Similarly, our most advanced orally administered RASP modulator, ADX-629, which has been administered to more than 150 patients across a number of Phase 1 and Phase 2 clinical trials for up to 90 days, has been observed to be generally well tolerated and has not been associated with any serious adverse events.

The RASP Modulator Platform

Because RASP affect many proteins simultaneously, the RASP modulator platform represents a unique and novel pharmacologic approach that, unlike almost all drugs in use today, is not designed to directly inhibit or activate a particular protein but instead targets a family of small molecules that in turn affect the activity and structure of many proteins at once. RASP modulation, therefore, has the potential to down-regulate pro-inflammatory systems or groups of proteins, and may lead to multiple beneficial clinical effects while avoiding toxicity associated with single-target inhibition or activation.

We are currently developing ADX-629, ADX-246, ADX-248, and other novel RASP modulators for the treatment of a number of diseases associated with RASP. RASP modulators are novel small molecules designed specifically to bind, and thereby allow for the degradation of, RASP. The validity of the RASP platform is supported by reproxalap, our first-in-class product candidate for the treatment of dry eye disease, which has demonstrated broad-based, rapid-onset activity and consistent safety across a number of Phase 2 and Phase 3 clinical trials. In *in vitro* and animal studies, reproxalap does not appear to affect most cellular components, including most receptors, enzymes, ion channels, or other proteins. Reproxalap has been shown to outcompete cellular constituents to covalently bind and trap RASP. Reproxalap-RASP adducts appear to be rapidly degraded in cellular environments, after which neither reproxalap nor RASP are detectable. Outside of biological systems, reproxalap-RASP adducts have shown to be remarkably non-reactive and stable, suggesting that reproxalap-RASP binding may be effectively irreversible. By forming covalent drug-RASP adducts that are then degraded, reproxalap and other RASP modulators have the potential to substantially lower RASP levels.

We believe that we are the first biotechnology company to demonstrate the beneficial effects of RASP modulation in a variety of animal models relating to immune-mediated disease, suggesting that RASP modulators may have potent anti-inflammatory effects that persist hours after administration at a variety of different doses relevant to clinical testing

- In mouse models of ocular inflammation and post-surgical healing, topically applied reproxalap ophthalmic solution reduced ocular redness and inflammatory cytokines comparable to corticosteroid therapy and slowed the development of corneal haze (fibrosis). (Data presented at The Association for Research in Vision and Ophthalmology 2015 Annual Meeting)
- In mice injected with a pro-inflammatory agent known as endotoxin, intraperitoneally administered reproxalap statistically reduced a variety of inflammatory cytokines (protein inflammatory mediators), including IL 5, Il 1ß, IL 17, and TNFα, while up-regulating the primary anti-inflammatory cytokine IL 10. Additionally, in models of mouse contact dermatitis (induced by phorbol myristate acetate) and allergic contact dermatitis (induced by sensitivity to oxazolone), reproxalap statistically reduced inflammation as measured by edema (swelling). (Data presented at The American Academy of Asthma Allergy & Immunology 2015 Annual Meeting)
- In a model of radiation mucositis (oral inflammation) in hamsters, chronic subcutaneous administration of reproxalap reduced healing time and decreased fibrosis (scarring). (Data presented at the Multinational Association of Supportive Care in Cancer – International Society of Oral Oncology 2015 Annual Meeting)
- In two different mouse models of inflammatory pain, intraperitoneally administered reproxalap dose-dependently reduced nociceptive behavior, suggesting that reproxalap down-regulates pain signaling in inflammation. (Data presented at The 2016 International Conference on Pain Research and Management)
- In rat cardiomyocyte culture, reproxalap prevented fibrotic transformation, and inhibited NF κB activation and IL 1ß release. (Data presented at The American Society for Cell Biology® 2016 Annual Meeting)
- In a mouse model of lung inflammation, intraperitoneal administration of reproxalap reduced infiltration of inflammatory cells and levels of pro-inflammatory cytokines in the lung. (Data presented at The World Congress on Inflammation 2017 Annual Meeting)
- In a rat model of intraocular inflammation, a single intravitreal injection of the RASP modulator ADX 103 reduced the development of retinal pathology. (Data presented at The Association for Research in Vision and Ophthalmology 2018 Annual Meeting)
- In a rat model of diabetic macular edema, intravitreal injection of ADX 103 reduced retinal inflammatory cell infiltration. (Data presented at The Association for Research in Vision and Ophthalmology 2018 Annual Meeting)
- In mice injected with endotoxin, orally administered ADX 629 statistically reduced a variety of inflammatory cytokines, including IL 5, Il 1ß, IL 17, IFN , and TNFα, while up-regulating the primary anti-inflammatory cytokine IL 10.
- In a mouse model of lung inflammation, oral administration of ADX 629 reduced infiltration of inflammatory cells in the lung.
- In a mouse model of ulcerative colitis, intraperitoneal administration of ADX 629 reduced the disease activity index, a composite score of histology, organ weights, and other indicators of disease severity. • In a rat model of nephritis (kidney inflammation), oral administration of ADX 629 reduced proteinuria (protein in urine), an indicator of renal dysfunction.

Thus, we believe that the mechanism of action of RASP modulation is potentially multifactorial – lowering inflammation, reducing healing time, diminishing scarring, and mitigating inflammatory pain – and may ameliorate inflammatory and other diseases and deter disease progression in different ways simultaneously, consistent with a systems-based pharmacologic approach.

In addition to the development of ADX-629, ADX-246, and ADX-248, we intend to continue the discovery and development of other novel RASP modulators, and we intend to continue to develop intellectual property around the molecules derived from our RASP modulator platform.

The Potential of ADX-2191 to Treat Retinitis Pigmentosa

ADX-2191 is a novel intravitreal formulation of methotrexate, a dihydrofolate reductase inhibitor that has been administered intravenously for decades to treat cancer and inflammatory diseases.

Retinitis pigmentosa is a group of rare genetic eye diseases characterized by retinal cell death and loss of vision, for which there is no treatment. In vivo preclinical research has identified the activity of methotrexate in inducing misfolded rhodopsin (a visual cycle protein) clearance, suggesting the potential of ADX-2191 to treat genetic forms of retinitis pigmentosa that are characterized by misfolded rhodopsin.

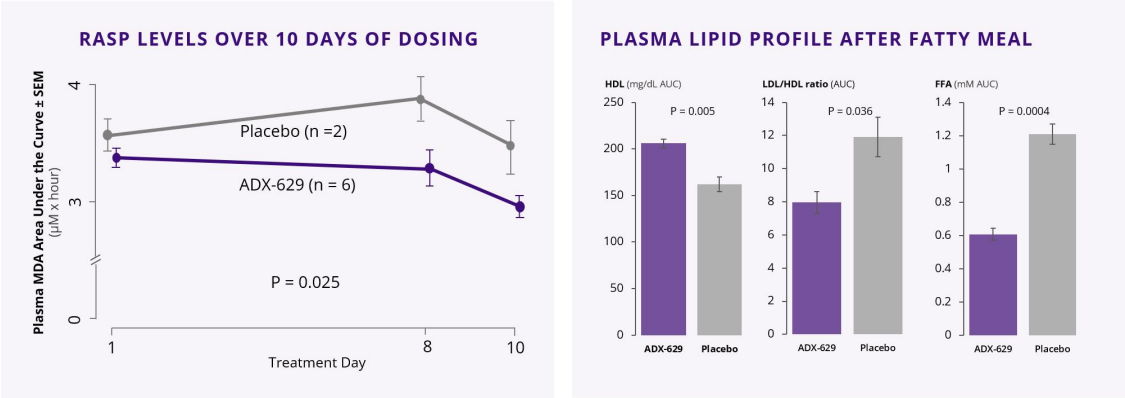
Clinical Trial Results and Development Plans

Prior to applying for marketing approval, our product candidates must satisfy regulatory authority requirements for safety and efficacy, including pivotal Phase 3 clinical assessment. Our material clinical results have been previously disclosed elsewhere in detail, and we encourage review of all of our clinical trial disclosures in addition to this annual report on Form 10-K. All of our development plans and timelines are subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, funding, and other factors that could delay the initiation, completion, or reporting of clinical trials.

Systemic RASP Modulation for the Treatment of Immune-Mediated Diseases

ADX-629 is a novel, orally administered RASP modulator in Phase 2 clinical development for the treatment of systemic immune-mediated diseases. In a Phase 1 clinical trial of ADX-629, no treatment-related adverse events were observed at any dose tested, and target engagement was evidenced by statistically lower levels of the RASP malondialdehyde in drug-treated subjects relative to controls. Additionally, following ingestion of a controlled high-fat meal, free fatty acids were statistically lower and HDL statistically higher in drug-treated subjects relative to placebo-treated subjects. The lipid results in the Phase 1 clinical trial suggested that ADX-629 diminished the inflammatory and pathologic metabolic response that typically occurs following ingestion of a high-fat meal.

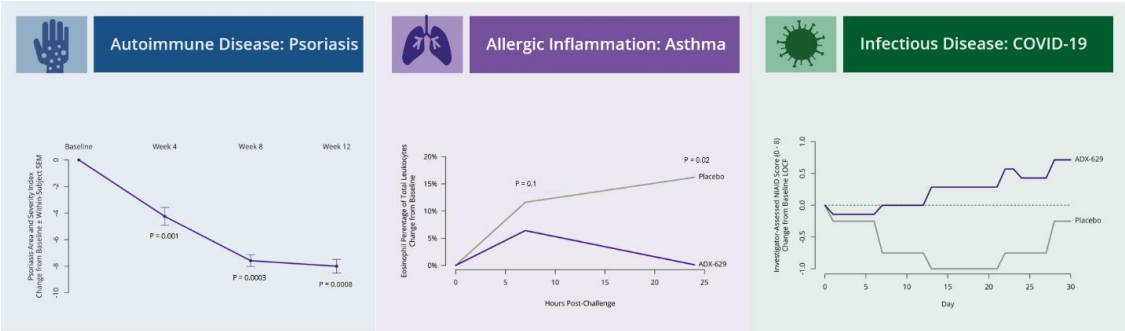
Figure 1: Phase 1 Clinical Trial of ADX-629



MDA = malondialdehyde; SEM = standard error of the mean; HDL= high-density lipoprotein; LDL = low-density lipoprotein; FFA = free fatty acids

In 2022, we announced results from Phase 2 clinical trials of ADX-629 in patients with psoriasis, atopic asthma, COVID-19, or alcohol intoxication, all of which suggested preliminary pharmacodynamic activity of ADX-629. The Phase 2 trials were performed as part of a systematic strategy to assess activity in different types of immunological and metabolic diseases, including autoimmune disease, allergic inflammation, infectious disease, and alcohol intoxication. Across all Phase 2 clinical trials, in patients treated with ADX-629, no safety concerns were evident from adverse events and there were no treatment-related serious adverse events observed.

Figure 2: Phase 2 Clinical Trials of ADX-629 Psoriasis, Asthma, and COVID-19



SEM = standard error of the mean; NIAID = National Institute of Allergy and Infectious Diseases;
LOCF = Last Observation Carried Forward

Psoriasis

Following treatment of 10 moderate psoriasis patients with ADX-629 for 12 weeks, psoriasis area and severity index (PASI) scores were statistically significantly decreased (P=0.0008 vs. baseline at Week 12), and peak PASI 50% and PASI 75% responder percentages were 57% (P=0.001) and 25% (P=0.051), respectively. Investigator global assessment scores decreased over the duration of treatment (P=0.01 vs. baseline at Week 12). Lesional pan-gene expression analysis suggested a trend toward normalization of global gene expression patterns; by Week 12 no gene expression pathways in lesional tissue were dysregulated compared to non-lesional skin. Plasma levels of the commonly described pro-inflammatory RASP malondialdehyde were reduced relative to baseline as soon as four weeks after initiation of treatment (P=0.02).

Asthma

In a placebo-controlled crossover trial of eight mild asthma patients treated for seven days, asthma symptom scores and sputum eosinophil cell counts were numerically reduced following treatment with ADX-629 relative to treatment with placebo. Compared to placebo treatment, treatment with ADX-629 led to statistically significant reductions in plasma levels of the pro-inflammatory cytokines IL-5 (P=0.02) and TNFα (P<0.0001), and numerical reductions in symptoms and in plasma levels of malondialdehyde.

COVID-19

Following treatment of 11 mild to moderate COVID-19 patients with ADX-629 or placebo for four weeks, change from baseline in the National Institute of Allergy and Infectious Diseases Score (1=death, 8=no activity limitation) was numerically higher in ADX-629-treated patients (n=7) than in placebo-treated patients (n=4) over all days assessed. Consistent with the clinical findings, relative to placebo-treated patients, reductions in plasma levels of the cytokines CXCL9 (P=0.0008), IFNγ (P=0.02), and TNFα (P=0.07) were observed in patients treated with ADX-629.

Alcohol Intoxication

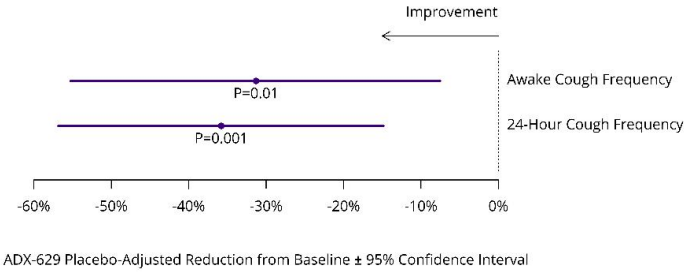
In a crossover trial of 23 healthy volunteers, where each subject received ADX-629 or placebo prior to ethanol ingestion, ADX-629 was statistically superior to placebo in improving Romberg test balance time (P=0.02); reducing facial flushing (P=0.0007); and lowering levels of the RASP acetaldehyde (P=0.03), total cholesterol (P=0.02), and LDL (P=0.047).

In 2023, as an extension of the strategy to assess activity in different types of diseases, we announced results from Phase 2 clinical trials of ADX-629 in patients with chronic cough and atopic dermatitis, both of which are persistently disturbing diseases thought to be related, at least in part, to inflammation.

Chronic Cough

Fifty-one patients with refractory or unexplained chronic cough, which is often defined as a cough that persists for more than eight weeks and is unresponsive to treatment were enrolled in a multicenter, randomized, double-blind, placebo-controlled, two-period Phase 2 crossover trial. Patients were randomized to receive ADX-629 or placebo twice daily for 14 days, followed by a 14-day washout period prior to crossing over to 14 days of treatment with ADX-629 or placebo, whichever was not received in the first period. All patients completed both treatment periods. Relative to placebo, statistical significance was achieved for the key secondary endpoint of reduction in awake cough frequency (P=0.01), the secondary endpoint of 24-hour cough frequency (P=0.001), and the related post-hoc analyses of awake cough count (P=0.001) and 24-hour cough count (P=0.001).

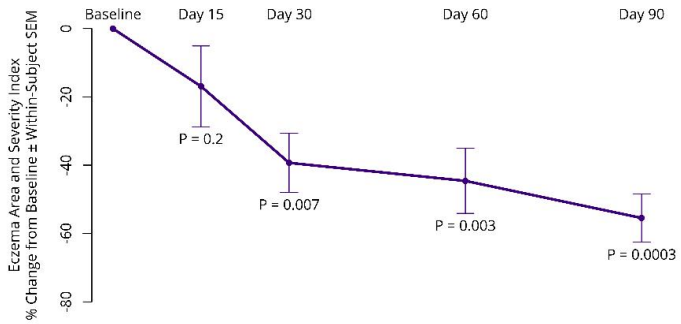
Figure 3: Phase 2 Clinical Trial of ADX-629 in Chronic Cough



Atopic Dermatitis

Eight mild to moderate atopic dermatitis patients were treated in an open-label, single-center Phase 2 clinical trial of ADX-629. Relative to baseline, over three months of treatment, improvement was observed in all patients. Statistical significance was achieved for improvement in Eczema Area and Severity Index (EASI, p=0.0006). EASI thresholds for 50% improvement (EASI 50), 75% improvement (EASI-75), and 90% improvement (EASI-90) were met in four patients (50%), three patients (38%), and one patient (13%), respectively. Statistical significance was achieved for improvement in affected body surface area (p<0.0001); one patient (13%) achieved complete clearance of affected body surface area. Statistical significance was achieved for improvement in Investigator Global Assessment (IGA, p<0.0001). The IGA threshold score of 0 (clear) or 1 (almost clear) was met in one (13%) patient. Statistical significance was achieved for improvement in patient-reported itching (p=0.0002); the clinically relevant threshold of improvement by four or more points was met in three patients (38%), and two patients (25%) reported elimination of itching. Statistical significance was achieved for improvement in patient-reported eczema severity (p<0.0001); the clinically relevant threshold of improvement by four or more points was met in six patients (75%). Statistical significance was achieved for improvement in depression the Hamilton Rating Scale for Depression (p=0.02) and numerical improvement was observed for improvement in the Beck Anxiety Inventory (p=0.1).

Figure 4: Phase 2 Clinical Trial of ADX-629 in Atopic Dermatitis



ADX-629 is currently in Phase 2 clinical trials for moderate alcohol-associated hepatitis and Sjögren-Larsson Syndrome. Clinical trials of the RASP modulators ADX-246 in systemic immune-mediated disease and ADX-248 in retinal disease are expected to be initiated in 2024, pending completion of FDA Investigational New Drug (IND) requirements.

Dry Eye Disease

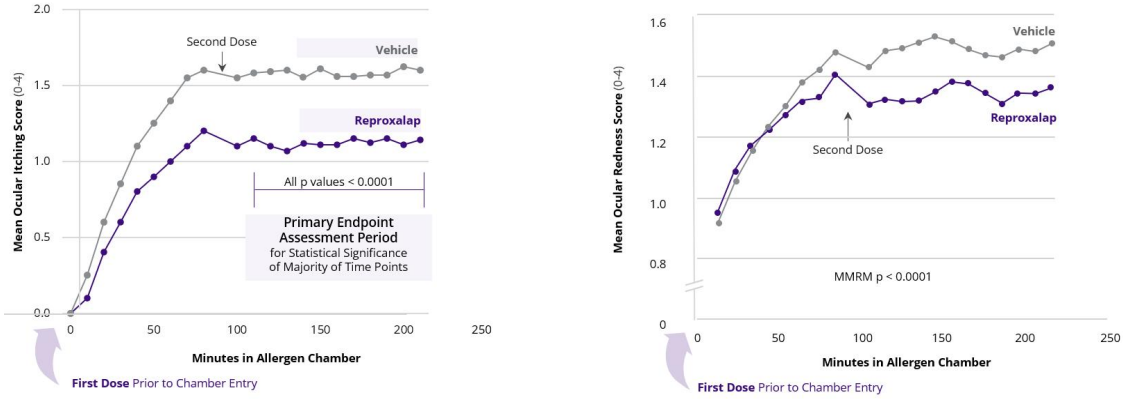
Reproxalap is a first-in-class, topically administered RASP modulator for the treatment of anterior segment ocular inflammation, and is currently in late-stage development for the treatment of dry eye disease. In 2022, Aldeyra submitted to the FDA a NDA for reproxalap for the treatment of dry eye disease. On November 27, 2023, Aldeyra announced that the FDA issued a Complete Response Letter regarding the NDA submission. Although no safety or manufacturing issues with reproxalap were identified, the FDA stated in the letter that the NDA did not demonstrate "efficacy in treating ocular symptoms associated with dry eyes" and that "at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye" should be conducted. On November 16, 2023, Aldeyra submitted to the FDA a Special Protocol Assessment for a dry eye disease chamber clinical trial. Aldeyra received feedback on the protocol and remains in discussions with the FDA and based on feedback received from the FDA, Aldeyra has amended the proposed clinical trial protocol and statistical analysis plan. The potential NDA resubmission is anticipated in the second half of 2024, pending continuing FDA discussions and positive results from the proposed trial. Aldeyra intends to include in the potential NDA resubmission a draft label describing chronic and acute symptomatic benefit, in addition to acute reduction of ocular redness. The review period for the potential NDA resubmission is expected to be six months.

Allergic Conjunctivitis

Allergic conjunctivitis is an anterior segment ocular inflammatory disease characterized by ocular itching and redness, and is often associated with dry eye disease. We estimate there to be 66 million patients with allergic conjunctivitis in the United States. In a number of Phase 2 and Phase 3 clinical trials in allergic conjunctivitis, reproxalap demonstrated consistent statistically significant and clinically relevant activity in improving ocular itching and redness. Thus, we believe reproxalap could offer differentiated efficacy relative to existing dry eye disease medications with regard to the potential treatment of the signs and symptoms of allergic conjunctivitis.

In 2021, we announced that the randomized, double-masked, vehicle-controlled allergen chamber Phase 3 INVIGORATE Trial of topically administered reproxalap in patients with allergic conjunctivitis achieved the primary endpoint (patient-reported ocular itching score after the second dose of test article) and all secondary endpoints (investigator-assessed ocular redness score and patient-reported ocular tearing score). In June 2023, we announced that INVIGORATE-2, a confirmatory clinical trial substantially similar to INVIGORATE, achieved the primary endpoint (patient-reported ocular itching score after the second dose of test article) and all secondary endpoints (investigator-assessed ocular redness score and patient-reported ocular tearing score).

Figure 5: Phase 3 INVIGORATE Trial Results for Reproxalap in Allergic Conjunctivitis



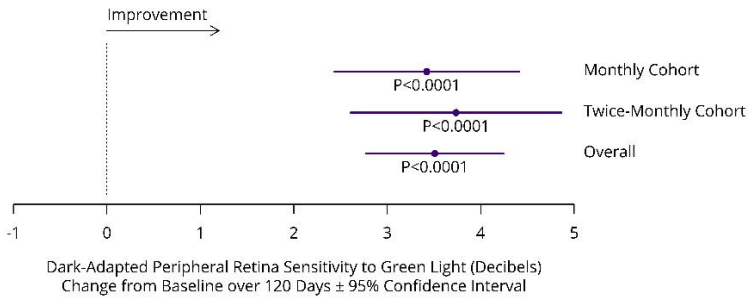
Pending the NDA resubmission for dry eye disease, and potentially the results of the NDA resubmission, Aldeyra plans to discuss remaining regulatory requirements for reproxalap for the treatment of allergic conjunctivitis in light of the positive results from INVIGORATE and INVIGORATE-2. Across all clinical indications, topical ocular reproxalap has been studied in more than 2,300 patients with no observed clinically significant safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Retinitis Pigmentosa

Retinitis pigmentosa is a group of rare genetic eye diseases characterized by retinal cell death and loss of vision, for which there is no treatment. In vivo preclinical research has identified the activity of methotrexate in inducing misfolded rhodopsin (a visual cycle protein) clearance, suggesting the potential of ADX-2191 to treat genetic forms of retinitis pigmentosa that are characterized by misfolded rhodopsin .

In June 2023, we announced top-line results from the Phase 2 clinical trial of intravitreal ADX-2191 in patients with retinitis pigmentosa. Relative to baseline, across all patients, statistical significance was achieved for improvement in best corrected visual acuity (P<0.0001), low-light visual acuity (P=0.0001), time to electroretinographic response to light (P=0.02), macular sensitivity to light (P<0.0001), and dark-adapted peripheral sensitivity to light (P<0.0001). All enrolled patients completed the trial per protocol. ADX-2191 was well tolerated, and no safety concerns were identified. No treatment-related adverse events associated with retinal morphology were observed. No serious adverse events were reported, and no patients discontinued due to adverse events.

Figure 6: Phase 2 Clinical Trial Results for ADX-2191 in Retinitis Pigmentosa



The Markets for Our Product Candidates

Immune-Mediated and Metabolic Systemic Diseases

Immune-mediated systemic diseases, such as autoimmune disease, and metabolic diseases, such as diabetes and liver disease, are generally chronic conditions that impair quality of life and lead to significant healthcare expenditures. In aggregate, immune-mediated and metabolic diseases afflict in excess of millions of individuals worldwide.

Given the complex pathophysiology of systemic immune-mediated and metabolic disorders, therapy often requires combinations of drugs with distinct mechanisms of action. As such, we believe novel product candidates for immune-mediated and metabolic diseases are in high demand.

Our RASP modulator platform represents a potential novel therapeutic approach for a variety of common diseases. We are not aware of any other company actively developing therapeutics that target RASP. Because RASP appear to be involved in the generation and potentiation of inflammation in general, we believe the potential therapeutic applicability of RASP modulators is broad. In 2022 and 2023, we announced results from Phase 2a clinical trials of ADX-629, a first-in-class orally administered RASP modulator, in patients with COVID-19, atopic asthma, psoriasis, alcohol intoxication, chronic cough, and atopic dermatitis, all of which suggested preliminary pharmacodynamic activity of ADX-629. The Phase 2 clinical trials followed a successful Phase 1 clinical trial of ADX-629, in which ADX-629 was well-tolerated; no treatment-related adverse events were observed; and, following ingestion of a fatty meal, levels of cholesterol and fatty acids were lower during ADX-629 treatment than with placebo.

Dry Eye Disease

The validity of the RASP platform is supported by reproxalap, our first-in-class product candidate for the treatment of dry eye disease, which has demonstrated broad-based, rapid-onset activity and consistent safety across a number of Phase 2 and Phase 3 clinical trials. Dry eye disease is an immune-mediated disease, the symptoms of which - ocular pain, dryness, burning, and stinging - are chronic and persistently disturbing, impacting quality of life and leading to loss of work and substantial economic burden. Dry eye disease is one of the most common diseases treated by ophthalmologists and optometrists, and healthcare providers and patients regard therapy as inadequate in a substantial number of cases.

There are approximately 18 million dry eye disease patients diagnosed in the United States, but only four classes of prescription topical ocular drugs are approved for dry eye disease treatment, cyclosporine (a generic immune modulator), lifitegrast (an immune modulator), loteprednol (a generic corticosteroid), and perfluorohexyloctane (a water-free solution). The activity of cyclosporine and lifitegrast has been observed to be minimal or lacking in the majority of patients, and weeks or months of treatment may be required to achieve even modest clinical benefit; over 60% of patients discontinue treatment within 12 months of initiation. Loteprednol, a generically available corticosteroid, is indicated only for short-term treatment (up to two weeks) due to corticosteroid-associated toxicity, which includes increases in intraocular pressure that may lead to glaucoma, the development of cataracts, ocular infection, and other ocular morbidities. Perfluorohexyloctane is available over-the-counter in certain countries outside the United States as a lubricating eyedrop. Thus, there is considerable demand for a novel, efficacious topical ocular drug that can be used chronically but that acts quickly.

By modulating RASP, which are elevated in a variety of inflammatory diseases, reproxalap represents a novel mechanism for diminishing ocular inflammation. In a number of Phase 2 and Phase 3 clinical trials in dry eye disease, reproxalap demonstrated consistent statistically significant and clinically relevant activity across a variety of symptoms and signs, occurring as early as within minutes of dosing. Given the broad activity and rapid onset of action observed in clinical trials, we believe that reproxalap may have a commercially differentiated product profile versus currently approved drugs for dry eye disease.

Many patients with dry eye disease also manifest symptoms of allergic conjunctivitis, another common inflammatory disease that affects the front of the eye and is characterized by ocular itching and redness. Distinguishing between dry eye disease and allergic conjunctivitis can be challenging for healthcare providers. Approximately half of dry eye patients complain of itching, which is generally considered the result of allergy, and

approximately half of allergic conjunctivitis patients complain of dryness, which is generally considered the result of dry eye disease. There are currently no FDA-approved products that are indicated for the chronic treatment of both dry eye disease and allergic conjunctivitis. Other than corticosteroids, which cannot be used chronically due to toxicity concerns, no approved dry eye disease drug has also been approved for use in patients with allergic conjunctivitis. Further, antihistamines, which are commonly used in allergic conjunctivitis, are known to exacerbate ocular dryness. In a number of Phase 2 and Phase 3 clinical trials in allergic conjunctivitis, reproxalap demonstrated consistent statistically significant and clinically relevant activity in improving ocular itching and redness. Thus, we believe reproxalap could offer differentiated efficacy relative to existing dry eye disease medications with regard to the potential treatment of the signs and symptoms of allergic conjunctivitis.

Retinitis Pigmentosa

Retinitis pigmentosa is a group of rare genetic eye diseases characterized by retinal cell death and loss of vision, for which there is no treatment. In vivo preclinical research has identified the activity of methotrexate in inducing misfolded rhodopsin clearance, suggesting the potential of ADX-2191 to treat genetic forms of retinitis pigmentosa that are characterized by misfolded rhodopsin. The prevalence of retinitis pigmentosa is more than one million people worldwide, and mutations leading to rhodopsin misfolding account for approximately one-third of cases. ADX-2191 has received Orphan Drug Designation from the FDA for the treatment of retinitis pigmentosa.

The Competitive Landscape of Our Product Candidates

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies, academic institutions, government agencies, and research institutions. We believe that the key competitive factors that will affect the development and potential commercial success of our product candidates are efficacy, safety, tolerability, and the ability to reduce the dependence on, or the dose of, other drug products.

Many of our potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for products and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product that we may commercialize, and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. Further, competitors with numerous approved products may be able to negotiate pricing and reimbursement that is more favorable than that which we may be able to achieve. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. In addition, the development of new treatment methods for the diseases we are targeting could render our products non-competitive or obsolete.

While our product candidates may manifest efficacy, tolerability, or safety advantages, many marketed therapies are generic or may be priced considerably lower than the pricing we anticipate for our product candidates. Pricing, in addition to healthcare plan coverage, prior authorization requirements, step edits, co-pay amounts, and related factors, may discourage the initial or prolonged use of our product candidates. Further, the recent growth of Pharmacy Benefit Managers has diminished the profitability of drug commercialization for smaller companies, and may hamper our ability to support our operations or compete effectively in the marketplace following regulatory approval, if any.

RASP Modulator Platform

A number of academic groups have published on the concept of reducing RASP levels, primarily by using compounds with amines (certain nitrogen-containing molecules) that react with RASP through a chemical process known as the Schiff base reaction. Various RASP-binding amines have been described, particularly carnosine (a naturally occurring dipeptide), which has other potential mechanisms of action unrelated to RASP. At least one group has published on the use of certain nitrogen-containing marketed products to temporarily bind the RASP retinaldehyde as a potential therapy for retinal disease. Schiff base reactions have also been mentioned as possible

explanations for a portion of the activity of aminoguanidine, pyridoxamine, and possibly other non-proprietary amine-containing compounds that have been tested in clinical trials for diabetic nephropathy. However, the Schiff base reaction is reversible, and generally the substrates (precursors) and products of the reaction exist in equilibrium such that, at any point in time, the RASP substrate may be bound or unbound. In this way, Schiff base reactions alone represent temporary RASP binding, and likely lead to the relocation of RASP rather than the elimination or long-term modulation of RASP. We believe that our RASP modulator product candidates that we have discovered are differentiated from the above approaches in that the chemical structures of our product candidates are novel, and the reaction with RASP has been observed to be essentially irreversible *in vivo*, which, we believe, may result in a more effective means of modulating RASP levels.

Other Immune-Modulating Pharmacotherapies

A myriad of new treatments have been or are being developed to treat inflammatory diseases, and have been used, or in theory could be used, for the treatment of the diseases that our product candidates are intended to target. Immune-modulating products include cytokine inhibitors, immune cell receptor inhibitors, complement inhibitors, phosphodiesterase inhibitors, and Janus kinase inhibitors. Companies that currently market such therapies include AbbVie Inc., Johnson & Johnson, UCB Inc. and UCB S.A., Amgen, Inc., Bristol-Myers Squibb Co., Eli Lilly and Company, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche, Sanofi, Takeda, AstraZeneca, GlaxoSmithKline, Merck, and Pfizer, Inc. Currently marketed products may manifest efficacy and safety advantages over our product candidates, and may be used to treat the diseases for which we are developing our product candidates.

Methotrexate, the active drug substance of ADX-2191, is generically available and has been used as a chemotherapeutic and immune modulating agent, and other formulations or application methods of methotrexate could be developed for the treatment of retinal diseases. Though not approved by the FDA for the treatment of retinal disease, intraocular injection of intravenous methotrexate formulations is the de facto standard of care for primary vitreoretinal lymphoma (a cancer that affects the back of the eye), and off-label methotrexate is now commonly administered for the treatment of proliferative vitreoretinopathy, posterior uveitis, and other retinal diseases. The off-label intraocular injection of intravenous methotrexate for retinal diseases is an example of a practice known as compounding. The disadvantages of compounding are significant, and include a risk of microbial contamination that can lead to severe ocular infection resulting in vision loss or surgical removal of the eye. Unlike compounded intravenous formulations, ADX-2191 is specifically formulated for intraocular injection such that pH, viscosity, and tonicity have been designed to be compatible with the vitreous humor, the fluid in the back of the eye. Further, ADX-2191 is a concentrated formulation of methotrexate that requires a small injection volume, thereby reducing injection site reflux and ensuing corneal toxicity relative to off-label ocular injections of methotrexate. Unlike off-label ocular injections of methotrexate, ADX-2191 is denser than the vitreous, the fluid in the back of the eye, allowing for the concentration of methotrexate in the vicinity of retina.

Competitive Pharmaceuticals by Indication

We believe the primary competitors by indication with respect to our current programs in late stage-clinical testing are as follows:

Competitive Pharmaceuticals for Reproxalap

Indication	Competitive Products
Dry Eye Disease	Topical immunomodulators, such as cyclosporine (0.05% as Restasis®, 0.09% as Cequa®, and 0.1% as Vevye®) and lifitegrast (Xiidra®); loteprednol (a corticosteroid as Eysuvis®); an intranasal spray (varenicline as Tyrvaya®), a lubricating eyedrop (perfluorohexyloctane as Miebo™); and other generic steroids; and artificial tear solutions
Allergic Conjunctivitis	Over-the-counter and prescription topical ocular and oral antihistamines, and prescription mast cell stabilizers and corticosteroids

We believe that there is significant unmet medical need for the diseases that we intend to target. If proven to be safe and effective, we believe that our product candidates could be used in place of, or in addition to, current therapies. Currently available therapies for the chronic treatment of dry eye disease are often considered by physicians and patients to be inadequate, may require weeks or months of treatment to achieve even moderate clinical benefit, and have not demonstrated clinical activity in allergic conjunctivitis, a common comorbidity.

Many drugs are in development for dry eye disease or related indications. In addition, generic versions of Restasis® became available in the United States in 2022. The competitive products for allergic conjunctivitis, which may be generic or sold over-the-counter, include topical antihistamines and corticosteroids, nonsteroidal anti-inflammatory drugs, and mast cell stabilizers. For the diseases we intend to study, there may be other developmental therapies of which we are not aware.

Our ability to compete successfully will depend in part on our ability to utilize our drug development expertise to identify, develop, secure rights to, and obtain regulatory approvals for promising pharmaceutical products before others are able to develop competitive products. Our ability to compete successfully will also depend on our ability to attract and retain skilled and experienced personnel. Additionally, our ability to compete may be diminished by insurers and other third-party payors, which often encourage the use of less expensive, non-innovative, or generic products.

Intellectual Property and Proprietary Rights

Overview

In the United States and abroad, we are building an intellectual property portfolio for reproxalap and other RASP modulators and for therapeutic methods of use of methotrexate for the treatment of retinal disease. We currently seek, and intend to continue to seek, patent protection in the United States and internationally for our product candidates, methods of use, and processes for manufacture, and for other technologies, where appropriate. Our current policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad relating to proprietary technologies that are important to the development of our business. We also rely on, and will continue to rely on, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies that we consider important to our business, our ability to defend our patents, and our ability to preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

Patent Portfolio

Our patent portfolio currently includes patents and patent applications covering the composition, formulation, and uses of reproxalap, ADX-629, ADX-246, ADX-248, and other novel compounds. As of December 31, 2023, we owned thirty United States patents and eighteen pending United States non-provisional patent applications, as well as numerous foreign counterparts to these patents and patent applications, relating to reproxalap and other RASP modulators. Additionally, we retain an exclusive license to certain patents covering the formulation of ADX-2191 and uses thereof in preventing and treating retinal indications including proliferative vitreoretinal disease and primary vitreoretinal lymphoma. As of December 31, 2022, our patent applications included one pending U.S. provisional application, five pending U.S. non-provisional patent applications, and approximately eight pending foreign counterparts to these patent applications, relating to ADX-2191.

We expect the issued reproxalap composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2028. It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the

provisions of the Hatch-Waxman Act. We expect the foreign reproxalap composition of matter patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2026 to 2041. Reproxalap composition of matter patents have been issued in Australia, Canada, China, Europe (validated in approximately 14 member countries), Hong Kong, India, Japan, Mexico, Russia and South Korea. Reproxalap composition of matter patent claims are pending in Brazil.

Licenses and Agreements

AbbVie Option Agreement

On October 31, 2023 (the Option Agreement Effective Date), we entered into an exclusive option agreement (the Option Agreement) with AbbVie Inc. (AbbVie), pursuant to which we granted AbbVie an exclusive option (the Option) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with us to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by us in the field of ophthalmology relating to treating conditions of the ocular surface, and (d) a right to review data for any other compounds that are owned or otherwise controlled by us in the fields of ophthalmology and immunology before such data is shared with any other third party (the Collaboration Agreement). AbbVie has paid us a non-refundable payment of $1 million in consideration of the Option (the Option Payment).

On December 21, 2023, pursuant to the Option Agreement, AbbVie extended the period during which it may exercise the Option (the Exercise Period Extension) by paying us a non-refundable payment of $5 million (the Option Extension Fee). As a result of the Exercise Period Extension, AbbVie may exercise the Option by delivering written notice to us at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the date, if any, that we receive approval from the U.S. Food and Drug Administration of the NDA for reproxalap in dry eye disease (the FDA Decision) and (b) the date that is eighteen (18) months after the Option Agreement Effective Date. If the Collaboration Agreement is entered into, the Option Payment and the Option Extension Fee will be credited against the upfront cash payment payable by AbbVie.

Upon AbbVie's delivery of the agreement execution notice and the parties entering into the Collaboration Agreement, AbbVie would pay us a $100 million upfront cash payment, less the Option Payment and the Option Extension Fee. In addition, we would be eligible to receive up to approximately $300 million in regulatory and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA Decision is received prior to or after the execution of the Collaboration Agreement. In the United States, we would share profits and losses with AbbVie from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for us. Outside of the United States, we would be eligible to receive tiered royalties on net sales of reproxalap.

MEEI Agreement

We are developing ADX-2191 pursuant to an Exclusive License Agreement with Massachusetts Eye and Ear Infirmary (MEEI) originally entered into in July 2016 between MEEI and Helio Vision, Inc.(Helio), as amended, (MEEI Agreement). We assumed the MEEI Agreement in connection with our 2019 acquisition of Helio.

Pursuant and subject to the MEEI Agreement, we obtained an exclusive, worldwide license from MEEI to develop and commercialize ADX-2191 under certain patents and patent applications, and other licenses to intellectual property (MEEI Patent Rights). We have agreed to use our commercially reasonable efforts to develop ADX-2191 and to meet certain specified effort and achievement benchmarks by certain dates.

In consideration for the rights licensed under the MEEI Agreement, Helio issued MEEI a number of shares of its preferred stock and Helio agreed to pay non-creditable non-refundable license maintenance fees to MEEI of $15,000 on each of the second and third anniversary of the MEEI Agreement, $25,000 on each of the fourth and fifth anniversary of the MEEI Agreement and $35,000 on the sixth and each subsequent anniversary of the MEEI Agreement during the term of such agreement. In addition, Helio was obligated to make future sales-dependent milestone payments to MEEI of up to the low seven figures in the aggregate, as well as royalty payments to MEEI at

a rate which, as a percentage of net sales, is in the low single digits for products that incorporate or use the MEEI Patent Rights in the United States and as a percentage in the low single digits for products that incorporate or use the MEEI Patent Rights outside the United States. We are also obligated under the MEEI Agreement to pay MEEI a percentage of certain sublicense revenue that we receive in connection with entering into any sublicensing arrangements with any third parties, at a percentage rate which tiers downward from low-double digits to mid-single digits based on the date of the sublicense. Following our acquisition of Helio, we became obligated to make any future payments owed under the MEEI Agreement. There is no additional equity consideration issuable under the MEEI Agreement.

The MEEI Agreement will remain in effect until the expiration date of the last to expire patent licensed under the MEEI Agreement. We may terminate the MEEI Agreement with timely written notice to MEEI. MEEI has the right to terminate the MEEI Agreement if we, subject to certain specified cure periods, cease all business operations with respect to licensed products, fail to pay amounts due under the MEEI Agreement, fail to comply with certain due diligence obligations, default in our obligation to maintain insurance, one of our officers is convicted of a felony relating to the manufacture, use, sale or importation of licensed products, we materially breach any provisions of the MEEI Agreement or in the event of our insolvency or bankruptcy.

In the event of an early termination of the MEEI Agreement, all rights licensed and developed by us under the MEEI Agreement may revert back to MEEI. We have agreed to indemnify MEEI for certain claims that may arise under the MEEI Agreement.

Other Intellectual Property Rights

Our marks ALDEYRA THERAPEUTICS and our logo are registered with the United States Patent and Trademark Office.

Confidential Information and Inventions Assignment Agreements

We currently require and will continue to require each of our employees and consultants to execute confidentiality agreements upon the commencement of such individual's employment, consulting, or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from such individual's work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. Our consulting agreements also provide for assignment to us of any intellectual property resulting from services performed by a consultant for us.

Sales and Marketing

We have retained worldwide commercial rights for our product candidates, provided, however, that on October 31, 2023, we entered into the Option Agreement with AbbVie, pursuant to which we granted AbbVie the Option to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with us to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by us in the field of ophthalmology relating to treating conditions of the ocular surface and (d) a right to review data for any other compounds that are owned or otherwise controlled by us in the fields of ophthalmology and immunology before such data is shared with any other third party, in each case for clauses (a) to (d), on the terms and conditions set forth in the form of Co-Development, Co-Commercialization and License Agreement filed as an exhibit hereto (the Collaboration Agreement). As of March 5, 2024, AbbVie has not exercised the Option. If we obtain marketing approval for reproxalap or any other product candidate that we develop, we intend to partner with other companies, including AbbVie, for commercialization, though there can be no guarantee that such partnership will be available.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished drug product for our preclinical research and clinical trials. We have no immediate plans to purchase, erect, or otherwise create any manufacturing facilities to be owned by us for any of these purposes, and intend to continue to depend on third-party contract manufacturers for the foreseeable future. Other than for the purposes of regulatory approval, we do not have any current contractual relationships for the manufacture of commercial supplies of our product candidates. If our product candidates are approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for commercial production at such time. We may utilize third-party consultants to manage our manufacturing contractors. We believe that the active pharmaceutical ingredient and other materials needed for the formulation of our product candidates are relatively easy to manufacture, and that multiple suppliers and formulators could be employed for this purpose. Further, we believe the raw materials needed for manufacture of our product candidates, as well as other components of our formulations, are generally readily available currently from multiple sources.

Employees

As of December 31, 2023, we had 10 full-time employees and had engaged a number of consultants. We expect that a number of consultants previously engaged in development of our product candidates will participate in ongoing clinical and manufacturing activities. None of our employees is represented by a labor union. We have not experienced any work stoppages, and we consider our relations with our employees to be good.

Human Capital

We recognize that attracting, motivating, and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an equitable, inclusive, and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to successfully commercialize our products following approval, if any, support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our stockholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where we believe that our employees thrive and are inspired to contribute to the development of novel therapies. We recognize and appreciate the importance of creating an environment where all team members feel valued, included, and empowered to do their best work and to bring great ideas to the table. We recognize that each team member’s unique experiences, perspectives, and viewpoints add value to our ability to develop and deliver innovative diagnostic products and make a meaningful impact on patient care. We aim to foster and maintain a work culture that treats all employees fairly and with respect, promotes inclusivity, and provides equal opportunities for the professional growth and advancement based on merit. Our Code of Business Conduct and Ethics prohibits discrimination on the basis of race, color, religion, national origin, sex (including pregnancy), sexual orientation, age, disability, veteran status, or other characteristics protected by law.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating, and integrating our existing and future employees. The principal purpose of our incentive plans is to increase shareholder value by attracting, retaining, and motivating employees, consultants, and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package is designed to meet the individual health and wellness needs of our employees. We plan to continue to refine our efforts related to optimizing our use of human capital as we grow, including improvements in the way we hire, develop, motivate, and retain employees.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Food Drug and Cosmetic Act (FDCA) and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new drug, new dosage form, new therapeutic use, or new route of administration of a previously approved product, can be marketed in the United States. The process required by the FDA before a new drug product may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's good laboratory practice (GLP) regulation;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board (IRB) at each site where a clinical trial will be performed before the trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices (cGCP) to establish the safety and efficacy of the proposed product candidate for each intended use;
- submission to the FDA of an NDA which must be accepted for filing by the FDA;
- satisfactory completion of an FDA pre-approval inspection(s) of our office and the facility or facilities at which the product is manufactured to assess compliance with the FDA's current Good Manufacturing Practices (cGMP) regulations;
- satisfactory completion of an FDA advisory committee review, if applicable;
- payment of user fees, if applicable;
- FDA may also inspect sponsor facilities to determine if nonclinical and clinical studies were conducted in compliance with applicable regulations and guidelines; and
- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources. Preclinical tests include laboratory evaluation of product chemistry, formulation, manufacturing and control procedures, and stability, as well as animal studies to assess the toxicity and other safety characteristics of the product. The results of preclinical tests, together with manufacturing information, analytical data, and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Preclinical testing may continue even after the IND is submitted. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions and places the clinical trial on a partial or complete clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Even if the IND becomes effective and the trial proceeds without initial FDA objection, the FDA may stop the trial at a later time if, among other reasons, the potential for unacceptable safety risks arises.

Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the FDA's or IRB's requirements. Other conditions may also be imposed.

Clinical trials involve the administration of the investigational new product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide informed consent in writing for participation in the clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters and results of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* The investigational drug product is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution, and excretion.
- *Phase 2:* The investigational drug product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications, and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.
- *Phase 3:* When Phase 2 evaluations suggest that certain dosing regimens may be efficacious and may have an acceptable safety profile, Phase 3 trials may be undertaken in larger patient populations to further evaluate dosage and to obtain evidence of potential clinical efficacy and safety. Phase 3 trials may include multiple, geographically-dispersed clinical trial sites. Data generated from these studies may be used to establish the overall risk-benefit profile of the investigational drug product and to provide adequate information for the labeling of the product, if approved.
- *Phase 4:* In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's commitment to conduct additional clinical trials to further assess the product's safety and/or effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 trials.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacturing and controls, and proposed labeling, among other things.

A sponsor may be able to request a Special Protocol Assessment (SPA) the purpose of which is to reach concurrence with the FDA on the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a trial intended to support a future marketing application. If such an agreement is reached, it will be documented and made part of the administrative record, and will be binding on the FDA unless the sponsor fails to follow the agreed-upon protocol or makes substantive changes to the protocol without agreement with the FDA, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. Even if an SPA is agreed to, approval of the NDA is not guaranteed because a final determination that an agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision will be based on a complete review of all the data in the NDA.

For some products, the FDA may require a risk evaluation and mitigation strategy (REMS) which could include measures imposed by the FDA such as prescribing restrictions, requirements for post-marketing studies, and reporting or certain restrictions on distribution and use. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to prescription drug program fees. In accordance with the FDAs guidance, the agency has 60 days from receipt of an NDA to determine whether the application will be accepted for filing to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast track program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat patients with a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In September 2019, ADX-2191 received fast track designation from the FDA for the prevention of proliferative vitreoretinopathy. Fast track designation provides additional opportunities for interaction with the FDA's review team and may allow for rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request breakthrough therapy designation for a drug if it is intended, alone or in combination with one or more other drugs, to treat patients with a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for intensive guidance from the FDA on an efficient drug development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the NDA. Both fast track and breakthrough product candidates may be eligible for accelerated approval and/or priority review, if relevant criteria are met.

Once the submission has been accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act (PDUFA), the FDA agrees to specific performance goals for NDA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review NDAs have a goal of being completed within a ten-month timeframe after acceptance of filing. A Priority Review designation is given to products that offer major advances in treatment or provide a treatment where no adequate therapy exists. The goal for completing a Priority Review is six months after acceptance of filing.

It is likely that our product candidates will be granted a Standard Review, with the exception of ADX-2191 which may be designated as Priority Review for the treatment of retinitis pigmentosa. The review process may be extended by the FDA for three additional months to consider certain information or obtain clarification regarding information already provided in the submission. The FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. In addition, for combination products, the FDA's review may include the participation of both the FDA's Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the FDA's Center for Devices and Radiological Health. The participation of multiple distinct groups within the FDA has the potential to complicate or prolong review of the application. If the product is deemed a combination product, additional supporting studies may be required, and may delay an NDA submission.

Before approving an NDA, the FDA may inspect our offices and the facility or facilities where the drug substance or drug product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP. FDA may also inspect sponsor facilities to determine if nonclinical and clinical studies were conducted in compliance with applicable regulations and guidelines.

After the FDA evaluates the NDA and, in some cases, the related manufacturing facilities, it may issue an approval letter or a Complete Response Letter (CRL) to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if potential adverse safety findings are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Products may be promoted only for the approved labeled indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms, such as a Black Box Warning, which highlights a specific warning. Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, a company may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the company to develop additional data or conduct additional preclinical studies and clinical trials.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to product/facility listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and may require prior FDA approval before being implemented. FDA regulations may also require investigation and correction of any deviations from cGMP and may impose reporting and documentation requirements upon us and any third-party manufacturers. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated seriousness, severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. The FDA does not regulate the practice of medicine. Physicians may prescribe for off-label uses; manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability, both at the federal and state levels.

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a REMS from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. In determining whether a REMS is necessary, FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy at 18 months, three years, and seven years after the strategy's approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the BBA and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that

initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, in August 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

The heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics, also has resulted in executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024. Further, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated but it is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, as well as the trend toward managed healthcare and increasing influence of managed care organizations, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our product candidate.

Orphan Drug Designation

The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States. Orphan drug designation must be requested before submitting an NDA and does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. ADX-2191 has received orphan designation for the treatment of retinitis pigmentosa.

If an orphan drug-designated product subsequently receives the first FDA approval for the disease specified in the orphan drug designation, the sponsor will be entitled to seven years of product marketing exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited and rare circumstances, for seven years. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application fee. If a competitor obtains approval of the same drug, as defined by the Orphan Drug Act, before we do or if our product candidate is determined to be contained within the competitor's product for the same indication or disease, the competitor's exclusivity could block the approval of our product candidate in the designated orphan indication for seven years, unless superior safety or efficacy of our drug is demonstrated.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of FDA approval of the use of our drug candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond the current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a 505(b)(1) NDA, 505(b)(2) NDA, or supplement to an approved NDA if new clinical investigations other than bioavailability studies (e.g., investigations that support new indications, dosages, or strengths of an existing drug) were conducted or sponsored by the applicant and are deemed by the FDA to be essential to the approval of the application. The three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full 505(b)(1) NDA.

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations and, if applicable, quality system regulation requirements for medical devices. The cGMP regulations include requirements relating to, among other things, organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing of the drug product requires multiple starting raw materials and excipients of a specified purity level to obtain the required product quality. Failure of any of the raw materials or excipients to meet specification could impact product quality and may impact regulatory review by the FDA. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA and may be subject to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic unannounced inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including, among other things, warning letters, voluntary corrective action, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have an adverse effect on our ability to operate our business and generate revenues. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition. There are evolving legal requirements and other statutory and regulatory regimes that will continue to affect our business.

Research and Development Expenses

Substantially all of our research and development expenses incurred to date have been related to the development of reproxalap and our other product candidates. Our research and development expenses totaled $29.5 million for the year ended December 31, 2023 and $47.3 million for the year ended December 31, 2022.

We anticipate that we will incur additional research and development expenses in the future as we evaluate and possibly pursue the development of our product candidates for additional indications, or develop additional product candidates.

We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel;
- fees paid to consultants and contract research organizations in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;
- costs incurred with third parties related to the establishment of a commercially viable manufacturing process for our product candidates;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- costs related to upfront, milestone payments under in-licensing agreements as well as costs for unapproved inventory for which there is no future alternative use;

- costs related to compliance with FDA regulatory requirements;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

We expense both internal and external development costs as they are incurred.

We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future non-clinical, preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in terms of both their timing and total cost to completion. We expect to continue to develop stable formulations of our product candidates, test such formulations in preclinical studies for toxicology, safety and efficacy and to conduct clinical trials for each product candidate. We anticipate funding clinical trials for our product candidates ourselves, but we may engage collaboration partners at certain stages of clinical development. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus our resources on more promising product candidates or programs. Completion of clinical trials by us or our future collaborators may take several years or more, the length of time generally varying with the type, complexity, novelty and intended use of a product candidate. The costs of clinical trials may vary significantly over the life of a project owing to but not limited to the following:

- the number of sites included in the trials;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of the product candidate.

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

None of our product candidates have received FDA or foreign regulatory marketing approval. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of our product candidates with an appropriate benefit to risk profile relevant to a particular indication, and that the product can be manufactured under cGMP in a reproducible manner to deliver the product's intended performance in terms of its stability, quality, purity and potency. Until a health authority has completed their review of our submission, there is no way to predict the outcome of their review. Even if the clinical studies meet their predetermined primary endpoints, and a registration dossier is accepted for filing, a health authority could still determine that an appropriate benefit to risk relationship does not exist for the indication that we are seeking.

We cannot forecast with any degree of certainty which of our product candidates will be subject to future collaborations or how such arrangements would affect our development plan or capital requirements.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will receive cash inflows from the commercialization and sale of an approved product candidate.

Corporate Information

We were incorporated in the state of Delaware on August 13, 2004 as Neuron Systems, Inc. On December 20, 2012, we changed our name to Aldexa Therapeutics, Inc. and on March 17, 2014, we changed our name to Aldeyra Therapeutics, Inc. Our principal executive offices are located at 131 Hartwell Avenue, Suite 320, Lexington, Massachusetts 02421. Our telephone number is (781) 761-4904. Our website address is www.aldeyra.com. Information contained on our website is not incorporated by reference into this annual report on Form 10-K, and you should not consider information contained on our website to be part of this annual report on Form 10-K or in deciding whether to purchase shares of our common stock. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on the Investors portion of our website at http://ir.aldeyra.com/ as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ITEM 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below together with the other information set forth in this annual report on Form 10-K, which could materially affect our business, financial condition, and future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, prospects, financial condition, and operating results.

Summary of Risks Related to our Business

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this annual report on Form 10-K and our other filings with the Securities and Exchange Commission before making investment decisions regarding our common stock.

- Our business is dependent in large part on the successful commercialization of reproxalap. If we are unable to successfully obtain marketing approval for reproxalap, or experience significant delays in doing so, or if, after obtaining marketing approval, we or our strategic partners fail to successfully commercialize reproxalap, our business will be materially harmed.
- To generate revenue, we will depend on FDA approval and successful commercialization of reproxalap. Our success in obtaining regulatory approval of reproxalap from the FDA depends on our ability to address the issues raised by the FDA in the reproxalap Complete Response Letter, and address any issues the FDA may raise in the future. If we are unable to successfully obtain FDA approval, or FDA approval is delayed or limited, our ability to generate revenue will be significantly delayed.
- If we remain responsible for funding further development and commercialization of reproxalap, we may be unable to raise the additional capital required to further develop and commercialize reproxalap or enter into a collaboration agreement with another pharmaceutical company with equivalent or comparable terms, or at all.
- If we fail to develop and commercialize other product candidates, we may be unable to grow our business.
- Reproxalap and our other product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.
- If our competitors develop treatments for the target indications of our product candidates that are approved more quickly than ours, marketed more successfully, or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.
- We have incurred significant operating losses since inception and we expect to incur significant losses over the next several years. We may never become profitable or, if achieved, be able to sustain profitability.
- We will require substantial additional financing, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our product development, other operations or commercialization efforts.
- We rely on third parties to conduct our clinical trials. If any third party does not meet our deadlines or otherwise conduct the trials as required and in accordance with regulations, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates when expected, or at all.
- Public health emergencies, epidemics or pandemics may impact our business.
- Adverse developments affecting the financial services industry, which could adversely affect our current and projected business operations and our financial condition and results of operations.

Risks Related to the Potential Development and Commercialization of Reproxalap and our Product Candidates

Our business is dependent in large part on the successful commercialization of reproxalap, if approved. If we are unable to successfully obtain marketing approval for reproxalap or experience significant delays in doing so, or if, after obtaining marketing approvals, we or our strategic partners fail to successfully commercialize these product candidates, our business will be materially harmed.

We are dependent in large part on regulatory approval and successful commercialization of reproxalap for our future business success. There is a significant risk that we will fail to successfully obtain marketing approval and/or we or our partners will fail to successfully commercialize reproxalap. Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA, and even fewer are approved for commercialization.

Prior to and following potential NDA approval, we will invest a significant portion of our time and financial resources on the commercialization of reproxalap. We cannot accurately predict when or if reproxalap will receive marketing approval. Our ability to generate product revenues will depend on our obtaining marketing approval for, and commercializing reproxalap alone or with others. The future regulatory and commercial success of reproxalap and our other product candidates is subject to a number of risks, including the following:

- obtaining marketing approval for reproxalap or any other product candidates;
- our ability to negotiate and enter into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;
- hiring and building a full commercial organization required for the marketing, selling and distributing for those products which we obtain marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize;
- obtaining, maintaining and protecting our intellectual property rights;
- we may not be able to provide sufficient evidence of safety and efficacy to obtain regulatory approval;
- the FDA, or comparable foreign regulatory bodies, may implement new standards, or change the interpretation of existing standards or requirements for the regulatory approval, in general or with respect to the indications for which we seek approval;
- the FDA, or comparable foreign bodies, may require additional clinical data, as was the case with the reproxalap Complete Response Letter;
- we may not have sufficient financial and other resources to pursue our business plans, complete necessary clinical trials of our product candidates and commercialize our approved products, if any;
- if approved, reproxalap and our other product candidates will compete with well-established and other products or therapeutic options already approved for marketing by the FDA, or comparable foreign regulatory bodies;
- competitive products may be more effectively or comprehensively marketed to physicians or patients, or contracted with payors more successfully;
- the results of our clinical trials may not meet the endpoints, or level of statistical or clinical significance required by the FDA, or comparable foreign regulatory bodies, for marketing approval;
- the safety and efficacy results of our later phase or larger clinical trials may not confirm the results of our earlier trials;
- patients in our clinical trials may demonstrate greater response rates or improvements from vehicle or in the non-treatment arm then was expected when designing and powering our clinical trials;

- there may be variability in patients, adjustments to clinical trial procedures, and inclusion of additional clinical trial sites;
- the initial parts of adaptive clinical trials are not designed to be pivotal or definitive, and as such we may not satisfy the designated endpoints and also may need to revise the design or endpoints to achieve success in later parts of the trial or potentially abandon the trial;
- we may not be able to timely or adequately finalize the design or formulation of any product candidate or demonstrate that a formulation of our product candidate will be stable for commercially reasonable time periods;
- we may be adversely affected by legislative or regulatory reform of the health care system in the United States or other jurisdictions in which we may do business; and
- we may not be able to obtain, maintain, or enforce our patents and other intellectual property rights.

Furthermore, even if we do receive regulatory approval to market reproxalap or any of our other product candidates, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to commercialize our product candidates or continue to fund our development programs, we cannot assure that reproxalap will be successfully commercialized, or our other product candidates will be successfully developed or commercialized. If we are unable to obtain regulatory approval for or, if approved, we or any of our future partners are unable to successfully commercialize reproxalap, and our other product candidates, we may not be able to generate sufficient revenue to continue our business.

To generate revenue, we will depend on FDA approval and successful commercialization of reproxalap. Our success in obtaining regulatory approval of reproxalap from the FDA depends on our ability to address the issues raised by the FDA in the reproxalap Complete Response Letter, and address any issues the FDA may raise in the future. If we are unable to successfully obtain FDA approval, or FDA approval is delayed or limited, our ability to generate revenue will be significantly delayed.

Our ability to generate revenue will depend on the successful development, regulatory approval and commercialization of reproxalap. We submitted an NDA for reproxalap for the treatment of the signs and symptoms of dry eye disease in December 2022. In February 2023, the FDA accepted the reproxalap NDA for filing and set a PDUFA date of November 23, 2023. On November 27, 2023, we announced that we had received a Complete Response Letter from the FDA (the reproxalap Complete Response Letter). In the reproxalap Complete Response Letter, the FDA stated that the NDA did not demonstrate "efficacy in treating ocular symptoms associated with dry eyes" and that "at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye" should be conducted. On November 16, 2023, prior to receiving the reproxalap Complete Response Letter, we submitted to the FDA a Special Protocol Assessment (SPA) for a dry eye disease chamber crossover clinical trial (the proposed trial), which could potentially result in data acceptable for FDA review towards a potential NDA resubmission for reproxalap for the treatment of the signs and symptoms of dry eye disease. A SPA is an advanced declaration from the FDA that a planned trial's design, clinical endpoints, and statistical analyses could potentially result in data acceptable for FDA review towards approval for the proposed indication. Based on SPA feedback received from the FDA in December 2023, we have amended the design and protocol of the proposed trial.

We expect the next steps will include ongoing FDA discussions and initiating the proposed trial. There can be no assurance that the feedback from the FDA will be positive. Without the concurrence of the FDA on a SPA or otherwise, we cannot be certain that the design, conduct, and analysis of the results of the proposed trial will be sufficient to establish the effectiveness of reproxalap for treatment of dry eye disease to the FDA's satisfaction, and therefore allow us to resubmit or receive approval of a NDA for reproxalap. As part of the SPA or in connection with its review of the potential NDA resubmission, the FDA could require additional studies or clinical trials, and the submission of the results of those studies or clinical trials before a potential NDA resubmission will be reconsidered, which would require us to expend more resources than we planned or that are available to us, and could substantially delay acceptance and/or approval, if any, of a potential NDA resubmission. Any such requirement would increase our costs and delay approval and commercialization of reproxalap for the treatment of

dry eye disease and would have a material adverse effect on our business and financial condition. Additionally, the FDA has substantial discretion in the approval process and may disagree with our interpretation of or the sufficiency of the data from our clinical trials. Clinical trial results frequently are susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, which may delay, limit or prevent regulatory approvals. There can be no assurance that a potential NDA resubmission to the FDA will be accepted or approved in a timely manner or at all. If marketing approval for reproxalap is delayed, limited or denied, our ability to market reproxalap, and our ability to generate product sales, would be adversely affected. Even if reproxalap is approved for the treatment of dry eye disease, the FDA may limit use to certain patient populations, include extensive warnings on the product labeling, or require costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of reproxalap.

Any regulatory approval of reproxalap, once obtained, may be withdrawn. Ultimately, the failure to obtain and maintain regulatory approvals would prevent reproxalap from being marketed and would have a material adverse effect on our business.

If the Option is not exercised by AbbVie and we remain responsible for funding further development and commercialization of reproxalap, we may be unable to raise the additional capital required to further develop and commercialize reproxalap or enter into a collaboration agreement with another pharmaceutical company with equivalent or comparable terms, or at all.

If the exclusive option (the Option) to enter into the Co-Development, Co-Commercialization and License Agreement (the Collaboration Agreement) is not exercised by AbbVie Inc. (AbbVie), pursuant to the exclusive option agreement with AbbVie, we will be responsible for funding further development and commercialization of reproxalap, and may be unable to raise the additional capital required to further develop and commercialize reproxalap or enter into a collaboration agreement with another pharmaceutical company with equivalent or comparable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs and reproxalap commercialization efforts.

If we are required to continue the development and commercialization of reproxalap on our own, we may need to build its marketing, sales, distribution, managerial and other non-technical capabilities to commercialize reproxalap or make arrangements with third parties to perform these services. The establishment and development of our own sales force or the establishment of a contract sales force to market reproxalap would be expensive and time-consuming and could delay any commercial launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. We would also face competition in its search for third parties to assist it with the sales and marketing efforts of reproxalap.

If the Option is exercised and the Collaboration Agreement is executed, then pursuant to the terms of the Collaboration Agreement, we would work closely with AbbVie to execute a commercialization plan for reproxalap in the United States, and this commercialization plan may never achieve its desired outcomes.

Pursuant to the terms of the Collaboration Agreement, we would work with AbbVie to execute a joint commercialization plan for reproxalap in the United States, and execute upon the commercialization plan with the intention to optimize the commercial potential of reproxalap. If this collaboration is not successful, then our business, financial condition, and results of operations could be adversely affected.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

As part of our growth strategy, we plan to evaluate the development and commercialization of other therapies related to immune-mediated diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to continue to in-license or acquire other product candidates, as well as commercial products, to treat patients suffering from immune-mediated disorders with high unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials, and approval by the FDA and/or applicable foreign regulatory authorities. In-licensed product candidates may have been unsuccessfully developed by others in indications similar to those that we may pursue. All product candidates are prone to the risks of failure that are inherent in

pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. For example, in June 2023, we received a Complete Response Letter from the FDA regarding our NDA for ADX-2191 for the treatment of primary vitreoretinal lymphoma (the ADX-2191 Complete Response Letter). The ADX-2191 Complete Response Letter stated that there was a "lack of substantial evidence of effectiveness" due to "a lack of adequate and well-controlled investigations" in the literature-based NDA submission. In light of the FDA's ADX-2191 Complete Response Letter, we halted pre-commercial activities related to ADX-2191 for the treatment of primary vitreoretinal lymphoma. In January 2024 we de-prioritized the previously announced programs of ADX-629 in chronic cough and idiopathic nephrotic syndrome due to regulatory and trial feasibility challenges, respectively. Additionally, we deprioritized ADX-2191 for the treatment of proliferative vitreoretinopathy and primary vitreoretinal lymphoma due to the requirement from the FDA to run clinical trials that we did not deem to be feasible. If marketing approval for our other product candidates is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected. Such a delay could occur because a competitor product is approved before our product and secures patent protection, market exclusivity, or both, and thereby precludes our product approval for a number of years. It is also possible that additional studies or clinical trials may not suffice to make our application approvable. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, adequately priced, successfully commercialized, or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Any termination or suspension of, or delays in the commencement or completion of, our clinical trials could result in increased costs to us, delay or limit our ability to generate revenue, and adversely affect our commercial prospects.

Delays in the commencement or completion of our ongoing or planned clinical trials for our product candidates could significantly affect our product development costs and timeline. We do not know whether future trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- public health epidemics or pandemics or responses thereto;
- the FDA, or an institutional review board, or IRB, failing to grant permission to proceed or placing a clinical trial on hold;
- subjects failing to enroll or remain in our clinical trials at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe, serious, or unexpected drug-related adverse effects, whether drug-related or otherwise;
- a facility manufacturing our product candidates, or drug product components being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- inability to timely manufacture sufficient quantities of the applicable product candidate for a clinical trial or expiration of materials intended for use in a clinical trial;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, cGMP, or regulatory requirements, or other third parties not performing data collection or analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or the finding of regulatory violations by the FDA or IRB, that require us or others to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold in part or on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;

- delays in shipment of clinical trial material reaching clinical sites;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending, or terminating the trial at an investigational site; precluding enrollment of additional subjects; or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of our product candidates or if we need to perform more, larger, or longer clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we or our partners may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in completion of, or if we, the FDA, or other regulatory authorities, the IRB, other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for a product candidate may be harmed and our ability to generate product revenues, if any, will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Reproxalap and our other product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive and time-consuming, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indication, and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval, and subsequent commercial success is uncertain and not guaranteed.

Reproxalap and our other product candidates, and the activities associated with development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other jurisdictions.

Our ongoing research and development activities and planned clinical development and commercialization for our product candidates may be delayed, modified, or ceased for a variety of reasons, including:

- determining that a product candidate is ineffective or potentially causes harmful side effects during preclinical studies or clinical trials;
- adverse events which had initially been considered unrelated to the product candidate may later, even following approval and/or commercialization, be found to be caused by the product candidate;
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;
- patients in our clinical trials may demonstrate greater response rates or improvements from vehicle or standard of care than was expected when designing and powering our clinical trials;

- lack of availability of, or difficulty recruiting and retaining, a sufficient number of patients to adequately power our clinical trials;
- difficulties in manufacturing a product candidate, including the inability to manufacture a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under processes acceptable to the FDA for marketing approval or commercial sale;
- the proprietary rights of third parties, which may preclude us from developing or commercializing a product candidate;
- determining that a product candidate may be uneconomical for us to develop or commercialize, or may fail to achieve market acceptance or adequate pricing or reimbursement;
- our expectations regarding our expenses and revenue, the sufficiency or use of our cash resources, and needs for additional financing;
- a safety concern or signal may arise that triggers a clinical hold;
- any negative results or perceived negative results in clinical trials for one indication may have an adverse effect on our ability to develop and potentially commercialize reproxalap or our other product candidates for the treatment of another indication;
- our inability to secure strategic partners which may be necessary for advancement of a product candidate into clinical development or commercialization; or
- our prioritization of other indications or product candidates for advancement.

The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including but not limited to:

- such authorities may disagree with the design, conduct, or implementation of our or any of our future development partners' clinical trials, including the endpoints of our clinical trials;
- such authorities may require clinical data in addition to clinical trial programs we expect, or may require changes to the designs and endpoints of subsequent clinical trials;
- a competitor product may have patent protection or another type of market exclusivity that delays approval of our product;
- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials if conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the design of such trials or require additional trials and data;
- changes in the leadership or operation of such authorities, which may result in, among other things, the implementation of new standards, or changes to the interpretation or enforcement of existing regulatory standards and requirements;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies; or
- the approval policies, standards, or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods, and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our future development partners from commercializing our product candidates. Moreover, we cannot predict healthcare reform initiatives, including potential reductions in federal funding or insurance coverage, that may be adopted in the future and whether or not any such reforms would have an adverse effect on our business and our ability to obtain regulatory approval for our current or future product candidates. There are evolving legal requirements that will continue to affect our business.

Because the Company has no experience in commercializing pharmaceutical products, there is a limited amount of information about us upon which to evaluate our product candidates and business prospects.

We have not yet demonstrated an ability to successfully overcome many of the pre-commercial and commercial risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan we will need to successfully:

- execute our product candidate development activities, including successfully designing and completing our clinical trial programs and product design and formulation of future product candidates, in a cost- effective manner;
- file for and obtain required regulatory approvals for our product candidates;
- enter into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap;
- manage our spending as costs and expenses increase due to the performance and completion of clinical trials, attempting to obtain regulatory approvals, manufacturing, and commercialization;
- secure substantial additional funding;
- develop and maintain successful strategic relationships;
- build and maintain a strong intellectual property portfolio;
- build and maintain appropriate clinical, regulatory, quality, manufacturing, compliance, sales, distribution, and marketing capabilities on our own or through third parties;
- implement and maintain operational, financial, and management systems;
- price our product candidates, if approved, at expected levels and obtain and maintain sufficient insurance and reimbursement from insurers and other payors; and
- gain broad market acceptance for our product candidates.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business, or continue our operations. Further, even if we are successful in clinical trials of product candidates, we may choose to place further development or commercialization on hold given perceived marketing challenges or the relative differences in commercial attractiveness within our portfolio.

The results of preclinical studies and earlier clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Drug development has inherent risk. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Drug development is a long, expensive, and uncertain process, and delay or failure can occur

at any stage of development, including after commencement of any of our clinical trials. Any negative results or perceived negative results in clinical trials for one indication may have an adverse effect on our ability to develop and potentially commercialize reproxalap or our other product candidates for the treatment of another indication. In addition, as product candidates proceed through development, the trial designs may often be different and may need to evolve and change from phase to phase or within the same phase or same trial, as is the case for adaptive trials; the vehicles or controls may be modified from trial to trial; and the product formulations or manufacturing process may differ due to the need to test product candidate samples that can be manufactured on a commercial scale. Success in run-in cohorts, earlier clinical trials, or clinical trials focused on a different indication does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through other phases of clinical testing. In addition, discussions with regulatory bodies, such as the FDA, may lead to changes in trial designs or programs. Companies frequently suffer significant setbacks in advanced clinical trials, even after run-in cohorts or earlier clinical trials have shown promising results. For example, the results of the TRANQUILITY Trial did not reflect the results of the TRANQUILITY run-in cohort. Moreover, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Because we are developing novel product candidates for the treatment of diseases in a manner which there is little clinical drug development experience and, in some cases, are designing adaptive trials or using new endpoints or methodologies, the regulatory pathways for approval are not well defined, and, as a result, there is greater risk that our clinical trials will not result in our desired outcomes or require additional trials.

Our clinical focus is on the development of new products for immune-mediated diseases. We performed an adaptive trial in proliferative vitreoretinopathy, the GUARD trial, and may do so with other indications in the future. In an adaptive trial, the initial parts of the trial are not designed to be pivotal or definitive. Rather, the initial parts of adaptive trials are expected to provide data to guide subsequent parts of the trial, which could require design changes, including but not limited to, different endpoints. In addition, following the initial parts of adaptive trials, we may, among other things, decide to continue to the subsequent parts of the trial, conclude the trial based on its success or failure in such initial parts, or discuss the trial results and regulatory pathway with regulatory authorities prior to determining next steps with respect to the trial and development program. As such, the likelihood of success in our late-stage clinical programs cannot necessarily be predicted.

We could also face challenges in designing clinical trials and obtaining regulatory approval of our product candidates due to the lack of historical clinical trial experience for novel classes of therapeutics. Thus, it is difficult to determine whether regulatory agencies will be receptive to the approval of our product candidates, and to predict the time and costs associated with obtaining regulatory approvals. The clinical trial requirements of the FDA and other regulatory agencies and the criteria regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and require more time and trial data than for other, better known, or more extensively studied classes of product candidates. In addition, it is possible that, as regulatory bodies gain more familiarity with our type of product candidates by reviewing competitor candidates, those agencies could impose new conditions on our product candidates that we did not expect. Any inability to design clinical trials with protocols, methodology, and endpoints acceptable to applicable regulatory authorities, and to obtain regulatory approvals for our product candidates, would have an adverse impact on our business, prospects, financial condition, and results of operations.

Because some of our product candidates are, to our knowledge, new chemical entities, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of these product candidates and obtain the necessary regulatory approvals for commercialization.

Some of our product candidates are, to our knowledge, new chemical entities, and unexpected problems related to new technologies may arise that can cause us to delay, suspend, or terminate our development efforts. As a result, short and long-term safety, as well as prospects for efficacy, are not fully understood and are difficult to predict. Regulatory approvals of new product candidates can be more expensive and take longer than approvals for well-characterized or more extensively studied pharmaceutical product candidates. Following discussions with the FDA and experts in the field, we may determine that it is not cost effective for us to develop one or more of our products in certain indications or we may decide to cease development in that area or seek a strategic partner.

We may not be able to qualify for or obtain various designations from regulators that would have the potential to expedite the review process of one or more of our product candidates, and even if we do receive one or more of such designations there is no guarantee that they will ultimately expedite the process, or aid in our obtaining marketing approval or provide market exclusivity.

There exist several designations that we can apply for from the FDA and other regulators that would provide us with various combinations of the potential for expedited regulatory review, certain financial incentives as well as the potential for post-approval exclusivity for a period of time. These designations include but are not limited to orphan drug designation, breakthrough therapy designation, accelerated approval, fast track status, and priority review for our product candidates. We may seek one or more of these designations for our current and future product candidates. For example, ADX-2191 has received orphan designation for the treatment of retinitis pigmentosa. There can be no assurance that any of our other product candidates will qualify for any of these designations. There can also be no assurance that any of our product candidates, that do qualify for these designations, will be granted such designations or that the FDA will not revoke such a designation it grants at a later date. Further, there can be no assurance that any of our product candidates that are granted such designations will ever benefit from such designations or that the FDA would not withdraw such designations once granted. Were we to receive a designation that promised a period of market exclusivity, such as orphan drug exclusivity, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Further, with respect to orphan drug status, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care.

To preserve trial integrity, clinical data from the initial parts of adaptive clinical trials may not be disclosed.

Adaptive clinical trials are often performed such that the initial parts of the trial are used to determine sample size and endpoints for subsequent, possibly pivotal parts of the trial. Results from the initial parts of adaptive trials are therefore not designed to be pivotal or definitive, and, in some cases, detailed trial data may not be disclosed so as not to positively or negatively bias investigators or patients involved in subsequent parts of the trial. Further, the initial parts of adaptive trials may be performed in part to assess biomarkers or surrogate markers that may require substantial time to generate, analyze, and interpret. Thus, disclosure of clinical results from the initial parts of adaptive trials may also be delayed due to the time required for biomarker or surrogate marker assessment.

We may find it difficult to enroll patients in our clinical trials or identify patients during commercialization (if our products are approved by regulatory agencies) for product candidates addressing orphan or rare diseases.

As part of our business strategy, we have and continue to evaluate the development and commercialization of product candidates for the treatment of orphan and other rare diseases, including Sjögren-Larsson and retinitis pigmentosa. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients willing and able to participate in the clinical trials required by the FDA or other non-United States regulatory agencies. In addition, if others develop products for the treatment of similar diseases, we would potentially compete with them for the enrollment in rare patient populations, which may adversely impact the rate of patient enrollment in and the timely completion of our current and planned clinical trials. Any negative results or perceived negative results in clinical trials of our product candidates may make it difficult or impossible to recruit or retain patients in other clinical trials of the same product candidate. Insufficient patient enrollment may be a function of other factors, including the size and nature of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the timing and magnitude of disease symptom presentation, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Our inability to identify and enroll a sufficient number of eligible patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials or development program. Public health epidemics or pandemics and the response thereto may have an impact on our ability to enroll and retain patients in our clinical trials. For instance, patient enrollment in our GUARD trial of ADX-2191 and our 12-month safety trial of reproxalap were negatively impacted as a result of limited clinical trial staffing at trial sites and some patients electing to delay surgery. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates. For instance, in rare diseases such as proliferative vitreoretinopathy and idiopathic nephrotic syndrome, lack of availability of, or

difficulty recruiting or retaining a sufficient number of, patients may make it difficult or cost-prohibitive to sufficiently power our clinical trials, which may not enable us to continue development and seek regulatory approval for the applicable product candidate. Further, if our products are approved by regulatory agencies, we may not be able to identify sufficient number of patients to generate significant revenues.

Any product candidate we or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Unacceptable adverse events caused by any of our product candidates that we or others advance into clinical trials could cause us or regulatory authorities to interrupt, delay, or halt clinical trials, or impose a clinical hold, potentially resulting in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale.

We continue to develop our product candidates for the treatment of the indications for which we intend to seek approval, and we currently do not know the full extent of adverse events that will be observed in subjects that receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, which may be larger or longer than those previously conducted, we may not be able to obtain regulatory approval or commercialize such product candidate.

Even if we obtain marketing approval for reproxalap or any other product candidate, it could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any are approved.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies or clinical trials, post-market surveillance, or other potential additional clinical trials. Following approval, if any, of reproxalap or any other product candidate, such candidate will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping, and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements, including those relating to quality control, quality assurance, and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated seriousness, severity, or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for reproxalap or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy (REMS) plan as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria, and requiring treated patients to enroll in a registry.

In addition, if reproxalap or any of our other product candidates is approved, its product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also entered into consent decrees and Corporate Integrity Agreements under which specified promotional conduct is changed or curtailed.

Even if we receive regulatory approval for reproxalap or any other product candidate, we or are partners, if any, still may not be able to successfully commercialize, and the revenue that we generate from its sales, if any, could be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, is also generally necessary for commercial success. In addition, we or are partners, if any, may not be able to secure advantageous contracts with payors or price our products at the expected level or at levels that make successful commercialization viable. The pricing of our products will be subject to numerous factors, many of which are outside of our control, including the pricing of similar products. The degree of market acceptance of our product candidates will depend on a number of factors, including but not limited to:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient populations and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulations by health care providers and their patients;
- the prevalence, seriousness, and severity of any adverse effects;
- new procedures or methods of treatment that may be more effective in treating conditions for which our products are intended to treat;
- the safety of product candidates seen in a broader patient group, including their use outside the approved indications;
- pricing and cost-effectiveness, including the cost of treatment in relation to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient, commercially advantageous, and timely third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts;

- unfavorable publicity; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

In addition, because the active ingredient of ADX-2191 (methotrexate) is a generic drug, a generic manufacturer may be able to develop and market a competitive intravitreal formulation of methotrexate following expiration of commercial exclusivity mandated via certain orphan drug designations. Generic drug competition would have a material and adverse effect on the commercial potential of ADX-2191. Further, our ability to successfully commercialize ADX-2191, if approved, depends on a number of additional factors, including but not limited to, the level of enforcement by the FDA to ensure that compounded copies of commercially available FDA-approved products manufactured by compounding pharmacies, including compounded copies of ADX-2191, that may be in violation of the federal Drug Quality and Security Act (DQSA) and other relevant provisions of the United States Federal Food, Drug, and Cosmetic Act (FDCA), are not produced and dispensed to patients.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect that ongoing initiatives in the United States will increase pressure on drug pricing. Such reforms could have an adverse effect on the pricing of and anticipated revenues from our current or future product candidates for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, or patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Our or our partners' efforts to educate the medical community and third-party payors on the benefits of reproxalap or any of our other product candidates may require significant resources and may never be successful. In addition, our or our partners' ability to successfully commercialize our product candidate will depend on our ability to manufacture our products, differentiate our products from competing products and defend the intellectual property of our products. Competitors with numerous approved products may be able to negotiate pricing and reimbursement that is substantially more advantageous than that which we will be able to negotiate.

Additionally, if any of our competitors' products are approved and are unable to gain market acceptance for any reason, there could be a market perception that products like reproxalap are not able to adequately meet an unmet medical need. If we or are partners, if any, are unable to demonstrate to physicians, hospitals, third-party payors, and patients that our products are better alternatives, we or are partners, if any, may not be able to gain market acceptance for our products at the levels we anticipate and our business may be materially harmed as a result.

If the market opportunities for reproxalap and our other product candidates are smaller than we believe they are and, if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

We focus our research and product development on treatments for immune-mediated diseases. Our estimated addressable markets and market opportunities for our drug candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected. In addition, our product candidates may not achieve commercial success due to market conditions or regulatory challenges.

Any of these factors may negatively affect our ability to generate revenues from sales of our product and our ability to achieve and maintain profitability, and as a consequence, our business may suffer. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. The reimbursement levels may be significantly less than the currently anticipated pricing of our product candidates. As a result of negative trends in the general economy in the United States or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective, including cost effectiveness relative to existing contracts with other pharmaceutical companies; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost effectiveness data for the use of the applicable product candidate to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Further, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only in limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to the United States healthcare system, including changes to the methods for, and amounts of, Medicare reimbursement. Many members of the United States Congress have attempted to repeal and replace the Patient Protection and Affordable Care Act (PPACA), but they have been unsuccessful in doing so as of the date of the filing of this report. We cannot predict the ultimate form or timing of any repeal or replacement of PPACA or the effect such repeal or replacement would have on our business. Regardless of the impact of repeal or replacement of PPACA on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments, or the imposition of enrollment limitations on new providers, may change the availability, methods, and rates of reimbursements from Medicare, private insurers, and other third-party payers for our current and future product candidates, if any, for which we are able to obtain regulatory approval. Some of these changes and proposed changes could result in reduced reimbursement rates for such product candidates, if approved, which would adversely affect our business strategy, operations, and financial results.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. Payors may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for use of newly approved drugs, which in turn could lower drug pricing. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, larger companies contracting with payors to diminish reimbursement for competitive products, and additional legislative proposals as well as country, regional, or local healthcare budget limitations.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The process of manufacturing our products is complex, highly regulated, and subject to several risks, including:

- The manufacturing of compounds is extremely susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures, and numerous other factors.
- We and our contract manufacturers must comply with the cGMP regulations and guidelines. We and our contract manufacturers may encounter difficulties in achieving quality control and quality assurance, and may experience shortages in qualified personnel. We and our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or any delay, interruption, or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical trials, the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions, and criminal prosecutions, any of which could damage our reputation or impair our ability to develop and commercialize our products. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

In order to conduct clinical trials of our drug candidates, we will need to manufacture them in large quantities. Quality issues may arise during scale-up activities. Our reliance on a limited number of Contract Manufacturing Organizations (CMOs), the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our drug candidates, and cause us to incur higher costs and prevent us from commercializing our drug candidates successfully. Furthermore, if our CMOs fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement CMOs capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. In addition, failure of CMOs to comply with regulatory and quality requirements could delay manufacturing or the review of our marketing applications.

Any adverse developments affecting manufacturing operations for our products, including public health epidemics or pandemics or responses taken thereto, may result in shipment delays; inventory shortages; lot failures; product withdrawals, recalls, approvals; or other interruptions in the supply of our products. We may also have to account for inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality controls, assurance, and management plays an essential role in meeting customer requirements, preventing defects, improving our product candidates and services, and assuring the safety and efficacy of our product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations, or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly than ours, marketed more successfully, or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology market. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies (including generic and over-the-counter drugs) as well as with new treatments that may be introduced by our competitors. With the exception of proliferative vitreoretinopathy and retinitis pigmentosa, there are a variety of approved drugs and drug candidates in development for the indications that we intend to test. Current treatments that are used in the United States for dry eye disease include over the counter artificial tears, Restasis®, Xiidra®, Cequa®, Eysuvis®, Tyrvaya®, Miebo™, and Vevye®. In February 2022, the FDA approved the first generic version of Restasis®, which is now available for sale in the U.S. Many of our competitors have significantly greater financial, product candidate development, manufacturing, and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, universities and private and public research institutes could be in direct competition with us. We also may compete with these organizations to recruit management, scientists, and commercial and clinical development personnel. We will also face competition from these third parties in establishing clinical trial sites, registering subjects for clinical trials, and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. Other parties may discover and patent treatment approaches and compositions that are similar to or different from ours. Competition in drug development is intense. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

Our future success depends on our or our partners' ability to demonstrate and maintain a competitive advantage with respect to the design, development, and commercialization of reproxalap or our other product candidates. Inflammatory diseases may be treated with general immune suppressing therapies, including corticosteroids, some of which are generic. Our potential competitors in inflammatory diseases may be developing novel immune modulating therapies that may be safer or more effective than our product candidates.

If we are unable to successfully establish and maintain sales, distribution, and marketing capabilities or enter into agreements with third parties to market, sell, and distribute our product candidates, we may be unable to generate any revenues.

We have only recently begun to establish a sales or marketing infrastructure and have no experience as a Company in the sale, marketing or distribution of biopharmaceutical products. Although we currently plan to commercialize reproxalap through a collaboration with a third party, if reproxalap or any of our other product candidates ultimately receives regulatory approval and we remain responsible for the commercialization of such approved product, we may not be able to effectively market and distribute the product candidate. We will have to invest significant amounts of financial and management resources to develop and maintain internal sales, distribution, and marketing capabilities, some of which will be committed prior to any confirmation that the applicable product candidates will be approved.

We currently plan to commercialize reproxalap through a collaboration with a third party. However, if we are not able to establish a suitable collaboration, we expect that we may need to build our own sales and marketing organization to support the commercialization in the United States of reproxalap. In addition, we expect that we may build our own sales and marketing organization to support the commercialization in the United States of other product candidates for which we receive marketing approval. If we do obtain marketing approval for reproxalap or any other product candidate that we develop, we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of reproxalap or any product candidate for which we or our partners establish a commercial infrastructure is delayed or does not occur for any reason, including if we do not receive marketing approval on the timeframe we expect, we or our partners would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we are unable to establish our own sales and marketing capabilities and enter into arrangements with third parties to perform these services, our revenue from product sales and our profitability, if any, are likely to be lower than if we ourselves were to market and sell any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug candidates or may be unable to do so on terms that are acceptable to us. Any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our product candidates that receive marketing approval, or such authorities do not grant our product candidates appropriate periods of data or market exclusivity before approving generic versions of our product candidates, the sales of our product candidates could be adversely affected.

Once an NDA is approved, the drug covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek marketing approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications (ANDAs) in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials demonstrating safety and efficacy. Rather, the applicant generally must show that its drug is pharmaceutically equivalent to the reference listed drug, in that it has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug, and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic drugs may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic drugs are generally able to offer drug products at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic drug.

The FDA may not approve an ANDA for a generic drug until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such product candidate where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity, enforceability or non-infringement. The FDCA also provides three years of marketing exclusivity for a 505(b)(1) NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations other than bioavailability studies (e.g., investigations that support new indications, dosages, or strengths of an existing drug) were conducted or sponsored by the applicant and are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving competitor products for product candidates containing the original active agent for other conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full 505(b)(1) NDA. Manufacturers may seek to launch these generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for our drug.

In the EU and the UK, innovative medicinal products are authorized based on a full marketing authorization application (as opposed to an application for marketing authorization that relies on data in the marketing authorization dossier for another, previously approved medicinal product). Applications for marketing authorization for innovative medicinal products must contain the results of pharmaceutical tests, preclinical tests, and clinical trials conducted with the medicinal product for which marketing authorization is sought (and where applicable the result of the pediatric studies unless a waiver or a deferral has been obtained - as described further below). In the EU, these applications must be made pursuant to either Directive 2001/83/EC (for the decentralized procedure or the mutual recognition procedure) or Regulation 726/2004 (for the centralized procedure). In the UK, there are various procedures available under the new regulatory legal framework to pharmaceutical products, including the possibility of a recognized assessment conducted by the European authorities under certain circumstance or by applying directly to the UK regulatory authority (MHRA).

Where an applicant for a marketing authorization submits a full dossier containing its own pharmaceutical, pre-clinical tests and clinical trials data, and where the application does not fall within the "global marketing authorization" of an existing medicinal product, the applicant is entitled to eight years of regulatory data protection upon grant of the marketing authorization (the period starts to run from the first marketing authorization in the EU/ European Economic Area (EEA)). During this period, applicants for approval of generics or biosimilars cannot rely on data contained in the marketing authorization dossier submitted for the already authorized, or reference, medicinal product to support their application. After the expiration of the eight-year period of regulatory data protection, the reference medicinal product benefits from a further two-year period of marketing protection. During these two years of marketing protection, no generic or biosimilar medicinal product that relies upon the reference medicinal product’s dossier may be placed on the EU market, but a generic or biosimilar marketing authorization application can be submitted to the competent regulatory authorities in the EU Member States during this time. The two-year period of marketing protection can further be extended by one year if, during the first eight years of the grant of the first marketing authorization, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, even if a compound is considered to be a new active substance and the innovator is able to gain the period of regulatory data protection and marketing protection, provided that no other IP or regulatory exclusivities applied, another unrelated company could also apply for a marketing authorization and market another competing medicinal product for the same therapeutic indication if such company obtained its own marketing authorization based on a separate marketing authorization application based on a full self-standing scientific data package supporting the application. The period of regulatory data protection and marketing protection applies in the UK (running from the date of the first authorization in Great Britain).

In the EU, pursuant to Regulation 1901/2006, and in the UK pursuant to the Human Medicines Regulations 2012 (as amended), marketing authorization applications must include pediatric data based on pediatric investigation plans agreed with the EMA if the MAA concerns (i) a new active substance, or (ii) a new indication, pharmacological form, or route of administration (where the product is protected by a supplementary protection certificate or a patent qualifying for a supplementary certificate). Applicants may obtain waivers or deferrals to these

requirements in certain circumstances (for example a waiver may be obtained if the condition only occurs in adult populations). Where required, pediatric studies must cover all sub-sets of the pediatric population for both existing and new indications, pharmacological forms and route of administrations. Limited further exclusions apply, including in relation to generic or biosimilar applications. Certain rewards may be available for completion of pediatric studies. For example, where MAAs include the results of all studies conducted in compliance with an agreed pediatric investigation plan, the holder of the patent or supplementary protection certificate may be entitled to a six-month extension to the supplementary protection certificate.

In order to obtain orphan designation in the EEA, the product must fulfill certain challenging criteria. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; and (2) either the prevalence of such condition must not be more than five in 10,000 persons in the EU when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EU to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000.

Products receiving orphan designation in the EU may receive 10 years of orphan market exclusivity, which can be further extended by two years if pediatric studies have been conducted in accordance with an agreed pediatric investigational plan. Applications must first satisfy the orphan designation criteria and apply for orphan designation before making the application for marketing authorization. The applicant must then successfully maintain the orphan designation at the time of the marketing authorization application in order to qualify for 10 years of orphan market exclusivity. During this 10-year period, the competent authorities of the EU Member States and European Commission may not accept applications or grant marketing authorization for other similar medicinal products for the same orphan therapeutic indication. The protection afforded by orphan market exclusivity in the EU may, in some circumstances, be circumvented by competitor products which are demonstrated not to be "similar" or which are authorized for different therapeutic indications. There may be a risk that products may be prescribed "off-label" for the orphan therapeutic indication by healthcare professions in some EU Member States.

There are also three exceptions to the orphan market exclusivity principle. Marketing authorization may be granted to a similar medicinal product for the same orphan therapeutic indication if:

- The second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective, or otherwise clinically superior;
- The holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- The holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

An orphan product can also obtain an additional two years of orphan market exclusivity in the EU if the marketing authorization application contains the results of all pediatric studies conducted in accordance with and agreed pediatric investigation plan. The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation; for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity.

The UK’s regulatory legal framework provides for similar periods of protection, namely regulatory data protection, marketing protection and market exclusivity.

It is important to note that the regulatory protection afforded to medicinal product such as data exclusivity, marketing protection, market exclusivity for orphan indications, and pediatric extension are currently under review at EU level. It is expected that the protection currently afforded in the EU will be reduced in the years to come.

Competition that our product candidates may face from generic versions of our product candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates. Our future revenues, profitability, and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those product candidates may be substantially limited if our product candidates, if and when approved, are not afforded the appropriate periods of non-patent exclusivity.

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels; ability to hire and retain key personnel; and statutory, regulatory, and policy changes.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels; ability to hire and retain key personnel; and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

In December 2016, the 21st Century Cures Act was signed into law, and was designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. In the past, the FDA was often unable to offer key leadership candidates (including scientists) competitive compensation packages as compared to those offered by private industry. The 21st Century Cures Act was designed to streamline the agency's hiring process and enable the FDA to compete for leadership talent by expanding the narrow ranges that are provided in the existing compensation structures.

Disruptions at the FDA and other governmental agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our operating results and business.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing and commercializing our products abroad and may limit our ability to generate revenue from product sales.

We intend to market and commercialize our product candidates internationally. To market and sell our drug candidates in jurisdictions outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals on a timely basis or non-compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our drug candidates in certain countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue.

The UK's exit from the EU continues to create political and economic uncertainty, particularly in the UK and the EU. The UK is now being treated as a "third country" by the EU and new UK legislation has taken effect. This means that some regulatory activities, such as batch testing and Qualified Person certification conducted in Great Britain is no longer recognized in the EU. However, the UK and EU have concluded a Trade and Cooperation Agreement (TCA), which has been approved by the UK Parliament, European Council and European Parliament and has limited the disruption to the supply of medicines, particularly by enabling tariff and quota-free trade between the

UK and the EU (provided that the rules of origin requirements are met), and has streamlined some issues, for example by enabling mutual recognition of cGMP inspections and certificates. The regulatory framework for medicines that existed before the end of the transition period has also effectively been preserved in UK domestic legislation as "retained EU law." By retaining a snapshot of EU legislation at its core, the UK has prevented substantial divergence to the regulation of medicines (although divergence has appeared in some areas). However, some changes to the UK legislation have been immediately necessary, including the implementation of the Northern Ireland Protocol (NIP), pursuant to which, the EU pharmaceutical legal framework acquis continues to apply in Northern Ireland (subject to periodic consent of the Northern Ireland Legislative Assembly), and only products compliant with EU law can be placed in the Northern Ireland market - adding an extra layer of regulatory complexity. As companies now need to comply with a separate UK regulatory legal framework in order to commercialize medicinal products in Great Britain (namely, England, Wales and Scotland, as EU law continues to apply in Northern Ireland). The UK government is currently trying to renegotiate fundamental aspects of the NIP so this is an unpredictable area for companies in the near future. The TCA allows for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products. It is also important to note that obtaining a marketing authorization is not sufficient to gain effective access to the market in the EU and in the UK; companies still need to agree to a reimbursement price for the products and in some jurisdictions, such as the UK and Germany, a further positive recommendation from health technology on cost-effectiveness is required for the products to be actually prescribed and reimbursed by the respective national health systems (see below). If we fail to comply with the regulatory requirements in international markets and thus receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our drug candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our drug candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that drug candidate and our business prospects could decline.

Risks Related to our Financial Position and Capital Requirements

We have incurred significant operating losses since inception and we expect to incur significant losses over the next several years. We may never become profitable or, if achieved, be able to sustain profitability.

We have incurred significant operating losses since we were founded in 2004 and expect to incur significant losses for the next several years as we continue our clinical trial, development programs, and commercial activities for reproxalap and our other product candidates. Net loss for the year ended December 31, 2023 and 2022 was approximately $37.5 million and $62.0 million, respectively. As of December 31, 2023, we had total stockholders' equity of $119.8 million and an accumulated deficit of $394.3 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, pre-commercial activities, and, if reproxalap or any of our other product candidates is approved and we do not enter into collaboration agreements with third parties, commercialization efforts, including sales and marketing activities, that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially as compared to prior periods as we prepare for commercializing of reproxalap alone or with others, if approved, and continue development of ADX-2191, ADX-629, ADX-246, ADX-248, and other product candidates, and as a result of increased headcount, including management personnel to support our clinical, manufacturing and commercialization activities, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company, and increased insurance premiums, among other factors. Our license agreement with Massachusetts Eye and Ear Infirmary, or MEEI, under which we license certain of our patent rights and a significant portion of the technology for ADX-2191, imposes royalty and other financial obligations on us, and we may enter into additional licensing and funding arrangements with third parties that may impose milestone payment, royalty, insurance and other obligations on us.

Our expenses will also increase if and as we:

- seek marketing approval for reproxalap and establish our sales, marketing and distribution capabilities for reproxalap in advance of and upon any such approval;
- are unable to enter into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap;
- conduct any necessary clinical trials and other development activities and/or seek marketing approvals for ADX-2191, ADX-629, ADX-246, ADX-248 and any other product candidates;
- pursue the clinical development of reproxalap for the treatment of other additional indications or for use in other patient populations or, if approved, seek to broaden the label of reproxalap;
- scale up our manufacturing processes and capabilities to support commercialization of reproxalap and any of our other product candidates for which we seek and/or obtain marketing approval and for which we remain responsible for the commercialization of;
- leverage our RASP-modulator discovery platform to advance additional therapeutics into preclinical and clinical development;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability insurance coverage as we initiate and expand our commercialization efforts; and
- expand our sales, marketing and distribution capabilities for our other product candidates, prior to or upon receiving marketing approval;

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase from what we anticipate if:

- we are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates; or
- there are any third-party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property-related claims.

Our ability to become and remain profitable depends on our ability to generate revenue. We currently generate no revenue from sales, and we may never be able to commercialize reproxalap or our other product candidates. We do not currently have the required approvals to market any of our product candidates and we may never receive them. We do not expect to generate revenue from sales of our product candidates that is sufficient to achieve profitability, excluding any upfront licensing fees we may receive, unless and until we obtain marketing approval for and commercialize one or more of our product candidates. We do not expect to commercialize reproxalap alone or with others or any of our other product candidates before at least the first half of 2025, if ever. Achieving profitability will require us or our partners, if any, to be successful in a range of challenging activities, including:

- obtaining marketing approval for reproxalap or any other product candidates;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;

- entering into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap;
- hiring and building a full commercial organization required for the marketing, selling and distributing for those products which we obtain marketing approval and for which we remain responsible for the commercialization of;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize; and
- obtaining, maintaining and protecting our intellectual property rights.

We may never succeed in these activities and may never generate revenue that is sufficient to achieve profitability. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

We will require substantial additional financing, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

The development and commercialization of biopharmaceutical products is capital intensive. We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we seek marketing approval and prepare for commercialization of reproxalap alone or with others, and continue the development of our product candidates through preclinical and clinical development, including multiple ongoing and planned clinical trials for our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we prepare for commercializing reproxalap alone or with others, if approved, and we continue the research and development of, and, if successful, seek marketing approval for, our product candidates.

We currently plan to commercialize reproxalap through a collaboration with a third party. If we do obtain marketing approval for reproxalap and are not able to establish a suitable collaboration for the commercialization of reproxalap, or any other product candidate that we develop, we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed on attractive terms, if at all, we will be forced to delay, reduce, or eliminate certain of our clinical development plans, research and development programs or future commercialization efforts. In addition, there can be no assurance that we will be able to obtain such financing on commercially reasonable terms or at all. The development process for our product candidates is highly uncertain, and we cannot estimate with certainty the actual amounts necessary to successfully complete the development, regulatory approval, and commercialization of our product candidates for which we remain responsible for the commercialization of. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than expected, through public or private equity, debt financings, or other sources. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the costs, timing and outcome of regulatory review of reproxalap, including any additional trials the FDA or other regulatory agencies may require for approval or label expansion;
- the progress, costs and results of any clinical activities for regulatory review of reproxalap outside of the United States;
- the exercise, if any, of the Option;

- the costs and timing of process development and manufacturing scale-up activities associated with reproxalap;
- the costs of commercialization activities for reproxalap if we receive marketing approval and if we are unable to enter into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap, and pre-commercialization costs for reproxalap or any other product candidates incurred prior to receiving, any such marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- assuming receipt of marketing approval, the amount of revenue received from commercial sales of reproxalap or any other product candidates;
- the terms and timing of establishing collaborations, license agreements, and other partnerships on terms favorable to us;
- the type, number, scope, progress, expansion costs, results, and timing of our clinical trials of any product candidates that we are pursuing or may choose to pursue in the future;
- costs associated with any other product candidates that we may develop, in-license, or acquire, including potential milestone or royalty payments; and
- the costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights.

Some of these factors are outside of our control. Our existing capital resources are not sufficient to enable us to fund the commercialization of reproxalap and completion of our clinical trials and remaining development through commercial introduction for our product candidates. We expect that we will need to raise substantial additional funds in the near future.

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through collaboration agreements and public or private financings, including debt financings. The state of the global economy and market instability has made the business climate volatile and more costly. Uncertain economic conditions, uncertainty as to the general direction of the macroeconomic environment, and the price of our common stock, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. For example, the capital and credit markets may be adversely affected by the ongoing conflict between Russia and Ukraine, Hamas' attack against Israel and the ensuing conflict, and the possibility of a wider regional or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as a global financial crisis, could affect our ability to raise additional capital. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders or be excessively dilutive. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, reduce or discontinue our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or curtail, delay, or discontinue one or more of our preclinical studies, clinical trials or other research or development programs. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, may need to restructure our organization, or may be required to relinquish rights to our product candidates or other technologies, or otherwise agree to terms unfavorable to us. Any of these occurrences could materially affect our business, financial condition, and results of operations.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- regulatory developments affecting reproxalap and our other product candidates;
- our establishment and maintenance of a sales, marketing and distribution infrastructure and outsourced manufacturing capabilities to commercialize any product candidate for which we may obtain marketing approval and for which we remain responsible for commercialization of;

- variations in the level of expenses related to our clinical trial and development programs;
- addition or termination of clinical trials or development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- the exercise, if any, of the Option;
- our ability to negotiate and enter into a collaboration agreement with a suitable third party on acceptable terms for the commercialization of reproxalap;
- our execution of any collaborative, licensing, or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the number of administrative, clinical, regulatory, and scientific personnel we engage;
- nature and terms of stock-based compensation grants; and
- derivative instruments recorded at fair value.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional capital may cause dilution to stockholders, restrict our operations or require us to relinquish rights to its technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate its product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market on our own.

We may allocate our cash, cash equivalents, and marketable securities in ways that you and other stockholders may not approve.

Our management has broad discretion in the application of our cash, cash equivalents, and marketable securities. Because of the number and variability of factors that will determine our use of our cash, cash equivalents, and marketable securities, management's ultimate use of cash, cash equivalents, and marketable securities may vary substantially from the currently intended use. Our management might not apply our cash, cash equivalents, and marketable securities in ways that ultimately increase the value of your investment. We expect to use our cash, cash equivalents, and marketable securities to: fund our planned clinical trials of a number of product candidates; continue to fund the potential NDA resubmission and approval process for reproxalap, including conducting any additional clinical trials or other activities that the FDA may require for approval of reproxalap; fund an initial commercialization and launch of reproxalap, if approved; develop other molecules that relate to immune-mediated disease; pursue regulatory approval for our product candidates; service our debt obligations; and provide working capital and capital for other general corporate purposes. The failure by our management to apply these funds effectively could harm our business. We may invest our cash, cash equivalents, and marketable securities in

short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash, cash equivalents, and marketable securities in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

The terms of our secured debt facility require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In March 2019, we entered into a credit facility with Hercules Capital, which was subsequently amended in April 2021 and December 2022, that is secured by a lien covering all of our assets, other than our intellectual property. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock, or make investments. If we default under the terms of the Hercules Credit Facility or any future debt facility, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the loan agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of transactions involving our common stock.

In general, under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and certain other tax assets (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock within the testing period, even those outside our control, such as purchases or sales by investors, could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs or credits could have a material adverse effect on our results of operations and cash flows. We believe, prior to December 31, 2021, that four ownership changes occurred since inception. Management believes that its aggregate Section 382 and 383 limitation (including the additional limitation for recognized "built-in gains") is sufficient so that no current impairment of its pre-ownership change tax attributes is required. We believe there were no ownership changes from December 31, 2021 through December 31, 2023, based on a review of our equity history during that period. Any future ownership changes, including those resulting from our recent or future financing activities, may cause our existing tax attributes to have additional limitations. However, subject to annual limitations, Federal NOLs generated in years 2018 and beyond will have an indefinite carryforward period and will not expire. Future changes in federal and state tax laws pertaining to NOL carryforwards may also cause limitations or restrictions from us claiming such NOLs. If the NOL carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. If we obtain approval in the United States, we will be subject to the Inflation Reduction Act of 2022 (IRA), which, among other things, will allow Department of Health and Human Services (HHS) to negotiate the

selling price of certain drugs and biologics that Centers for Medicare & Medicaid Services (CMS) reimburses under Medicare Part B and Part D. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product candidates. In some foreign countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. Furthermore, in some European countries, the authorities conduct a Health Technology Appraisal to assess the cost-effectiveness of the product, which may significantly impact effective access to the market. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to business disruptions such as earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health epidemics, regional or larger scale conflicts or geo-political actions, war or other military conflict, including an escalation of the conflict between Russia and Ukraine, Hamas' attack against Israel and the ensuing conflict, trade policies, sanctions, treaties and tariffs and other natural or man-made disasters or other business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition, and increase our costs and expenses. We rely on third-party manufacturers to produce reproxalap and our other product candidates. Our ability to obtain clinical and commercial supplies of reproxalap or our other product candidates could be disrupted, if the operations of these suppliers are affected by these business disruptions.

We are in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict. Our business, financial condition, and results of operations may be materially adversely affected by the negative impact on the global economy and capital markets resulting from the conflicts in Ukraine and Israel or any other geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the military conflict between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict. In February 2022, a full-scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit, and capital markets, as well as supply chain disruptions.

Additionally, various of Russia's actions have led to sanctions and other penalties being levied by the U.S., the European Union, and other countries, as well as other public and private actors and companies, against Russia and certain other geographic areas, including agreement to remove certain Russian financial institutions from the SWIFT payment system and restrictions on imports of Russian oil, liquefied natural gas, and coal. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could further adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

In addition, in October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Any of the above-mentioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions, and resulting market disruptions are impossible to

predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this annual report.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $250,000 Federal Deposit Insurance Corporation insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limits. Concerns regarding the U.S. or international financial systems, including bank failures and bailouts, and their potential broader effects and potential systemic risk on the banking sector generally, may adversely affect our access to capital. Any decline in available funding or access to our cash and liquidity resources could, among other risks, limit our ability to meet our capital needs and fund future growth or fulfill our other obligations, or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our business, financial condition and results of operations.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return these deposits, or if a depository institution is subject to other adverse conditions in the financial or credit markets, could further impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

If we engage in an acquisition, reorganization, or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have entered into, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies, or products, or entering into a business combination with another company. For example, in January 2019 we acquired Helio Vision, Inc. and obtained the rights to ADX-2191, a vitreous-compatible methotrexate formulation for intraocular injection, for the prevention of proliferative vitreoretinopathy. Any acquisitions we undertake or have recently completed will likely be accompanied by business risks which may include, among other things:

- the effect of the acquisition on our financial and strategic position and reputation;
- the failure of an acquisition to result in expected benefits, which may include benefits relating to new product candidates, human resources, costs savings, operating efficiencies, goodwill, and other synergies;
- the difficulty, cost, and management effort required to integrate the acquired businesses, including costs and delays in implementing common systems and procedures, and costs and delays caused by communication difficulties;
- the assumption of certain known or unknown liabilities of the acquired business, including litigation-related liabilities;
- the reduction of our cash available for operations and other uses, the increase in amortization expense related to identifiable assets acquired, potentially dilutive issuances of equity securities, or the incurrence of debt;

- the possibility that we will pay more than the value we derive from the acquisition;
- the impairment of relationships with our partners, consultants, or suppliers, or those of the acquired business; and
- the potential loss of key employees of the acquired business.

These factors could harm our business, results of operations, or financial condition.

In addition to the risks commonly encountered in the acquisition of a business or assets as described above, we may also experience risks relating to the challenges and costs of closing a transaction. The risks described above may be exacerbated as a result of managing multiple acquisitions at once.

Risks Related to our Reliance on Third Parties

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development, commercial readiness preparations, and supply of reproxalap and our other product candidates.

As of December 31, 2023, we had only 10 full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis, manufacturing, commercial readiness preparations, financial reporting and accounting, and human resources, as well as for certain functions required of publicly traded companies. We may have limited control over third parties and we cannot guarantee that any third-party will perform its obligations in an effective and timely manner.

In addition, during challenging and uncertain economic environments, in tight credit markets and during public health epidemics, and with the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, there may be a disruption or delay in the performance of our third-party contractors, suppliers, or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

We rely on third parties to conduct our clinical trials. If any third-party does not meet our deadlines or otherwise conduct the trials as required and in accordance with regulations, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates when expected, or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on third parties to conduct the clinical trials for our product candidates and, therefore, the timing of the initiation and completion of these trials is controlled by such third parties and may occur on substantially different timing from our estimates. Specifically, we use CROs to conduct our clinical trials and we also rely on medical institutions, clinical investigators, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that CROs, investigators, or other third parties on which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time, and may receive cash or equity compensation in connection with such services. Any worsening of the global business and economic environment may have the effect of heightening or exacerbating these risks.

Some of our product candidates may be studied in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have minimal or no control over the conduct of such trials.

We currently anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our product candidates will involve investigator-initiated clinical trials. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this "Risk Factor" section relating to our internal clinical trials. While investigator-initiated trials may provide us with clinical data that can inform our future development strategy, we generally have less control over the conduct and design of the trials. Because we are not the sponsors of investigator-initiated trials, we do not control the protocols, administration, or conduct of the trials, including follow-up with patients and ongoing collection of data after treatment. As a result, we are subject to risks associated with the way investigator-initiated trials are conducted. In particular, we may be named in lawsuits that would lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-initiated clinical trials could have a material adverse effect on our prospects and the perception of our product candidates. As a result, our lack of control over the conduct and timing of, and communications with the FDA regarding, investigator-sponsored trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates.

We rely completely on third parties to supply drug substance and manufacture drug product for our clinical trials and preclinical studies. We intend to rely on other third parties to produce commercial supplies of product candidates, and our dependence on third parties could adversely impact our business.

We are completely dependent on third-party suppliers of the drug substance and drug product for our product candidates. If third-party suppliers do not supply sufficient quantities of materials to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our supplies, which would adversely affect clinical development and commercialization. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications within regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. We do not have any control over the process or timing of the acquisition of raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial, including as a result of the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, could considerably delay completion of that clinical trial, product candidate testing, and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

We may not be successful in establishing and maintaining development, commercial, or other strategic partnerships, which could adversely affect our ability to develop and commercialize product candidates.

We have in the past chosen, and may in the future choose, to enter into development or other strategic partnerships, including collaborations with major biotechnology or pharmaceutical companies. For example, we currently plan to commercialize reproxalap through a collaboration with a third party. We face significant competition in seeking appropriate partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish other development partnerships or other alternative arrangements for any of our product candidates or programs because our research and development pipeline may be insufficient, our product candidates or programs may be deemed to be at too early a stage of development for collaborative effort, and/or third parties may not view our product candidates or programs as having the requisite commercial or technical potential. Even if we are successful in our efforts to establish development or commercial partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are below expectations. Any delay in entering into development partnership agreements or collaborations related to our product candidates could delay the development and commercialization of our product candidates and reduce competitiveness, if approved.

Moreover, if we fail to maintain partnerships related to our product candidates:

- the development and/or commercialization of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development and commercialization of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development and commercialization of any such product candidates.

We may not realize the benefits of our current or future strategic alliances.

We have in the past, and may in the future, form strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including the continued development or commercialization of reproxalap or our other product candidates. We currently plan to commercialize reproxalap through a collaboration with a third party. Research, development, regulatory and commercialization activities undertaken by our partners, if any, pose similar risks as those set forth elsewhere in this "Risk Factor" section relating to our research, development, regulatory and commercialization activities. Strategic alliances may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for reproxalap or our other product candidates because third parties may view the risk of development failure as too significant or the commercial opportunity for our product candidate as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

Our internal computer systems, or those of our development partners, third-party clinical research organizations, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war or other military conflict, including as a result of the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, and telecommunication and electrical failures. While to our knowledge we have not experienced any such material

system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed.

We rely on email and other messaging services in connection with our operations. We may be targeted by parties using fraudulent spoofing and phishing emails to misappropriate passwords, payment information, or other personal information, or to introduce viruses through Trojan horse programs or otherwise through our networks, computers, smartphones, tablets, or other devices. Despite our efforts to mitigate the effectiveness of such malicious email campaigns through a variety of control and non-electronic checks, spoofing and phishing may damage our business and increase our costs. These risks may be heightened as a result of remote working arrangements. In addition, due to the political uncertainty involving the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, there is an increased likelihood that escalation of tensions could result in cyberattacks that could either directly or indirectly impact our operations. Any of these events or circumstances could materially adversely affect our business, financial condition, and operating results.

Risks Relating to Our Intellectual Property

Our success depends on our and our licensors' ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and the use of our product candidates or proprietary technologies as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. While we have issued composition-of-matter patents in the United States and other countries for reproxalap, and other product candidates, we cannot be certain that the claims in our patent applications covering composition-of-matter of early stage candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are possibly treatment compositions and methods that we have not conceived of or attempted to patent, and other parties may discover and patent approaches and compositions that are similar to or different from ours.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, and advisors, third parties may still obtain this information or may come upon this or similar information independently. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of our trade secrets or proprietary know-how may be greatly reduced.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of reproxalap or our other product candidates. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development or commercialization delays;
- prevent us from commercializing reproxalap or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third-party has asserted a claim of patent infringement against us, others may hold proprietary rights that could prevent reproxalap or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market reproxalap or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing reproxalap or our other product candidates, which could harm our business, financial condition, and operating results.

Any such claims against us could also be deemed to constitute an event of default under the loan and security agreement. In the case of a continuing event of default under the loan, Hercules could, among other remedies, elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. In the event we do not or are not able to repay the obligations at the time a default occurred, Hercules may elect to commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Hercules under the loan.

Our issued patents could be found invalid or unenforceable if challenged in court.

If we or any of our future development partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.

We are a party to technology licenses, including an in-license agreement for ADX-2191 (in-license program), and we may enter into additional licenses in the future. Such licenses do, and may in the future, impose commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we could lose valuable rights under our collaboration agreements and our ability to develop product candidates could be impaired. Additionally, should such a license agreement be terminated for any reason, there may be a limited number of replacement licensors, and a significant amount of time may be required to transition to a replacement licensor.

Our rights to develop and commercialize our in-license program are each subject in part to the terms and conditions of a third-party license, pursuant to which we have acquired exclusive rights and other intellectual property. Our rights with respect to the intellectual property to develop and commercialize the in-license program may terminate, in whole or in part, if we fail to meet certain milestones contained in each of our license agreements relating to their development and commercialization. We may also lose our rights to develop and commercialize either in-license agreement if we fail to pay required milestones or royalties. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may be extinguished, which may have an adverse effect on our business and results of operations.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, consultants, or agents have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants and our employees were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that our company or an employee, consultant, or agent inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent terms and obtaining data exclusivity for our product candidate, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of reproxalap or other product candidates, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources, and could adversely impact our financial condition or results of operations.

Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming, and inherently uncertain. In addition, Congress may pass patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available or weakening the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents, or to enforce our existing patents and patents we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

While we have issued composition-of-matter patents covering reproxalap and certain of our other product candidates in the United States and other countries, filing, prosecuting, and defending patents on reproxalap and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive and of significantly shorter duration than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, the growing use of generative AI presents an increased risk of unintentional and/or unauthorized disclosure or use of our intellectual property rights.

We and the third parties with whom we work are increasingly utilizing social media tools as a means of communication both internally and externally, and noncompliance with applicable requirements, policies or contracts due to social media use or negative posts or comments could have an adverse effect on our business.

Social media is increasingly being used to communicate about our product candidates and clinical development programs, and we may intend to utilize appropriate social media in connection with our commercialization efforts following approval of any product candidates. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. In addition, our employees or third parties with whom we contract or may contract, such as CROs, may knowingly or inadvertently make use of social media in ways that may not comply with legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients and others or information regarding any product candidates or clinical trials along with the potential for litigation related to off-label marketing or other prohibited activities. For example, clinical trial patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about any product candidate.

There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, negative posts or comments about us or any of our product candidates on social media could seriously damage our reputation, brand image and goodwill. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to its business.

Risks Related to Employee Matters and Managing Growth

We are highly dependent on the services of our senior management team and certain key consultants.

As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial, and financial expertise of our senior management team comprised of: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer, Stephen G. Machatha, Ph.D., our Chief Development Officer, and Bruce M. Greenberg, our Senior Vice President of Finance and Interim Chief Financial Officer, as well as certain other employees. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, drug development, and commercialization consultants. Leadership transitions can be inherently difficult to manage, and an inadequate transition to a permanent Chief Financial Officer may cause disruption within our company. In addition, if we are unable to identify a qualified candidate to become the permanent Chief Financial Officer in a timely manner, our ability to meet operational goals and strategic plans could be adversely impacted. The loss of such individuals or the services of future members of our management team could delay or prevent the further development and commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business.

If we fail to attract and retain senior management and key commercial personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. Our success also depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel, and we may not be able to do so in the future due to intense competition among biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. If we are unable to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

We expect to expand our management team, including by identifying a permanent Chief Financial Officer. Our future performance will depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, adversely affecting future regulatory approvals, sales of our product candidates, and results of our operations.

In order to commercialize our product candidates for those we remain responsible for the commercialization of, we will need to substantially grow the size of our organization. We may encounter difficulties in managing our growth and expanding our operations successfully.

As of December 31, 2023, we only had 10 full-time employees. We currently plan to commercialize reproxalap through a collaboration with a third party. However, if we are not able to establish a suitable collaboration, we may need to grow our organization to continue development and pursue the potential commercialization of reproxalap. In addition, we expect that we will need to grow our organization to continue development and pursue the potential commercialization of our other product candidates, as well as function as a public company. As we seek to advance reproxalap, alone or with others, and other product candidates towards potential commercialization, increase the number of ongoing product development programs, and advance our future product candidates through preclinical studies and clinical trials, we will need to expand our financial, development, regulatory, manufacturing, marketing, and sales capabilities, or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train, and integrate additional management, clinical and regulatory, financial, administrative and sales, and marketing personnel. We may not be able to accomplish these tasks, and our failure to so accomplish could prevent us from successfully growing our company.

Risks Related to Other Legal or Regulatory Matters

Our business is subject to political, economic, legal, and social risks, which could adversely affect our business.

There are significant regulatory, economic and legal barriers in markets in the United States and outside the United States that we must overcome. We may be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs, and legal systems. Any sales and operations would be subject to political, economic, and social uncertainties including, among others:

- changes and limits in import and export controls;
- increases in custom duties and tariffs;
- changes in currency exchange rates;
- economic weakness, including inflation, and political instability, including effects of adverse developments affecting the financial services industry, the ongoing conflict between Russia and Ukraine, Hamas' attack against Israel and the ensuing conflict, and the possibility of a wider regional or global conflict, and global sanctions imposed in response thereto;
- the impact on employees, suppliers, customers, and the global economy related to public health epidemics or pandemics, and actions taken in response to such events;
- compliance with multiple complex, potentially conflicting and changing governmental regulations and laws;
- absence in some jurisdictions of effective laws to protect our intellectual property rights; and
- currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

Changes in United States social, political, regulatory, and economic conditions or in laws and policies governing foreign trade, manufacturing, development, and investment, and any negative sentiments towards the United States as a result of such changes, could adversely affect our business. Concerns over economic recession, interest rate increases and inflation, supply chain delays and disruptions, policy priorities of the U.S. presidential administration, trade wars, unemployment, or prolonged government shutdown may contribute to increased volatility and diminished expectations for the economy and markets. Additionally, concern over geopolitical issues may also contribute to prolonged market volatility and instability. For example, continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, could lead to disruption, instability, and volatility in global markets and industries. The U.S. government and other governments in jurisdictions have imposed severe economic sanctions and export controls against Russia and Russian interests, have removed Russia from the Society for Worldwide Interbank Financial Telecommunication payment (SWIFT) system, and have threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is unknown.

Any changes related to these and other factors could adversely affect any business operations that we conduct outside the United States**.**

Security breaches , cyberattacks, loss of data, and other disruptions impacting our information technology systems or those of our third-party collaborators, service providers, contractors or consultants could compromise the privacy, security, integrity or confidentiality of sensitive information related to our business or prevent us from accessing critical information and expose us to adverse consequences, including but not limited to regulatory investigations or actions, litigation, and significant fines and penalties, which could adversely affect our business, financial condition, and reputation.

In the ordinary course of our business, we and our current or future third-party collaborators, service providers, contractors, and consultants collect, may store and transmit sensitive data, including legally protected health information, personal data (also referred to as personal information or personally identifiable information under certain data privacy laws) about patients and employees, intellectual property, and our proprietary business

and financial information (collectively, sensitive information). We manage and maintain data, including sensitive information, utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We face a number of risks related to our protection of, and our third-party collaborators', service providers', contractors', and consultants' protection of, this sensitive information, including loss of access, inappropriate disclosure and inappropriate or unauthorized access, as well as risks associated with our ability to identify and audit such events.

The secure processing, storage, maintenance, and transmission of sensitive information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and those of our third-party collaborators, service providers, contractors, and consultants, may be vulnerable to breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war and telecommunications and electrical failures, as well as from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information) or viruses or otherwise breached due to employee or third-party error, malfeasance, or other activities. These risks may be heightened as a result of remote working arrangements.

While we are not aware of any such attack, breach or system failure, we cannot guarantee that our data protection efforts and our investment in information technology, or those of our third-party collaborators, service providers, contractors, and consultants will prevent significant breakdowns, data leakages, and breaches in the relevant systems or other cyber incidents. If such event were to occur and cause interruptions in our operations, our networks could be compromised and the sensitive information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such unauthorized access, disclosure or other loss of information, or the perception that any of these has occurred, could result in legal claims or proceedings, liability under federal, state, and international laws that protect the privacy of personal data, including but not limited to private lawsuits or class actions under the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020 (CPRA), and regulatory penalties, which could result in significant legal or financial exposure. In addition, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal data, which is a broader class of information than the health information protected by the Health Insurance Portability and Accountability Act (HIPAA). Unauthorized access, loss, or dissemination of sensitive information could also disrupt our ability to conduct research and development activities; collect, process, and prepare company financial information; provide information about our product candidates and other patient and physician education or outreach efforts through our website; manage the administrative aspects of our business; or prevent damage to our reputation, any of which could adversely affect our business.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; significant fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of our business, we process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data (also referred to as personal information or personally identifiable information under certain data privacy laws) and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, and patient information. Our data processing activities may subject us to numerous data privacy and security obligations, such as various federal, state, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. We strive to comply with applicable data privacy and security obligations to the extent possible. However, it is possible that these obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules and/or our practices. Any failure or perceived failure by us to comply with applicable privacy and data security laws and regulations, our privacy policies, or our privacy-related obligations to third parties, or any compromise of security that results in the unauthorized access, release or transfer of personal data or other sensitive information, may result in governmental enforcement actions and fines or orders requiring that we change our practices, private litigation (including class action lawsuits), or public statements against us by consumer advocacy groups or others and could cause a loss of trust in us, which could result in significant legal or financial exposure and reputational damage that could potentially have an adverse effect on our business.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, we may be subject to various state data privacy and security laws and regulations, including the California Consumer Privacy Act, as amended by the CPRA, which, among other things, requires covered "businesses" to provide specific disclosures to California consumers concerning the collection, sale, and sharing of their personal data, and gives such consumers the right to opt-out of certain sales of personal information. The CPRA provides for civil penalties for violations, as well as a private right of action for certain security breaches that may increase the likelihood of, and the risks associated with, security breach litigation. Additionally, the CPRA created a new state agency to oversee implementation and enforcement efforts, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Many of the CPRA's provisions became effective on January 1, 2023. Several states in the U.S. have proposed or enacted laws that contain obligations similar to the CPRA that have taken effect or will take effect in coming years. The U.S. federal government also is contemplating federal privacy legislation. The effects of recently proposed or enacted legislation potentially are far-reaching and could increase our potential liability, increase our compliance costs, and adversely affect our business.

Developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), and the Swiss Federal Act on Data Protection extend the geographical scope of European data protection laws to non-European entities and impose strict requirements for processing personal data. For example, under the EU GDPR and/or the UK GDPR, government regulators may impose temporary or definitive bans on data processing, as well as possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million, whichever is higher, for the most serious infringements. This exposes us to two parallel sets of regulations, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. Further, individuals or consumer protection organizations authorized at law to represent their interests may initiate litigation related to the processing of individuals' personal data.

In the ordinary course of our business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. The EU GDPR and UK GDPR prohibit the transfer of personal data to countries outside of the EEA, or the UK including the United States, that have not been deemed adequate by the European Commission or by the UK data protection regulator, respectively. Switzerland has adopted similar restrictions. Although there are legal mechanisms that allow for the transfer of personal data from the EEA, UK, and Switzerland to the United States, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. For example, legal developments in the EU have created complexity and uncertainty regarding such transfers and data protection authorities from the different EU Member States may interpret the EU GDPR differently. Additionally, guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. These transfer mechanisms have also been subject to various legal challenges. In particular, on July 16, 2020, the Court of Justice of the European Union, in the case of Data Protection Commissioner v. Facebook Ireland Limited, Maximillian Schrems (Case C-311/18) (Schrems II), invalidated the EU-U.S. Privacy Shield Program for transfers of personal data from the EU to the U.S., and added further uncertainty and complexity to the use of standard contractual clauses as a compliance mechanism for transfers of personal data outside the EU.

If there is no lawful manner for us to transfer personal data from the EEA, UK, or Switzerland to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third-parties, which could limit our ability to conduct clinical trial activities in Europe or elsewhere, and injunctions against our processing or transferring of personal data necessary to operate our business.

In addition to the EU, UK, and Switzerland, a growing number of other global jurisdictions are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of our business. Some of these laws, such as the General Data Protection Law in Brazil, or the Act on the Protection of Personal Information in Japan, impose similar obligations as those under the EU GDPR and UK GDPR. Others, such as those in Russia, India, and China, could potentially impose more stringent obligations, including data localization requirements. If we are unable to meet these evolving legal requirements or if we violate or are perceived to violate any laws, regulations, or other obligations relating to privacy, data protection, or information security, we may experience harm to our reputation and become subject to investigations, claims, and other remedies, which could expose us to significant fines, penalties, and other damages, all of which would harm our business.

Current and future legislation may increase the difficulty and cost for us to obtain regulatory and marketing approval of and commercialize our product candidates, alone or with others, and may affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

Healthcare reform measures that may be adopted in the future, may result in reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation and regulation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. For example, included in the Consolidated Appropriations Act, 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the HHS, the Department of Labor, and the Treasury. Additionally, both Congress and the Biden administration have each indicated willingness to continue to seek new legislative and/or administrative measures to address prescription drug costs. For example, on July 9, 2021, President Biden issued an Executive Order to promote competition in the U.S. economy that included several initiatives addressing prescription drugs. Among other provisions, the Executive Order stated that the Biden administration will "support aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms." In response to the Executive Order, on September 9, 2021, the HHS issued a Comprehensive Plan for Addressing High Drug Prices that identified potential legislative policies and administrative tools that Congress and the agency can pursue in order to make drug prices more affordable and equitable, improve and promote competition throughout the prescription drug industry, and foster scientific innovation. Congress has also continued to conduct inquiries into the prescription drug industry's pricing practices.

These initiatives recently culminated in the enactment of the IRA, in August 2022, which, among other things, will allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct

purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. Thus, it is unclear how the IRA will be implemented, but will likely have a significant impact on our business and the pharmaceutical industry as a whole.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. These include legislation and regulations regarding price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, legislative action designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the potential approval and marketing approvals of our drug candidates, if any, may be. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- our ability to identify and establish strategic partnerships;
- the level of taxes that we are required to pay;
- the availability of capital.

Our operations and relationships with actual and potential customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, exclusions from government programs, contractual damages, and reputational harm, and could diminish our future profits and earnings.

Our arrangements with third-party payors, physicians, and other potential customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drug candidates for which we obtain marketing approval.

Applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, a criminal law, which prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease, or order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal healthcare programs;
- the federal civil False Claims Act, which may be enforced through civil whistleblower or qui tam actions and imposes significant civil penalties, treble damages, and potential exclusion from federal healthcare programs against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Further, a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the federal civil False Claims Act. There is also the federal Criminal False Claims Act, which is similar to the federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious, or fraudulent claim to the federal government;
- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- federal criminal statutes created by the Health Insurance Portability and Accountability Act (HIPAA), which impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for health care benefits;
- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the FDCA which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use or misbranding or adulterating their products, and regulates the distribution of samples;
- the federal and state laws that require pharmaceutical manufacturers to report certain calculated product pricing metrics to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of product coverage and reimbursement under federal healthcare programs
- the federal Physician Payment Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, among others, to annually track and report payments and other transfers of value provided to U.S.-licensed physicians and teaching hospitals, and for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives, as well as certain ownership and investment interests held by physicians and their immediate families;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to our business practices, including sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant compliance guidance promulgated by the federal government;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures;
- other state laws that prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging; and certain state and local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties; damages; fines; imprisonment; exclusion of drug candidates from government-funded healthcare programs, such as Medicare and Medicaid; disgorgement; contractual damages; reputational harm; diminished profits and future earnings; and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may also be subject to criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause us to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Providing benefits or advantages to induce or reward improper performance generally to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance is governed by the national anti-bribery laws of EU Member States, and in respect of the U.K., the Bribery Act 2010. Infringement of these laws may result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, provides that, where medicinal products are being promoted to healthcare professionals, no gifts, pecuniary advantages, or benefits in kind may be supplied, offered or promised to such individuals unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision was transposed into the Human Medicines Regulations 2012 and as such remains applicable in the UK.

Payments made to physicians in certain EU Member States must be publicly disclosed. In addition, agreements with healthcare professionals must often be the subject of prior notification and approval by the healthcare professional's employer, his or her competent professional organization, and/or the regulatory authorities of individual EU Member States. These requirements are set out in national laws, industry codes, or professional codes of conduct, applicable in the EU Member States and in the UK. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on the marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims statutes and anti-kickback statutes. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formula managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants, and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Inadequate funding for the FDA, the SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels; ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of reproxalap or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if reproxalap or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for reproxalap or our other product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to continue to develop or commercialize reproxalap or our other product candidates; or
- a decline in our stock price.

We maintain product liability insurance with $5.0 million in coverage. We anticipate that we will need to increase our insurance coverage if we commercialize any product candidate. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of reproxalap or our other product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We and our development partners, third-party manufacturers, and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time consuming or costly.

We and our development partners, third-party manufacturers, and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our development partner, third-party manufacturers, and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We and any of our future development partners will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities will require that we and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe or to perform inadequate investigations of their causes. We and any of our future development partners may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we and any of our future development partners fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take enforcement action including the issuance of a Warning Letter, the requirement of a labeling change, the initiation of a criminal prosecution, the imposition of civil monetary penalties, the seizure of our products, or delay in approval or clearance of future products.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws, and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, or other remedial measures and legal expenses, any of which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act (FCPA), the Bribery Act and other anticorruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act, and other laws generally prohibit us, our officers, and our employees, and intermediaries from bribing, being bribed, or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also are subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, UK, and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, and currency exchange regulations, which we collectively refer to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, legal expenses, disgorgement, and other sanctions and remedial measures, which could have an adverse impact on our business, financial condition, results of operations, or liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Likewise, any investigation of any potential violations of the FCPA; the Bribery Act; or other anti-corruption laws or Trade Control Laws by U.S., U.K., or other authorities also could have an adverse impact on our reputation, our business, results of operations, or financial condition.

Our employees, independent contractors, vendors, principal investigators, contract research organizations (CROs), and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards, regulatory requirements, and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include:

- intentional, reckless, or negligent conduct or disclosure to us of unauthorized activities that violate the regulations of the FDA or similar foreign regulatory authorities;
- healthcare fraud and abuse in violation of U.S. and foreign laws and regulations;
- violations of U.S. federal securities laws relating to trading in our common stock; and
- failures to report financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations govern a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. While we have adopted a code of conduct and implemented other internal controls applicable to all our employees, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective. Additionally, we are subject to the risk that a person could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business or cause reputational harm, including the imposition of civil, criminal and administrative penalties, and damages; possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs; and diminished profits and future earnings.

In addition, during the course of our operations, our directors, executives, employees, consultants, and other third parties may have access to material nonpublic information regarding our business, our results of operations, or potential transactions we are considering. We may not be able to prevent trading in our common stock on the basis of, or while having access to, material nonpublic information. If any such person was to be investigated or an action were to be brought against them for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We are subject to litigation risks.

From time to time, we may become involved in various litigation matters and claims, including regulatory proceedings, administrative proceedings, governmental investigations, and contract disputes. We may face potential claims or liability for, among other things, breach of contract, defamation, libel, fraud, or negligence. We may also face employment-related litigation, including claims of age discrimination, sexual harassment, gender discrimination, immigration violations, or other local, state, and federal labor law violations. Because of the uncertain nature of litigation and insurance coverage decisions, the outcome of such actions and proceedings cannot be predicted with certainty and an unfavorable resolution of one or more of them could have a material adverse effect on our business, financial condition, results of operations, cash flows, and the trading price of our securities. In addition, legal fees and costs associated with prosecuting and defending litigation matters could have a material adverse effect on our business, financial condition, results of operations, and the trading price of our securities.

We are, and could in the future be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. The risk of securities class action litigation is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation could cause us to incur substantial costs and a diversion of management’s attention and resources, which could harm our business.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, product and clinical trial liability, workers' compensation, and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant, uninsured liability may require us to pay substantial amounts, which would adversely affect our working capital and results of operations.

U.S. federal income tax reform could adversely affect us.

New legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial conditions.

Risks Related to Our Common Stock

In the absence of an active trading market for our common stock, investors may not be able to resell their shares at or above the price at which they purchased them.

In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price they paid or at the time that they would like to sell. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could harm our business.

The trading price of the shares of our common stock has been and is likely to continue to be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been and will likely continue to be volatile for the foreseeable future. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid. The market price for our common stock may be influenced by many factors, including:

- the results of FDA regulatory review processes and other regulatory actions with respect to our product candidates;
- results of clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- the results and status of our research and development and regulatory plans for our product candidates;
- the exercise, if any, of the Option;
- the expectations of investors or securities analysts regarding our business and clinical development program, including interim or final top-line results that we may announce;
- regulatory developments in the United States and foreign countries;
- our ability to enroll and retain patients in our clinical trials;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the United States healthcare system;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;

- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- sales of our stock by insiders and 5% stockholders;
- trading volume of our common stock;
- general economic, industry, regional or larger scale conflicts or geo-political actions, and market conditions other events or factors, many of which are beyond our control, including frequent and dramatic fluctuations in industry indexes that may contain or influence our stock;
- additions or departures of key personnel; and
- intellectual property, product liability, or other litigation against us.

Concerns over economic recession, interest rate increases and inflation, adverse developments affecting financial services industry, supply chain delays and disruptions, policy priorities of the U.S. presidential administration, trade wars, unemployment, or prolonged government shutdown may contribute to increased volatility and diminished expectations for the economy and markets. Additionally, concern over geopolitical issues may also contribute to prolonged market volatility and instability. For example, the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict, could lead to disruption, instability and volatility in global markets and industries. In connection with the hostilities between Russia and Ukraine the U.S. government and other governments and jurisdictions have imposed severe economic sanctions and export controls against Russia and Russian interests, have removed Russia from the SWIFT system, and have threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is unknown.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market (Nasdaq), such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would expect to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

Because a small number of our existing stockholders own a substantial percentage of our outstanding common stock, your ability to influence corporate matters will be limited.

As of December 31, 2023, our executive officers, directors, and greater than 5% stockholders, in the aggregate, own approximately 38% of our outstanding common stock. As a result, such persons, acting together, may have the ability to control our management and business affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The Nasdaq Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock, and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the Hercules Credit Facility currently prohibits, and any future debt financing arrangements may contain terms prohibiting or limiting the amount of, dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in the value of our common stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased shares.

A substantial number of shares of our common stock could be sold into the public market in the near future, which could depress our stock price.

Sales of substantial amounts of our common stock in the public market could reduce the prevailing market prices for our common stock. Substantially all of our outstanding common stock is eligible for sale as is common stock issuable under vested and exercisable stock options and upon settlement of vested RSUs. If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Existing stockholder sales might also make it more difficult for us to sell additional equity securities at a time and price that we deem appropriate.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Securities Exchange Act of 1934. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

We are incurring significant increased costs and demands upon management as a result of operating as a public company.

As a public company, and particularly if and after we cease to be a "smaller reporting company," we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may result in substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If public company rules and regulations divert the attention of our management and personnel from other business concerns, our business, financial condition, and results of operations could be adversely affected. Increased costs associated with public company expenses will increase our net loss. For example, public company rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, the cost of which has continued to rise in recent years, and thus we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements, the impact of which could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To continue to comply with the requirements of being a reporting company under the Exchange Act, we will be required to continue to upgrade and maintain our systems including information technology; implement and maintain additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. Furthermore, we rely on third-parties, including software and system providers, for ensuring our reporting obligations and effective internal controls, and to the extent these third parties fail to provide adequate service including as a result of any inability to scale to handle our growth and the imposition of these increased reporting and internal controls and procedures, we could incur material costs for upgrading or switching systems and our business could be materially affected.

However, as a smaller reporting company and a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 for as long as we are not deemed an "accelerated filer" or "large accelerated filer."

If we are unable to establish and maintain effective internal controls it could have a material adverse effect on our business, financial condition, results of operations or cash flows.

As we grow, we plan to hire additional personnel and engage in external temporary resources and may implement, document, and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline. In addition, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

If securities or industry analysts do not continue to publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. If one or more of the analysts who covers us downgrades our stock or publish unfavorable research or reports about our business, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants and other awards upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, the provisions would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choices of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biotechnology industry over the last few years. We may be particularly vulnerable to activist stockholders due to fluctuations in our stock price. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or stockholder dispute involving us or our partners because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations, or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 1C. CYBERSECURITY

All companies utilizing technology are subject to threats of breaches of their cybersecurity programs. To mitigate the threat to our business and address regulatory requirements, we take a comprehensive approach to cybersecurity risk management and have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. We continue to make proactive and strategic investments to augment the capabilities of our people, processes, and technologies in order to address our cybersecurity risks. Our cybersecurity risks, and the controls designed to mitigate those risks, are imbedded into our overall risk management governance and are reviewed at least annually by the Audit Committee of our Board of Directors.

Risk Management and Strategy

We've implemented a set of comprehensive cybersecurity and data protection policies and procedures. Our employees and contractors receive regular cybersecurity awareness trainings, including specific topics related to social engineering and email frauds. We have engaged consultants with significant expertise and certifications in cybersecurity related to our industry. We invest in advanced technologies for continuous cybersecurity monitoring across our information technology environment which are designed to prevent, detect, and minimize cybersecurity attacks, as well as alert management of such attacks.

Our information security policy is based on recognized industry standards and cover areas such as risk management, data backup, and data recovery. We engage consultants and IT managed service providers (IT MSP), to help us design and implement our cybersecurity policies and procedures. These service providers assist us with monitoring security threats and vulnerabilities and responding to identified cybersecurity incidents, including prompt escalation and timely communication of major security incidents to senior business leadership and the Audit Committee. We conduct cybersecurity penetration testing as warranted to identify and remediate cybersecurity gaps.

Primary responsibility for assessing, monitoring, and managing our cybersecurity risks rests with our current IT consultants and IT MSP, who report to our interim Chief Financial Officer, to manage the risk assessment and mitigation process. Our interim Chief Financial Officer has served in various capacities in enterprise risk management and cybersecurity over five years, including serving as our Data Security Coordinator for the past two years, during which he has overseen our risk management process.

We evaluate each third-party service provider to verify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect the Company.

Governance

Our Board of Directors and Audit Committee are responsible for overseeing our cybersecurity risk management and strategy.

Our interim Chief Financial Officer periodically meets with our IT consultants and IT MSP about the Company’s ongoing compliance and risk management and provides periodic briefings to the Audit Committee regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.

Cybersecurity Threat Disclosure

There can be no guarantee that our policies and procedures will be properly followed in every instance or that those policies and procedures will be effective. Although our "Risk Factors" in Item 1A include further detail about the material cybersecurity risks we face, to date, we are not aware of any cybersecurity threats that have materially affected our business. We can provide no assurance that there will not be incidents in the future or that they will not materially affect us, including our business strategy, results of operations, or financial condition.

ITEM 2. *PROPERTIES*

Our offices are located in Lexington, Massachusetts. As of December 31, 2023, we had leased approximately 9,351 square feet of office space pursuant to lease that expires in December 2024, with the option to extend through December 2026. Management believes that this office space is suitable and adequate to meet our anticipated near-term needs. We anticipate that following the expiration of the lease, additional or alternative space will be available at commercially reasonable terms.

ITEM 3. *LEGAL PROCEEDINGS*

On July 31, 2023, a purported stockholder filed a putative class action lawsuit (the Securities Class Action) in the U.S. District Court for the District of Massachusetts, against us and certain current and former officers, captioned Juliana Paice v. Aldeyra Therapeutics, Inc., et al. (No. 23-cv-11737). On January 2, 2024, the lead plaintiff filed an amended complaint. The lawsuit alleges violations by the defendants of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. The plaintiff alleges that the defendants made false or misleading statements or failed to disclose certain information concerning (i) the NDA for and the prospects of ADX-2191 for the treatment of primary vitreoretinal lymphoma and (ii) the NDA for and the prospects of reproxalap for the treatment of dry eye disease. The lawsuit seeks, among other things, compensatory damages on behalf of herself and all persons and entities that purchased or otherwise acquired our securities between January 7, 2021, and October 16, 2023, as well as attorneys' fees and costs. On March 4, 2024, defendants filed a motion to dismiss the amended complaint. We dispute the plaintiff's claims and intend to vigorously defend the suit. At this time, we cannot reasonably predict the outcome or estimate potential losses, if any, that could result from this matter.

On October 25, 2023, a purported stockholder filed a derivative complaint in Middlesex Superior Court of the Commonwealth of Massachusetts, captioned Evan Leglar v. Todd C. Brady, et al. (No. 2381-cv-02980), against certain of our executive officers and directors, and naming us as a nominal defendant. The derivative complaint alleges, purportedly on behalf of us, breaches of fiduciary duty and unjust enrichment claims against all defendants. The claims are based on substantially identical allegations as the complaint in the Securities Class Action. The lawsuit seeks, among other things, an award of damages and restitution in favor of us, certain changes to our corporate governance, and attorneys' fees and costs. On November 14, 2023, the plaintiff voluntarily dismissed all claims without prejudice.

In addition, from time to time, we are subject to litigation and claims arising in the ordinary course of business but, except as stated above, we are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Market Information

Our common stock has been publicly traded on the Nasdaq Capital Market under the symbol "ALDX" since our initial public offering in May of 2014. Prior to our initial public offering, there was no public market for our common stock.

Holders of Record

As of December 31, 2023, there were 18 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not declared or paid any cash dividends on our common stock since our inception. We do not plan to pay dividends in the foreseeable future. Under our credit facility, we have agreed not to pay any dividends so long as it has any outstanding obligations thereunder. We currently intend to retain all available funds and any future earnings, if any, for use in the operation of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant, and subject to the restrictions contained in future financing instruments. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this annual report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. *[RESERVED]*

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this annual report on Form 10-K. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections of this annual report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. We are developing a novel pharmaceutical platform targeting a class of toxic endogenous small molecules known as RASP (reactive aldehyde species) that are associated with many inflammatory, metabolic, and neurodegenerative diseases. Our RASP modulator product pipeline includes ADX-629, a novel orally administered RASP modulator in clinical development for moderate alcohol-associated hepatitis and Sjögren-Larsson Syndrome. Our preclinical RASP platform includes ADX-246, ADX-248, and other drug candidates in development for systemic inflammatory, metabolic, and retinal diseases. The validity of the RASP platform is supported by reproxalap, our first-in-class product candidate in late-stage development for the treatment of dry eye disease. Reproxalap has demonstrated broad-based, rapid-onset activity and consistent safety across a number of Phase 2 and Phase 3 clinical trials. We have additional product candidates in development, including ADX-2191, which is in clinical development for the treatment of retinitis pigmentosa, a rare retinal disease characterized by inflammation and vision loss. ADX-2191 has received Orphan Drug Designation for the treatment of retinitis pigmentosa.

Since our incorporation, we have devoted substantially all of our resources to the preclinical and clinical development of our product candidates. Our ability to generate revenues largely depends upon our ability, alone or with others, to complete development of our product candidates to obtain regulatory approvals for and to manufacture, market, and sell our product candidates. The results of our operations will vary significantly from year-to-year and quarter-to-quarter, and depend on a number of factors, including risks related to our business and industry, risks relating to intellectual property and other legal matters, risks related to our common stock, and other risks that are detailed in the section of this annual report on Form 10-K entitled "Risk Factors".

In March 2019, we entered into the Hercules Credit Facility, which provided for a term loan of up to $60.0 million, $15.0 million of which has been drawn-down as of December 31, 2023. In April 2021, the Hercules Credit Facility was amended to, among other things, increase the amount which may become available for draw-down prior to May 2023, subject to the satisfaction of certain conditions contained therein, from $10.0 million to $20.0 million. In December 2022, the Hercules Credit Facility was further amended to, among other things, (i) extend the expiration of the period in which interest-only payments on borrowings from May 1, 2023 to May 1, 2024; (ii) extend the Maturity Date from October 1, 2023 to October 1, 2024; and (iii) extend the availability of the $20.0 million draw-down from May 2023 to May 2024, subject to the satisfaction of certain conditions contained therein. The Hercules Credit Facility contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. The Hercules Credit Facility, as amended, is described in Note 9 to the notes to the consolidated financial statements contained in this annual report on Form 10-K. As of December 31, 2023, $15.0 million was outstanding under the Hercules Credit Facility, and an additional $20.0 million may be available under the Loan and Security Agreement at our option through May 1, 2024, subject to approval of the Lender's investment committee.

In March 2021, we entered into an Open Market Sales Agreement SM (2021 Jefferies Sales Agreement) with Jefferies LLC (Jefferies), as sales agent, pursuant to which we may offer and sell, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $100.0 million. We have no obligation to sell any shares under the 2021 Jefferies Sales Agreement, and could at any time suspend solicitations and offers under the 2021 Jefferies Sales Agreement. No sales had been made pursuant to the 2021 Jefferies Sales Agreement as of December 31, 2023.

We will need to raise additional capital in the form of debt or equity or through partnerships to fund additional development of our product candidates and, subject to regulatory approval, if any, the commercialization of our product candidates, and we may in-license, acquire, or invest in complementary businesses or products. In addition, as capital resources permit, we may augment or otherwise modify the clinical development plans described herein. However, any disruption in the capital markets could make any financing more challenging, and there can be no assurance that we will be able to raise capital on commercially reasonable terms or at all.

Our Agreement with AbbVie

On October 31, 2023 (the Option Agreement Effective Date), we entered into an exclusive option agreement (the Option Agreement) with AbbVie Inc. (AbbVie), pursuant to which we granted AbbVie an exclusive option (the Option) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with us to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by us in the field of ophthalmology relating to treating conditions of the ocular surface and (d) a right to review data for any other compounds that are owned or otherwise controlled by us in the fields of ophthalmology and immunology before such data is shared with any other third party (the Collaboration Agreement). AbbVie has paid us a non-refundable payment of $1 million in consideration of the Option (the Option Payment).

On December 21, 2023, pursuant to the Option Agreement, AbbVie extended the period during which it may exercise the Option (the Exercise Period Extension) by paying us a non-refundable payment of $5 million (the Option Extension Fee). As a result of the Exercise Period Extension, AbbVie may exercise the Option by delivering written notice to us at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the date, if any, that we receive approval from the U.S. Food and Drug Administration of the new drug application (NDA) for reproxalap in dry eye disease (the FDA Decision) and (b) the date that is eighteen (18) months after the Option Agreement Effective Date. If the Collaboration Agreement is entered into, the Option Payment and the Option Extension Fee will be credited against the upfront cash payment payable by AbbVie.

Upon AbbVie's delivery of the agreement execution notice and the parties entering into the Collaboration Agreement, AbbVie would pay us a $100 million upfront cash payment, less the Option Payment and the Option Extension Fee. In addition, we would be eligible to receive up to approximately $300 million in regulatory, and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA Decision is received prior to or after the execution of the Collaboration Agreement. In the United States, we would share profits and losses with AbbVie from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for us. Outside of the United States, we would be eligible to receive tiered royalties on net sales of reproxalap.

Our Agreement with MEEI

We are developing ADX-2191 pursuant to an Exclusive License Agreement with Massachusetts Eye and Ear Infirmary (MEEI) originally entered into in July 2016 between MEEI and Helio Vision, Inc. (Helio), as amended, (MEEI Agreement). We assumed the MEEI Agreement in connection with our 2019 acquisition of Helio.

Pursuant and subject to the MEEI Agreement, we obtained an exclusive, worldwide license from MEEI to develop and commercialize ADX-2191 under certain patents and patent applications, and other licenses to intellectual property (MEEI Patent Rights). We have agreed to use our commercially reasonable efforts to develop ADX-2191 and to meet certain specified effort and achievement benchmarks by certain dates.

In consideration for the rights licensed under the MEEI Agreement, Helio issued MEEI a number of shares of its preferred stock and Helio agreed to pay non-creditable non-refundable license maintenance fees to MEEI of $15,000 on each of the second and third anniversary of the MEEI Agreement, $25,000 on each of the fourth and fifth anniversary of the MEEI Agreement and $35,000 on the sixth and each subsequent anniversary of the MEEI Agreement during the term of such agreement. In addition, Helio was obligated to make future sales-dependent milestone payments to MEEI of up to the low seven figures in the aggregate, as well as royalty payments to MEEI at a rate which, as a percentage of net sales, is in the low single digits for products that incorporate or use the MEEI Patent Rights in the United States and as a percentage in the low single digits for products that incorporate or use the MEEI Patent Rights outside the United States. We are also obligated under the MEEI Agreement to pay MEEI a percentage of certain sublicense revenue that we receive in connection with entering into any sublicensing arrangements with any third parties, at a percentage rate which tiers downward from low-double digits to mid-single digits based on the date of the sublicense. Following our acquisition of Helio, we became obligated to make any future payments owed under the MEEI Agreement. There is no additional equity consideration issuable under the MEEI Agreement.

The MEEI Agreement will remain in effect until the expiration date of the last to expire patent licensed under the MEEI Agreement. We may terminate the MEEI Agreement with timely written notice to MEEI. MEEI has the right to terminate the MEEI Agreement if we, subject to certain specified cure periods, cease all business operations with respect to licensed products, fail to pay amounts due under the MEEI Agreement, fail to comply with certain due diligence obligations, default in our obligation to maintain insurance, one of our officers is convicted of a felony relating to the manufacture, use, sale or importation of licensed products, we materially breach any provisions of the MEEI Agreement or in the event of our insolvency or bankruptcy.

In the event of an early termination of the MEEI Agreement, all rights licensed and developed by us under the MEEI Agreement may revert back to MEEI. We have agreed to indemnify MEEI for certain claims that may arise under the MEEI Agreement.

Our Acquisition of Helio Vision, Inc.

On January 28, 2019, we acquired Helio. Upon the closing of the acquisition, we issued an aggregate of 1,160,444 shares of common stock to the former securityholders and an advisor of Helio. In January 2021, pursuant to the terms of the acquisition agreement, we issued an additional 246,562 shares of common stock to the former securityholders of Helio. Subject to the conditions of the acquisition agreement, we are contingently obligated to make additional payments to the former securityholders of Helio as follows: (a) $10.0 million of common stock following approval by the FDA of a NDA for the prevention and/or treatment of proliferative vitreoretinopathy or a substantially similar label prior to the 10th anniversary of the closing date; and (b) $2.5 million of common stock following FDA of a NDA for an indication (other than proliferative vitreoretinopathy or a substantially similar label) prior to the 12th anniversary of the closing date, provided that in no event shall we be obligated to issue more than 5,248,885 shares of common stock in the aggregate. Additionally, in the event of certain change of control or divestitures by us, certain former convertible noteholders of Helio will be entitled to a tax gross-up payment in an amount not to exceed $1.0 million.

Research and development expenses

We expense all of our research and development expenses as they are incurred. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred. Research and development expenses primarily include:

- non-clinical development, preclinical research, and clinical trial and regulatory-related costs;
- expenses incurred under agreements with sites and consultants that conduct our clinical trials; and
- employee-related expenses, including salaries, benefits, travel, and stock-based compensation expense.

Substantially all of our research and development expenses to date have been incurred in connection with reproxalap and ADX-2191, as well as the proof of concept trials with ADX-629. We expect our research and development expenses to increase for the foreseeable future as we advance ADX-246 and ADX-248 and other

compounds through preclinical and clinical development. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates. Clinical development timelines, the probability of success, and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- delays of, or other effects on, clinical trials resulting from public health measures, and war or other military actions, or for other reasons;
- the length of time required to enroll eligible patients;
- the design of the trials;
- the cost of drug manufacturing;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the costs of assay development, assays, or other assessment of clinical trial endpoints;
- the cost of vehicle or active comparative agents used in trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of our product candidates.

Included in research and development are expenses associated with asset acquisitions. Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired are deemed to have an alternative future use. Acquired in-process research and development payments are immediately expensed, and include upfront payments, as well as transaction fees and subsequent milestone payments. Development costs incurred after the asset acquisition are expensed as incurred.

We do not expect reproxalap or any of our other product candidates to be commercially available, if at all, before at least the first half of 2025.

General and administrative expenses

Our general and administrative expenses consisted primarily of employee-related expenses, including benefits and stock-based compensation for our full-time employees during the years ended December 31, 2023 and 2022. Other general and administrative expenses include insurance premiums, consulting including pre-commercial costs, and professional fees for auditing, tax, investor relations, and legal services, including patent-related costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities, continue to incur additional costs associated with being a publicly-traded company, and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, fees for commercializing our product candidates, legal fees, accounting fees, insurance premiums, and fees associated with investor relations.

Other income (expense)

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts, and interest expense incurred on our outstanding debt.

Comprehensive loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. For the year ended December 31, 2023, comprehensive loss is equal to our net loss of $37.5 million and $0.1 million of losses on marketable securities reclassified to net loss. For the year ended December 31, 2022, comprehensive loss is equal to our net loss of $62.0 million and $0.1 million of unrealized loss on marketable securities.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States (US GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this annual report on Form 10-K, we believe that the following accounting estimates are the most critical in order to fully understand and evaluate our financial condition and results of operations.

Accrued and Deferred Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate our accrual for and any remaining deferred balances pertaining to our research and development expenses. This process involves the following:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing or deferring expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue or deferred include:

- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations in connection with non-clinical development, preclinical research, and the production of clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals and deferrals related to non-clinical development, preclinical studies, and clinical trials on our estimates of the services received and efforts expended pursuant to contracts with organizations/consultants that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these

contracts may depend on many factors, such as the successful enrollment of patients, site initiation, and the completion of clinical study milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of accrued or deferred research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2023, we had federal and state income tax net operating loss (NOL) carryforwards of approximately $250.6 million and $242.5 million, respectively. Federal NOL carryforwards generated through December 31, 2017 and state NOL carryforwards will expire at various dates through 2043. Federal NOLs generated during the years ended December 31, 2018 and thereafter will carry forward indefinitely. As of December 31, 2023, we had federal and state research and development tax credit carryforwards of approximately $10.1 million and $2.1 million, respectively, which will expire at various dates through 2043. Additionally, as of December 31, 2023, we had a federal orphan drug tax credit carryforward of approximately $2.1 million that expires in 2043.

Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs and certain other tax assets (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders’ lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock within the testing period, even those outside our control such as purchases or sales by investors, could result in an ownership change. A limitation on our ability to utilize some or all our NOLs or credits could have a material adverse effect on our results of operations and cash flows. We believe, prior to December 31, 2021 that four ownership changes occurred since inception. Management believes that its aggregate Section 382 and 383 limitation (including the additional limitation for recognized "built-in gains") is sufficient so that no current impairment of its pre-ownership change tax attributes is required. We believe there were no ownership changes from December 31, 2021 through December 31, 2023, based on a review of our equity history during that period. Any future ownership changes, including those resulting from our recent or future financing activities, may cause our existing tax attributes to have additional limitations.

Recent Accounting Pronouncements

Recent accounting pronouncements which may be applicable to us are described in Note 2 to our Consolidated Financial Statements included in the annual report on Form 10-K.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including the progress of our research and development efforts, the timing and outcome of clinical trials, regulatory requirements, and the exercise, if any, of the Option, including any related commercialization costs. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses.

Comparison of Years Ended December 31, 2023 and 2022

Net loss. Net loss for the years ended December 31, 2023 and 2022 was approximately $37.5 million and $62.0 million, respectively. As of December 31, 2023, we had total stockholders' equity of $119.8 million. Losses have resulted principally from costs incurred in our clinical trials and other research and development programs, and from our general and administrative expenses.

Research and development expenses. Research and development expenses were $29.5 million for the year ended December 31, 2023 compared to $47.3 million for the same period in 2022. The decrease of $17.8 million is primarily related to a decrease in external clinical development costs, drug product manufacturing costs, consulting expenditures, and personnel costs, partially offset by an increase in external preclinical development costs.

General and administrative expenses. General and administrative expenses were $13.3 million for the year ended December 31, 2023, compared to $15.4 million for the year ended December 31, 2022. The decrease of approximately $2.1 million is primarily related to lower consulting expenditures and personnel costs, partially offset by an increase in legal expenditures.

Other income (expense). Total other income (expense) was approximately $5.3 million for the year ended December 31, 2023, compared to $0.7 million for the year ended December 31, 2022. The increase in total other income (expense), was principally due to an increase in interest income as a result of increased interest rates on our investments.

Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and convertible equity securities and borrowings under credit facilities. Since inception, we have incurred operating losses and negative cash flows from operating activities and have devoted substantially all our efforts to research and development. At December 31, 2023, we had total stockholders' equity of approximately $119.8 million and cash and cash equivalents of $142.8 million. During the year ended December 31, 2023, we had net loss of approximately $37.5 million. We expect to generate operating losses for the foreseeable future.

In March 2021, we entered into an Open Market Sales Agreement [SM] (2021 Jefferies Sales Agreement) with Jefferies LLC (Jefferies), as sales agent, pursuant to which we may offer and sell, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $100.0 million. We have no obligation to sell any shares under the 2021 Jefferies Sales Agreement, and could at any time suspend solicitations and offers under the 2021 Jefferies Sales Agreement. No sales had been made pursuant to the 2021 Jefferies Sales Agreement as of December 31, 2023.

In March 2019, we entered into the Hercules Credit Facility (the Loan and Security Agreement), pursuant to which a term loan of up to an aggregate principal amount of $60.0 million may be made available to us. The Loan and Security Agreement provides for (i) an initial term loan advance of up to $5.0 million at our option, which expired unutilized on April 15, 2019; (ii) three additional term loan advances of up to $15.0 million each, at our option, available to us upon the occurrence of certain funding conditions prior to September 30, 2019 (2019 Tranche), March 31, 2020 (2020 Tranche), and March 31, 2021 (2021 Tranche); and (iii) a final additional term loan advance (Fourth Loan Tranche) of up to $10.0 million prior to December 31, 2021, at our option, subject to approval by Lender's investment committee. We drew down the 2019 Tranche in full in September 2019 and the 2020 Tranche and the 2021 Tranche expired unutilized prior to us satisfying the funding conditions for such tranche. On April 20, 2021, we entered into the First Amendment (First Amendment) to Loan and Security Agreement with Hercules. The First Amendment, among other things, (i) increased the Fourth Loan Tranche from $10.0 million to $20.0 million and extended the deadline for drawing down the Fourth Loan Tranche to July 1, 2022; (ii) lowered the variable per annum rate of interest on borrowings under the Loan and Security Agreement to the greater of (a) the Prime Rate plus 3.10% or (b) 8.60%; (iii) extended the expiration of the period in which interest-only payments on borrowings under the Loan and Security Agreement are required from May 1, 2021 to July 1, 2022; and (iv) following the satisfaction of certain conditions, which conditions were satisfied in April 2021, further extended the expiration of the interest-only period and the deadline for drawing down the Fourth Loan Tranche to May 1, 2023. On December 22, 2022, we entered into the Second Amendment (Second Amendment) to the Loan and Security

Agreement with Hercules, which became effective as of December 31, 2022 (Second Amendment Effective Date). The Second Amendment, among other things, (i) extended the expiration of the period in which interest-only payments on borrowings under the Loan and Security Agreement are made from May 1, 2023 to May 1, 2024; (ii) extended the Maturity Date from October 1, 2023 to October 1, 2024 (Maturity Date); (iii) extended the availability of the Fourth Loan Tranche commitment of $20 million from May 1, 2023 to May 1, 2024; and (iv) amended the Prepayment Charge (as defined therein) to equal 0.75% of the amount prepaid during the 12-month period following the Second Amendment Effective Date, and 0% thereafter. The ability to draw the Fourth Loan Tranche remains conditioned on approval by the Lenders' investment committee. In addition, a supplemental end of term charge of $292,500 (Supplemental End of Term Charge) shall be due on the earlier of (A) the Maturity Date, as amended, or (B) repayment of the aggregate amount of advances under the Loan and Security Agreement. The existing end of term charge of $1,042,500 (End of Term Charge) was paid on October 2, 2023. Repayment of the aggregate outstanding principal balance of the term loan, in monthly installments, commences upon expiration of the interest-only period and continues through the Maturity Date.

The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. As of December 31, 2023, $15.0 million was outstanding under the Loan and Security Agreement, and an additional $20.0 million under the Fourth Loan Tranche at our option through May 1, 2024, subject to approval of the Lender's investment committee.

On October 31, 2023 (the Option Agreement Effective Date), we entered into an exclusive option agreement (the Option Agreement) with AbbVie Inc. (AbbVie), pursuant to which we granted AbbVie an exclusive option (the Option) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with us to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by us in the field of ophthalmology relating to treating conditions of the ocular surface, and (d) a right to review data for any other compounds that are owned or otherwise controlled by us in the fields of ophthalmology and immunology before such data is shared with any other third party (the Collaboration Agreement). AbbVie has paid us a non-refundable payment of $1 million in consideration of the Option (the Option Payment).

On December 21, 2023, pursuant to the Option Agreement, AbbVie extended the period during which it may exercise the Option (the Exercise Period Extension) by paying us a non-refundable payment of $5 million (the Option Extension Fee). As a result of the Exercise Period Extension, AbbVie may exercise the Option by delivering written notice to us at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the date, if any, that we receive approval from the U.S. Food and Drug Administration of the NDA for reproxalap in dry eye disease (the FDA Decision) and (b) the date that is eighteen (18) months after the Option Agreement Effective Date. If the Collaboration Agreement is entered into, the Option Payment and the Option Extension Fee will be credited against the upfront cash payment payable by AbbVie.

AbbVie may exercise the Option by delivering the Option Exercise Notice to us at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the FDA Decision Date and (b) the date that is eighteen (18) months after the Option Agreement Effective Date.

Upon AbbVie's delivery of the agreement execution notice and the parties entering into the Collaboration Agreement, AbbVie would pay us a $100 million upfront cash payment, less the Option Payment and the Option Extension Fee. In addition, we would be eligible to receive up to approximately $300 million in regulatory, and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA Decision is received prior to or after the execution of the Collaboration Agreement. In the United States, we would share profits and losses with AbbVie from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for us. Outside of the United States, we would be eligible to receive tiered royalties on net sales of reproxalap.

Based on our current operating plan, we believe that our cash and cash equivalents, as of December 31, 2023, will be sufficient to fund our currently projected operating expenses and debt obligations beyond 2026, including continued early and late-stage development of our product candidates in ocular and systemic immune-mediated diseases. We base our projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization (as applicable) of product candidates, we are unable to estimate the exact amount of our working capital requirements. We will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of our planned research and development activities and regulatory activities, commence or continue ongoing commercialization, including manufacturing, sales, marketing and distribution for our product candidates, or conduct any substantial additional development requirements requested by the FDA. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued clinical development of reproxalap, and our other product candidates. Subsequent trials initiated at a later date will cost considerably more, depending on the results of our prior clinical trials, and feedback from the FDA or other third parties. Accordingly, we will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the costs, timing, and outcome of regulatory review of reproxalap, including any additional trials the FDA or other regulatory agencies may require for approval or label expansion;
- the progress, costs, and results of any clinical activities for regulatory review of reproxalap outside of the United States;
- the exercise, if any, of the Option;
- the costs and timing of process development and manufacturing scale up activities associated with reproxalap;
- the costs of commercialization activities for reproxalap if we receive marketing approval and pre commercialization costs for reproxalap incurred prior to receiving, any such marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- assuming receipt of marketing approval, the amount of revenue received from commercial sales of reproxalap or any other product candidates;
- the terms and timing of establishing collaborations, license agreements, and other partnerships on terms favorable to us;
- the type, number, scope, progress, expansion costs, results, and timing of our clinical trials of any product candidates that we are pursuing or may choose to pursue in the future;
- costs associated with any other product candidates that we may develop, in-license, or acquire, including potential milestone or royalty payments; and
- costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights.

We may need or desire to obtain additional capital to finance our operations through debt, equity, or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant additional liens on certain of our assets that may limit our flexibility. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. We are in a period of economic uncertainty, inflation, and capital markets disruption, which has been significantly impacted by adverse developments affecting the financial services industry, geopolitical instability due to, among other things, the continued hostilities between Russia and Ukraine and Hamas' attack against Israel and the ensuing conflict. In addition, the disruption in the capital markets could make any financing more challenging, and there can be no assurance that we will be able to obtain such financing on commercially reasonable terms or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities, which could harm our business, financial condition, and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

We will continue to incur costs as a public company, including, but not limited to, costs and expenses for directors' fees; increased directors' and officers' insurance; investor relations fees; expenses for compliance with the Sarbanes-Oxley Act of 2002 and related to rules implemented by the SEC and Nasdaq, on which our common stock is listed; and various other costs. The Sarbanes-Oxley Act of 2002 requires that we maintain effective disclosure controls and procedures and internal controls.

Cash Flows. The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (30,326,128)	$ (56,637,187)
Net cash provided by (used in) investing activities	30,000,000	(29,954,530)
Net cash (used in) provided by financing activities	(1,270,220)	1,220,092
Net decrease in cash and cash equivalents	$ (1,596,348)	$ (85,371,625)

Operating Activities. Net cash used in operating activities was $30.3 million in 2023, compared to net cash used in operating activities of $56.6 million in 2022. The primary use of cash was to fund our operations. The decrease in the amount of cash used in operating activities for 2023 as compared to 2022 was principally due to a decrease in our net loss, primarily from research and development activities; changes in accrued expenses, due to the amount and timing of payments for research and development activities; changes in prepayments, due to timing of payment and collection of a receivable; and a decrease in stock compensation and an increase in deferred collaboration revenue with AbbVie.

Investing Activities. Net cash provided by investing activities in 2023 was $30.0 million compared to net cash used in investing activities in 2022 of $30.0 million. Net cash provided by investing activities primarily related to the maturities of marketable securities in 2023. Net cash used in investing activities primarily related to the net purchases and maturities activity of marketable securities for 2022.

Financing Activities. Net cash used in financing activities was $1.3 million for the year ended December 31, 2023 and consisted of stock withheld for tax obligations on option settlement proceeds and repayment of the end of term fee on our long-term debt, offset by proceeds from stock option exercises and stock purchases under the employee stock purchase plan. Net cash provided by financing activities of $1.2 million for year ended 2022, consisted of proceeds from stock option exercises and stock purchases under the employee stock purchase plan.

Off-Balance Sheet Arrangements. Through December 31, 2023, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Because we are allowed to comply with the disclosure obligations applicable to a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, with respect to this Annual Report on Form 10-K, we are not required to provide the information required by this Item.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

The information required by this Item 8 is contained on pages 107 through 132 of this annual report on Form 10-K and is incorporated herein by reference.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this annual report on Form 10-K, we carried out an evaluation under the supervision and with the participation of our Disclosure Committee and our management, including our Chief Executive Officer and our Interim Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(e) and 15d-15(e). Disclosure controls are procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, or the Exchange Act, such as this annual report on Form 10-K, is recorded, processed, summarized, and reported within the time periods specified by the United States Securities and Exchange Commission. Disclosure controls are also designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Interim Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our quarterly evaluation of disclosure controls includes an evaluation of some components of our internal control over financial reporting. We also perform a separate annual evaluation of internal control over financial reporting for the purpose of providing the management report below.

The evaluation of our disclosure controls included a review of their objectives and design, our implementation of the controls and the effect of the controls on the information generated for use in this annual report on Form 10-K. In the course of the control evaluations, we reviewed data errors or control problems identified and sought to confirm that appropriate corrective actions, including process improvements, were being undertaken. This type of evaluation is performed on a quarterly basis so that the conclusions of management, including our Chief Executive Officer and our Interim Chief Financial Officer, concerning the effectiveness of the disclosure controls can be reported in our periodic reports on Form 10-Q and Form 10-K. The overall goals of our evaluation activities are to monitor our disclosure controls and to modify them as necessary. We intend to maintain our disclosure controls as dynamic processes and procedures that we adjust as circumstances merit.

Based on our management's evaluation (with the participation of our Chief Executive Officer and our Interim Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and our Interim Chief Financial Officer have concluded that our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management utilized the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. Based on the assessment, our management has concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Attestation Report on Internal Control over Financial Reporting

This annual report on Form 10-K does not include an attestation report of our independent registered public accounting firm because we qualified as a "smaller reporting company and non-accelerated filer."

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

Trading Arrangements

During the three months ended December 31, 2023, neither we nor any of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in the Securities and Exchange Commission's rules).

ITEM 9C. *DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS*

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2023 (Proxy Statement), and is incorporated in this annual report on Form 10-K by reference.

Code of Ethics and Business Conduct

Our board of directors adopted a code of ethics and business conduct that applies to each of our directors, officers and employees. The full text of our code of business conduct is posted on the Corporate Governance portion of our website at http://ir.aldeyra.com/corporate-governance. Any waiver of the code of ethics and business conduct for an executive officer or director may be granted only by our board of directors or a committee thereof and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish format protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to the audit committee.

ITEM 11. Executive Compensation

Other than with respect to the Securities Authorized for Issuance under Equity Incentive Plans contained in Item 12 below, the information required by this item will be contained in the Proxy Statement and is incorporated in this annual report on Form 10-K by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Securities Authorized for Issuance under Equity Incentive Plans

The following table provides information as of December 31, 2023, with respect to shares of our common stock that may be issued, subject to certain vesting requirements, under our existing equity compensation plans, including our 2023 Equity Incentive Plan (2023 Equity Plan), 2013 Equity Incentive Plan (Amended 2013 Plan), 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan), and our 2016 Employee Stock Purchase Plan (2016 ESPP).

	A		B		C	
Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)	
Equity compensation plans approved by security holders	6,813,313	(1)	$ 6.40	(2)	8,053,156	(3)
Equity compensation plans not approved by security holders	—		—		—	
Total	6,813,313	(1)	$ 6.40	(2)	8,053,156	(3)

(1) Of these shares, 944,497 were underlying then outstanding restricted stock unit awards, 5,724,105 were subject to options then outstanding under the Amended 2013 Plan, and 144,711 were subject to options then outstanding under the 2023 Equity Plan.

(2) Does not take into account restricted stock units, which have no exercise price.

(3) Represents 5,707,730 shares of common stock available for issuance under our 2023 Equity Plan and 2,345,426 shares of common stock available for issuance under our 2016 ESPP. No shares are available for future issuance under the Amended 2013 Plan and 2010 Plan. Our 2016 ESPP provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year equal to the lesser of: (1) 1% of the shares of common stock outstanding at that time; and (2) such other amount as our board of directors may determine. On January 2, 2024, an additional 588,897 shares became available for future issuance under the 2016 ESPP. The additional shares from the annual increase on January 2, 2024 are not included in the table above.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item will be contained in the Proxy Statement and is incorporated in this annual report on Form 10-K by reference.

ITEM 14. Principal Accounting Fees and Services

The information required by this item will be contained in the Proxy Statement and is incorporated in this annual report on Form 10-K by reference.

PART IV

ITEM 15. Exhibits and Financial Statements Schedules

The financial statements filed as part of this annual report on Form 10-K are listed in the Index to Financial Statements. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto. The Exhibits are listed in the Exhibit Index below.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1	Restated Certificate of Incorporation of Registrant, (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on May 1, 2020, and incorporated herein by reference)
4.1	Specimen stock certificate evidencing the shares of common stock (filed as Exhibit 4.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)
4.2	Description of Securities (filed as Exhibit 4.6 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (as filed on March 12, 2020, and incorporated herein by reference))
10.1	Form of Indemnity Agreement for Directors and Officers (filed as Exhibit 10.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)
10.2†	Offer Letter, effective as of August 1, 2013, between the Registrant and Todd C. Brady, M.D., Ph.D. (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 6, 2014, and incorporated herein by reference)
10.3†	Offer Letter, effective November 29, 2013 between the Registrant and Todd C. Brady, M.D., Ph.D. (filed as Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 6, 2014, and incorporated herein by reference)
10.3(a)†	Offer Letter Amendment, effective February 19, 2014 between the Registrant and Todd C. Brady, M.D., Ph.D. (filed as Exhibit 10.4(a) to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)
10.4†	2010 Employee, Director and Consultant Equity Incentive Plan, as amended, and form of option agreement thereunder (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 6, 2014, and incorporated herein by reference)
10.5†	2013 Equity Incentive Plan and form of option agreement thereunder (filed as Exhibit 10.8 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)
10.5(a)†	Form Notice of Stock Option Grant under the 2013 Equity Incentive Plan (filed as Exhibit 10.8(a) to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)
10.5(b)†	Form Notice of Stock Unit Award under the 2013 Equity Incentive Plan (filed as Exhibit 10.8(b) to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on March 17, 2014, and incorporated herein by reference)

10.6	Sublease dated September 12, 2014 between the Registrant and MacLean Power L.L.C. (filed as Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (as filed on November 12, 2014, and incorporated herein by reference))
10.7	Sublease dated as of March 7, 2016 between Planck, LLC and the Registrant and Master Lease dated June 3, 2014 between WLC Three VI, L.L.C. and Plank, LLC (filed as Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (as filed on March 30, 2016, and incorporated herein by reference))
10.8†	Aldeyra Management Cash Incentive Plan (filed as Exhibit 10.25 to the Registrant's Current Report on Form 8-K as filed on March 18, 2016, and incorporated herein by reference)
10.9†	Aldeyra Therapeutics, Inc. Amended and Restated Change in Control Plan (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (as filed on August 5, 2021, and incorporated herein by reference))
10.10	Lease Agreement by and between WLC Three VI, L.L.C. and the Registrant, dated as of September 11, 2017 (filed as Exhibit 10.27 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 (as filed on November 9, 2017, and incorporated herein by reference))
10.11	First Amendment to Lease between WLC Three VI, L.L.C. and the Registrant, dated as of November 27, 2017 (filed as Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (as filed on March 29, 2018, and incorporated herein by reference))
10.12	Second Amendment to Lease between WLC Three VI, L.L.C. and the Registrant, dated as of October 7, 2020 (filed as Exhibit 10.33 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 (as filed on November 5, 2020 and incorporated herein by reference))
10.13	Third Amendment to Lease between WLC Three VI, L.L.C. and the Registrant, dated as of August 12, 2021 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 (as filed on October 26, 2021 and incorporated herein by reference))
10.14*	Fourth Amendment to Lease between WLC Three VI, L.L.C. and the Registrant, dated as of November 22, 2023
10.15†	Amendment No. 1 to the Aldeyra Therapeutics, Inc. 2013 Equity Incentive Plan (filed as Exhibit 10.26 to the Registrant's Quarterly Report on Form 10-Q (as filed on August 10, 2016, and incorporated herein by reference))
10.16†	Amendment No. 2 to the Aldeyra Therapeutics, Inc. 2013 Equity Incentive Plan (filed as Exhibit 10.29 to the Registrant's Quarterly Form 10-Q (as filed on August 9, 2018, and incorporated herein by reference))
10.17†	Aldeyra Therapeutics, Inc. 2016 Employee Stock Purchase Plan (filed as Exhibit 10.27 to the Registrant's Quarterly Report on Form 10-Q (as filed on August 10, 2016, and incorporated herein by reference))
10.18	Agreement and Plan of Merger, dated as of January 24, 2019, by and among Aldeyra Therapeutics, Inc., Helio Vision, Inc., Halo Merger Sub, Inc., Halo Merger Sub, LLC and Josef von Rickenbach, as the Securityholder Representative (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K (as filed on January 29, 2019, and incorporated herein by reference))
10.19†	Offer Letter, effective as of October 21, 2015, between the Registrant and Stephen Machatha, Ph.D.(filed as Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (as filed on March 17, 2022, and incorporated herein by reference))
10.19(a)†	Offer Letter Amendment No. 1, effective as of January 1, 2018, between the Registrant and Stephen Machatha, Ph.D. (filed as Exhibit 10.19(a) to the Registrant's Annual Report on Form 10-K (as filed on March 17, 2022, and incorporated herein by reference))

10.19(b)†	Offer Letter Amendment No. 2, effective as of March 23, 2021, between the Registrant and Stephen Machatha, Ph.D. (filed as Exhibit 10.19(b) to the Registrant's Annual Report on Form 10-K (as filed on March 17, 2022, and incorporated herein by reference))
10.20	Loan and Security Agreement, dated as of March 25, 2019, by and among the Registrant, certain subsidiaries of the Registrant from time to time party thereto, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (as filed on March 26, 2019, and incorporated herein by reference))
10.21	First Amendment to Loan and Security Agreement, dated April 20, 2021, by and among the Registrant, Helio Vision, LLC, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K as filed on April 21, 2021, and incorporated herein by reference)
10.22	Second Amendment to Loan and Security Agreement, dated December 22, 2022 and effective as of December 31, 2022, by and among the Registrant, Helio Vision, LLC, the several banks and other financial institutions or entities from time to time parties thereto and Hercules Capital, Inc. (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K as filed on December 27, 2022, and incorporated herein by reference).
10.23**	Exclusive License Agreement, effective as of July 7, 2016, between the Massachusetts Eye and Ear Infirmary and Helio Vision, Inc. (filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (as filed on March 12, 2020, and incorporated herein by reference))
10.24**	Amendment Number 1 and Waiver Agreement dated December 20, 2018 by and between Helio Vision, Inc. and the Massachusetts Eye and Ear Infirmary (filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (as filed on March 12, 2020, and incorporated herein by reference))
10.25†	Offer Letter, effective as of November 27, 2019, between the Registrant and Bruce Greenberg (filed as Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (as filed on March 9, 2023, and incorporated herein by reference))
10.26+	Exclusive Option Agreement, between the Registrant and AbbVie Inc., dated as of October 31, 2023
10.27†	Aldeyra Therapeutics, Inc. 2023 Equity Incentive Plan, form of option agreement, and form of RSU agreement thereunder (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (as filed on August 3, 2023, and incorporated herein by reference))
21.1*	Subsidiaries of Aldeyra Therapeutics, Inc.
23.1*	Consent of BDO USA, P.C. independent registered public accounting firm
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350
97	Aldeyra Therapeutics, Inc. Policy for the Recovery of Erroneously Awarded Compensation
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Compensation Arrangement.
‡ Confidential treatment has been granted with respect to certain portions of this document.
* Filed herewith.
** Certain information (indicated by "*****") has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the Company if publicly disclosed.
+ In accordance with Item 601(b)(10)(iv) certain information (indicated by "[****]") has been excluded from this exhibit because it is both not material and is the type that the Company treats as private or confidential.

The Exhibits listed in the Exhibit Index are filed as part of this annual report on Form 10-K.

ITEM 16. Form 10-K Summary

None.

Signatures

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the Commonwealth of Massachusetts, on March 7, 2024.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady, M.D., Ph.D.
Todd C. Brady, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Todd C. Brady and Bruce Greenberg, and each of them, as his or her true and lawful attorneys-in-fact, proxies, and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies, and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies, and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this annual report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	Chief Executive Officer and Director (principal executive officer)	March 7, 2024
/s/ Bruce Greenberg Bruce Greenberg	Senior Vice President of Finance, Interim Chief Financial Officer (principal financial and accounting officer)	March 7, 2024
/s/ Richard H. Douglas, Ph. D. Richard H. Douglas, Ph.D.	Chairman of the Board of Directors	March 7, 2024
/s/ Ben Bronstein, M.D. Ben Bronstein, M.D.	Director	March 7, 2024
/s/ Martin J. Joyce Martin J. Joyce	Director	March 7, 2024
/s/ Nancy Miller-Rich Nancy Miller-Rich	Director	March 7, 2024
/s/ Gary Phillips, M.D. Gary Phillips, M.D.	Director	March 7, 2024
/s/ Neal Walker, D.O. Neal Walker, D.O.	Director	March 7, 2024

ALDEYRA THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Aldeyra Therapeutics, Inc.
Lexington, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aldeyra Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Estimation of Accrued or Deferred Research & Development Clinical Trial Expenses

As described in Notes 2, 7 and 8 to the consolidated financial statements, the Company's deferred research and development expenses and accrued research and development expenses totaled approximately $4.5 million and $1.7 million, respectively, as of December 31, 2023. A portion of the accrued research and development expenses and the deferred research & development expenses relate to clinical trial activities. Clinical trial activities pertain to third-party services, including subject-related fees at the sites where the Company's clinical trials are being conducted and investigator fees, amongst other costs. Costs associated with these clinical trial expenses are generally payable on the passage of time or when certain milestones are achieved. Accrued liabilities are recorded related to those clinical trial expenses for which vendors have not yet billed the Company with respect to services provided that the Company has received. The accrual for these clinical trial expenses is based on such assumptions as expected total cost, the number of subjects and clinical trial sites and length of the study. Payments made by the Company in advance for clinical trial services not yet provided and/or for materials not yet received are recorded as deferred research & development expenses. Actual results may differ from these estimates.

We identified the determination of accrued clinical trial expenses for certain contracts and deferred clinical trial expenses for certain contracts as a critical audit matter. Estimating certain assumptions related to expected total cost, the number of subjects and clinical trial sites and length of the study for certain contracts requires significant judgment due to the subjectivity and uncertainty of these assumptions. Auditing these elements involved especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address the matter.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of certain assumptions related to expected total cost, the number of subjects and clinical trial sites, and length of the study for certain contracts, by: i) evaluating the consistency of those assumptions for certain contracts with the Company's press releases and other public information, ii) evaluating the consistency of those assumptions for certain contracts with the Company's communications with vendors relating to these contracts, iii) interviewing respective clinical operations personnel to obtain information related to the status of the projects, iv) assessing original clinical vendor contract terms and change orders for the certain contracts, including the expected timeline for the related study, v) confirming clinical costs, contracted fees and total amounts billed with the clinical vendors to evaluate the completeness of costs in the estimates and vi) evaluating patient enrollment status.
- Testing the completeness and accuracy of the data used in the estimate of certain assumptions for clinical trial expenses for certain contracts, by inspecting on a sample basis invoices received from and payments made by the Company to clinical vendors throughout the year and comparing invoice and payment amounts to the related contract details.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2013.

Boston, Massachusetts

March 7, 2024

ALDEYRA THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 142,823,016	$ 144,419,364
Marketable securities	—	29,881,520
Prepaid expenses and other current assets	4,987,317	6,722,229
Total current assets	147,810,333	181,023,113
Fixed assets, net	5,764	19,279
Right-of-use assets	510,814	249,265
Total assets	$ 148,326,911	$ 181,291,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,338,057	$ 133,625
Accrued expenses	5,536,464	14,065,885
Current portion of long-term debt	15,146,546	911,763
Operating lease liabilities	239,183	249,265
Total current liabilities	22,260,250	15,360,538
Deferred collaboration revenue, long-term	6,000,000	—
Operating lease liabilities, long-term	271,631	—
Long-term debt, net of current portion	—	14,923,090
Total liabilities	28,531,881	30,283,628
Commitments and contingencies (Notes 3, 9, & 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock, voting, $0.001 par value; 150,000,000 authorized and 59,195,951 and 58,560,078 shares issued and outstanding, respectively	59,196	58,560
Additional paid-in capital	513,994,982	507,770,045
Accumulated other comprehensive loss	—	(103,938)
Accumulated deficit	(394,259,148)	(356,716,638)
Total stockholders’ equity	119,795,030	151,008,029
Total liabilities and stockholders’ equity	$ 148,326,911	$ 181,291,657

The accompanying notes are an integral part of these consolidated financial statements.

ALDEYRA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 29,458,719	$ 47,306,066
General and administrative	13,335,364	15,373,921
Loss from operations	(42,794,083)	(62,679,987)
Other income (expense):		
Interest income	7,323,008	2,349,449
Interest expense	(2,071,435)	(1,694,098)
Total other income, net	5,251,573	655,351
Net loss	$ (37,542,510)	$ (62,024,636)
Net loss per share - basic and diluted	$ (0.64)	$ (1.06)
Weighted average common shares outstanding - basic and diluted	58,943,205	58,405,897

The accompanying notes are an integral part of these consolidated financial statements.

ALDEYRA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years ended December 31,	
	2023	2022
Net loss	$ (37,542,510)	$ (62,024,636)
Other comprehensive income (loss):		
Unrealized loss on marketable securities	—	(103,938)
Reclassification of losses to net loss	103,938	—
Total other comprehensive income (loss)	$ 103,938	$ (103,938)
Comprehensive loss	$ (37,438,572)	$ (62,128,574)

The accompanying notes are an integral part of these consolidated financial statements.

ALDEYRA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Stockholders' Equity					
	Common Voting Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income/(Loss), net of tax	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2021	58,081,215	$ 58,081	$ 500,369,444	$ —	$ (294,692,002)	$ 205,735,523
Stock-based compensation	—	—	6,180,988	—	—	6,180,988
Release of restrictions on Helio founders' shares	10,890	11	(11)	—	—	—
Issuance of common stock, exercise of stock options	236,962	237	1,123,190	—	—	1,123,427
Issuance of common stock, employee stock purchase plan	28,485	29	96,636	—	—	96,665
Issuance of common stock, vested restricted stock awards	202,526	202	(202)	—	—	—
Other comprehensive loss	—	—	—	(103,938)	—	(103,938)
Net loss	—	—	—	—	(62,024,636)	(62,024,636)
Balance, December 31, 2022	58,560,078	58,560	507,770,045	(103,938)	(356,716,638)	151,008,029
Stock-based compensation	—	—	6,453,293	—	—	6,453,293
Issuance of common stock, exercise of stock options	306,328	307	193,822	—	—	194,129
Issuance of common stock, employee stock purchase plan	26,168	26	111,076			111,102
Issuance of common stock, vested restricted stock awards	377,184	377	(377)	—	—	—
Common stock withheld for tax obligations on option exercise	(73,807)	(74)	(532,877)	—	—	(532,951)
Other comprehensive income	—	—	—	103,938	—	103,938
Net loss	—	—	—	—	(37,542,510)	(37,542,510)
Balance, December 31, 2023	59,195,951	$ 59,196	$ 513,994,982	$ —	$ (394,259,148)	$ 119,795,030

The accompanying notes are an integral part of these consolidated financial statements.

ALDEYRA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (37,542,510)	$ (62,024,636)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,752,771	8,288,976
Non-cash interest expense	354,193	331,150
Net amortization of premium on marketable securities	(14,542)	(47,245)
Depreciation and amortization expense	262,780	258,707
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	1,734,912	(3,760,448)
Accounts payable	1,204,432	(886,077)
Accrued expenses and other liabilities	(8,078,164)	1,202,386
Deferred collaboration revenue	6,000,000	—
Net cash used in operating activities	(30,326,128)	(56,637,187)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of fixed assets	—	(16,317)
Purchases of marketable securities	—	(92,938,213)
Maturities of marketable securities	30,000,000	63,000,000
Net cash provided by (used in) investing activities	30,000,000	(29,954,530)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	194,129	1,123,427
Tax withholding payments for net share-settled equity awards	(532,951)	—
Proceeds from employee stock purchase plan	111,102	96,665
Debt end of term charge paid in cash	(1,042,500)	—
Net cash (used in) provided by financing activities	(1,270,220)	1,220,092
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,596,348)	(85,371,625)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	144,419,364	229,790,989
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 142,823,016	$ 144,419,364
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	$ 1,702,188	$ 1,338,542

The accompanying notes are an integral part of these consolidated financial statements.

ALDEYRA THERAPEUTICS, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

Aldeyra Therapeutics, Inc. (Aldeyra, Company, we, us and our) was incorporated in the state of Delaware on August 13, 2004 as Neuron Systems, Inc. On December 20, 2012, the Company changed its name to Aldexa Therapeutics, Inc. and, on March 17, 2014, the Company changed its name to Aldeyra Therapeutics, Inc. Aldeyra, together with its wholly-owned subsidiaries, is a clinical-stage biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases.

The Company's principal activities to date include research and development activities along with related general business planning, including raising capital.

2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Consolidation – The accompanying consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America (US GAAP) and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated.

Risks and Uncertainties –The ongoing research and development activities will be subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any drug developed by the Company must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process implemented by the United States Food and Drug Administration (FDA) under the Food, Drug and Cosmetic Act. The Company has limited experience in conducting and managing the preclinical and clinical testing necessary to obtain regulatory approval. There can be no assurance that the Company will not encounter problems in the clinical trials that will cause the Company or the FDA to delay or suspend clinical trials.

The Company's success will depend in part on its ability to obtain patents and product license rights, maintain trade secrets, and operate without infringing on the property rights of others, both in the United States and other countries. There can be no assurance that patents issued to or licensed by the Company will not be challenged, invalidated, circumvented, or that the rights granted thereunder will provide proprietary protection or competitive advantages to the Company.

Based on its current operating plan, the Company believes that its cash and cash equivalents will be sufficient to fund the Company's currently projected operating expenses and debt obligations for at least the next 12 months from the date the financial statements are issued. The Company's assessment of its liquidity and capital resources includes an estimate of the financial impacts of these changes. The Company has based its projections of operating capital requirements on its current operating plan, which includes several assumptions that may prove to be incorrect, and the Company may use all of its available capital resources sooner than the Company expects. The Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of the Company's planned research and development activities and regulatory activities; commence or continue ongoing commercialization activities, including manufacturing, sales, marketing and distribution, for any of its product candidates for which the Company may receive marketing approval; or conduct any substantial, additional development requirements requested by the FDA. Additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to secure additional funding, it could be forced to delay, reduce or eliminate its research and development programs and its reproxalap commercialization efforts.

Curtailment of operations would cause significant delays in the Company's efforts to develop and introduce its products to market, which is critical to the realization of its business plan and the future operations of the Company.

Use of Estimates – The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions, including fair value estimates for investments, that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's consolidated financial statements include, but are not limited to, clinical trial accruals, deferred and accrued research and development costs, stock-based compensation, and accounting for income taxes and related valuation allowance. Although these estimates and assumptions are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Loss Contingencies – The outcome of loss contingencies, legal proceedings, indemnification matters, and claims brought against us is subject to uncertainty. An estimated loss contingency is accrued by a charge to earnings if it is probable that an asset has been impaired or a liability has been incurred and the amount can be reasonably estimated. Determination of whether to accrue a loss requires evaluation of the probability of an unfavorable outcome and the ability to make a reasonable estimate. Changes in these estimates could affect the timing and amount of accrual of loss contingencies and could be material to the financial statements.

Segment Information – Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of next-generation medicines to improve the lives of patients with immune-mediated diseases.

Cash and Cash Equivalents – The Company classifies all highly liquid investments with original maturities of three months or less as cash equivalents and all highly liquid investments with original maturities of greater than three months but less than 12 months as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in reverse repurchase agreements (RRAs), government securities and obligations, and money market funds.

RRAs are collateralized by deposits in the form of 'Government Securities and Obligations' for an amount not less than 102% of their value. The Company does not record an asset or liability related to the collateral as the Company is not permitted to sell or repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third-party custodian to manage the exchange of funds as well as the requirement that collateral received is maintained at 102% of the value of the RRAs on a daily basis.

Marketable Securities – Marketable securities consist of government securities and obligations with original maturities of more than 90 days. Debt investments are classified as available-for-sale and are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of other comprehensive income/(loss). Management determines the appropriate classification of its investments at the time of purchase and re-evaluates such determination at each balance sheet date.

Fair Value of Financial Instruments – Financial instruments including cash equivalents and accounts payable are carried in the financial statements at amounts that approximate their fair value based on the short maturities of those instruments. Marketable securities are carried at fair value and are more fully described in Note 6. The carrying amount of the Company's credit facility with Hercules Capital, Inc. approximates fair value since the effective interest rate approximates market rates currently available to the Company.

Concentration of Credit Risk – Financial instruments that potentially subject the Company to significant concentrations of credit risk principally consist of cash, cash equivalents and marketable securities, if any. The Company places its cash and cash equivalents and marketable securities with financial institutions which management believes have high credit ratings and may hold some amounts exceed federally insured limits. As part of its cash and investment management processes, the Company performs periodic evaluations of the credit standing of the financial institutions with whom it maintains deposits.

Intellectual Property – The legal and professional costs incurred by the Company to acquire its patent rights are expensed as incurred and included in general and administrative expenses. At December 31, 2023 and 2022, the Company has determined that these expenses have not met the criteria to be capitalized since the future benefits to be derived from the patents is uncertain. Intellectual property related expenses for the years ended December 31, 2023 and 2022 were $1.2 million and $1.0 million, respectively.

Collaborative Arrangements – The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC 808, *Collaborative Arrangements (ASC 808)*. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain units of account, the Company first determines which units of account of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers (ASC 606)*, if any, and which units of may be subject to other specific recognition guidance, if any. For units of account of collaboration arrangements that are accounted for pursuant to ASC 808, and not subject to other specific recognition guidance, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election.

For collaboration arrangements that are within the scope of ASC 808, the Company evaluates the income statement classification for presentation of amounts due from or owed to other participants associated with multiple activities in a collaboration arrangement based on the nature of each separate activity. Payments or reimbursements that are the result of a collaborative relationship instead of a customer relationship, such as co-development and co-commercialization activities, are recorded as research and development expense or selling, general and administrative expense, in the event of a payment to the collaborative partner in a period, or a reduction to these expense line items in the event of a reimbursement from the collaboration partner in a period, as appropriate.

Income Taxes – The Company follows the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 740, *Income Taxes (ASC 740)*, in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax liabilities and assets for expected future income tax consequences of events that have been recognized in the Company's financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if based on the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740 which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes. Management is not aware of any uncertain tax positions.

Research and Development Costs – Research and development (R&D) costs are charged to expense as incurred and relate to salaries, employee benefits, stock-based compensation related to employees, consulting services, other operating costs and expenses associated with preclinical and clinical trial activities. Payments made by the Company in advance for research and development services not yet provided and/or for materials not yet received are recorded as prepaid expenses. Accrued liabilities are recorded related to those expenses for which vendors have not yet billed us with respect to services provided and/or materials that we have received.

Preclinical and clinical trial expenses relate to third-party services, subject-related fees at the sites where the Company's clinical trials are being conducted, laboratory costs, analysis costs, toxicology studies and investigator fees. Costs associated with these expenses are generally payable on the passage of time or when certain milestones are achieved. Expense is recorded during the period incurred or in the period in which a milestone is achieved. In order to ensure that the Company has adequately provided for preclinical and clinical expenses during the proper period, the Company maintains an accrual for these expenses. These accruals are assessed on a quarterly basis and are based on such assumptions as expected total cost, the number of subjects and clinical trial sites and length of the study. Actual results may differ from these estimates and could have a material impact on the Company's reported results. The Company's historical accrual estimates have not been materially different from actual costs.

In-process research and development – Assets purchased in an asset acquisition transaction are expensed as in-process research and development (IPR&D) unless the assets acquired are deemed to have an alternative future use, provided that the acquired asset did not also include processes or activities that would constitute a "business" as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Acquired IPR&D payments are immediately expensed in the period in which they are incurred and include upfront payments, as well as transaction fees and subsequent pre-commercial milestone payments. Research and development costs incurred after the acquisition are expensed as incurred.

Stock-Based Compensation – Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. For options, the fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes option pricing model. For restricted stock units, fair value is based on the fair value of the underlying stock on the date of grant. The resulting fair value for restricted stock units and options expected to vest is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the applicable restricted stock units or option. The Company records the effect of forfeitures and cancellations when they occur.

For performance-based awards, at each reporting period we assess the probability that the performance condition(s) will be achieved. We use the accelerated attribution method to expense the awards over the continuous service period based on the probability of achieving the performance conditions. We estimate the continuous service period based on our best estimate of the period over which an award's vesting condition(s) will be achieved. We review and evaluate these estimates on a quarterly basis.

The Company has cash awards and performance cash settled bonus awards, which are awards that will be settled in cash on their vesting dates (Liability Awards), rather than in equity units. The fair value of Liability Awards is updated at each balance sheet date and changes in the fair value of the vested portions of the Liability Awards are recorded as increases or decreases to compensation expense. The Company recognizes forfeitures as they occur.

Comprehensive Loss – Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. For December 31, 2023, comprehensive loss is equal to the Company's net loss of $37.5 million and a reclassification of losses on marketable securities to net loss of $0.1 million. For December 31, 2022, comprehensive loss is equal to the Company's net loss of $62.0 million and an unrealized loss on marketable securities of $0.1 million.

Net Loss Per Share – The Company computes net loss per share in accordance with the two-class method. Under the two-class method, net loss is allocated between common stock and other participating securities based on their participation rights. The Company has determined that the nonvested shares issued to the Helio founders represents a participating security and as such the nonvested shares are excluded from basic earnings per share. Net losses are not allocated to the nonvested stockholders for computing net loss per share under the two-class method because nonvested stockholders do not have contractual obligations to share in the losses of the Company. Basic earnings per share is calculated by dividing net loss allocable to common stockholders by the weighted average number of common stock outstanding during the period, excluding the effects of any potentially dilutive instruments.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method, or (b) treasury stock method, as applicable, to the potentially dilutive instruments. The weighted-average number of common shares outstanding gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and restricted stock units, warrants, if any, and nonvested shares.

Recent Accounting Pronouncements – In June 2016, the FASB issued (ASU) No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13). ASU 2016-13 requires that credit losses be reported as an allowance using an expected losses model, representing the entity's current estimate of credit losses expected to be incurred. The accounting guidance currently in effect is based on an incurred loss model. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The amendments under ASU 2016-13 are effective for interim and annual fiscal periods beginning after December 15, 2022. The Company adopted this standard as of January 1, 2023, and there was no material impact to the Company's financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07). ASU 2023-07 is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses, including for single reportable segment entities. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. We are evaluating the disclosure requirements related to the new standard.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures (ASU 2023-09). ASU 2023-09 requires more detailed income tax disclosures. The guidance requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We are evaluating the disclosure requirements related to the new standard.

3. HELIO VISION ACQUISITION

On January 28, 2019 (Closing Date), the Company acquired Helio Vision, Inc. (Helio). As a result of the acquisition, the Company initially issued an aggregate of 1,160,444 shares of common stock to the former securityholders and an advisor of Helio. The founders of Helio were issued 568,627 shares and non-founders were issued 591,817 shares. The Helio founders' shares were subject to vesting based on continued service to the Company through January 28, 2022. The Company recognized the expense associated with the founders' restricted shares as research and development compensation expense on a straight-line basis as the shares vested over the three-year period. For the year ended December 31, 2022, the Company recorded $0.1 million of research and development compensation expense, for the founders' restricted shares. There are no further obligations related to founders' restricted shares.

In January 2021, pursuant to the terms of the acquisition agreement, the Company issued 246,562 shares of its common stock to the former securityholders of Helio (January Shares). In addition, the Company, subject to the conditions of the acquisition agreement, is contingently obligated to make additional payments to the former securityholders of Helio as follows: (a) $10.0 million of common stock following approval by the FDA of an new drug application (NDA) for the prevention and/or treatment of proliferative vitreoretinopathy or a substantially similar label prior to the 10th anniversary of the Closing Date; and (b) $2.5 million of common stock following FDA approval of an NDA for an indication (other than proliferative vitreoretinopathy or a substantially similar label) prior to the 12th anniversary of the Closing Date (the shares of common stock issuable pursuant to the preceding clauses (a) and (b) are referred to herein as the Milestone Shares), provided that in no event shall the Company be obligated to issue more than an aggregate of 5,248,885 shares of common stock in connection with the Helio acquisition. Additionally, in the event of certain change of control or divestitures by the Company, certain former convertible noteholders of Helio will be entitled to a tax gross-up payment in an amount not to exceed $1.0 million in the aggregate.

The Company determined that liability accounting is not required for the Milestone Shares under FASB ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480). The Company also determined that the Milestone Shares meet the scope exception as a derivative under FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815), from inception of the Milestone Shares through December 31, 2023. Accordingly, the Milestone Shares are evaluated under FASB ASC Topic 450, *Contingencies* (ASC 450) and the Company will record a liability related to the Milestone Shares if the milestones are achieved, and the obligation to issue the Milestone Shares becomes probable. At such time, the Company will record the cost of the Milestone Shares issued to the founders as compensation expense and to the Helio non-founders as an IPR&D expense if there is no alternative future use. No other milestones related to the remaining Milestone Shares are considered probable of being achieved as of December 31, 2023.

4. NET LOSS PER SHARE

For the years ended December 31, 2023 and 2022, diluted weighted-average common shares outstanding is equal to basic weighted-average common shares due to the Company's net loss position.

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact:

	Years ended December 31,	
	2023	2022
Options to purchase common stock	5,868,816	5,403,982
Nonvested restricted stock units	944,497	1,184,603
Total of common stock equivalents	6,813,313	6,588,585

5. CASH, CASH EQUIVALENTS, AND MARKETABLE SECURITIES

At December 31, 2023, cash and cash equivalents were comprised of:

	Carrying Amount	Estimated Fair Value	Cash and Cash Equivalents
Cash	$ 128,510,451	$ 128,510,451	$ 128,510,451
Money market funds	14,312,565	$ 14,312,565	14,312,565
Total cash and cash equivalents	$ 142,823,016	$ 142,823,016	$ 142,823,016

There were no marketable securities held at December 31, 2023.

At December 31, 2022, cash, cash equivalents, and marketable securities were comprised of:

	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities
Cash	$ 135,151,081	$ —	$ —	$ 135,151,081	$ 135,151,081	$ —
Money market funds	9,268,283	—	—	9,268,283	9,268,283	—
Total cash and cash equivalents	$ 144,419,364	$ —	$ —	$ 144,419,364	$ 144,419,364	$ —
U.S. government agency securities	$ 29,985,458	$ —	$ (103,938)	$ 29,881,520	$ —	29,881,520
Available for sale [1]	29,985,458	—	(103,938)	29,881,520	—	29,881,520
Total cash, cash equivalents, and current marketable securities					$ 144,419,364	$ 29,881,520

(1) Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes, if material, in other comprehensive loss.

The contractual maturities of all cash equivalents and available for sale securities were less than one year at December 31, 2023

6. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820, *Fair Value Measurements*, establishes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 – Quoted prices in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table presents information about the Company's assets measured at fair value at December 31, 2023 and December 31, 2022:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (a)	$ 14,312,565	$ —	$ —	$ 14,312,565
Total assets at fair value	$ 14,312,565	$ —	$ —	$ 14,312,565

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (a)	$ 9,268,283	$ —	$ —	$ 9,268,283
U.S. government agency securities (b)	—	29,881,520	—	29,881,520
Total assets at fair value	$ 9,268,283	$ 29,881,520	$ —	$ 39,149,803

(a) Money market funds included in cash and cash equivalents in the consolidated balance sheets, are valued at quoted market prices in active markets.
(b) U.S. government agency securities are recorded at fair market value, which are determined based on the most recent observable inputs for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active or are directly or indirectly observable.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2023 and 2022 were:

	December 31, 2023	December 31, 2022
Deferred research and development expenses	$ 4,463,783	$ 2,605,252
Prepaid insurance expenses	340,388	432,230
Other current receivables	—	3,242,026
Miscellaneous prepaid expenses and other current assets	183,146	442,721
Total prepaid expenses and other current assets	$ 4,987,317	$ 6,722,229

8. ACCRUED EXPENSES

Accrued expenses at December 31, 2023 and 2022 were:

	December 31, 2023	December 31, 2022
Accrued compensation	$ 3,087,937	$ 3,821,904
Accrued research and development expenses	1,687,327	8,476,422
Accrued other expenses	761,200	1,767,559
Total accrued expenses	$ 5,536,464	$ 14,065,885

9. CREDIT FACILITY

The Company's current and long-term debt obligation consists of amounts the Company is obligated to repay under its credit facility with Hercules Capital, Inc. (Hercules). In March 2019, the Company entered into a Loan and Security Agreement (Loan and Security Agreement or Hercules Credit Facility) with Hercules and several banks and other financial institutions or entities, from time-to-time parties thereto (collectively, referred to herein as Lender), providing for a term loan of up to $60.0 million, subject to the satisfaction of certain conditions contained therein, that is secured by a lien covering all of the Company's assets, other than the Company's intellectual property. The Loan and Security Agreement provided for (i) an initial term loan advance of up to $5.0 million at the Company's option, which expired unutilized on April 15, 2019; (ii) three additional term loan advances of up to $15.0 million each, at the Company's option, available to the Company upon the occurrence of certain pre-specified funding conditions prior to September 30, 2019 (2019 Tranche), March 31, 2020 (2020 Tranche), and March 31, 2021 (2021 Tranche); and (iii) a final additional term loan advance (Fourth Loan Tranche) of up to $10.0 million prior to December 31, 2021, at the Company's option, subject to approval by the Lender's investment committee. The 2019 Tranche was drawn down in full by the Company in September 2019 and the 2020 Tranche and 2021 Tranche expired unutilized prior to the Company satisfying the funding conditions for such tranche. On April 20, 2021, the Company entered into the First Amendment to the Loan and Security Agreement (First Amendment). The First Amendment, among other things, (i) increased the Fourth Loan Tranche from $10.0 million to $20.0 million and extended the deadline for drawing down the Fourth Loan Tranche to July 1, 2022; (ii) lowered the variable per annum rate of interest on borrowings under the Loan and Security Agreement from the greater of (a) 9.10% and (b) the prime rate (as reported in the Wall Street Journal or any successor publication thereto) plus 3.10% to the greater of (x) the Prime Rate (as defined therein) plus 3.10% or (y) 8.60%; (iii) extended the expiration of the period in which interest-only payments on borrowings under the Loan and Security Agreement are required from May 1, 2021 to July 1, 2022; and (iv) following the satisfaction of certain conditions, which conditions were satisfied in April 2021, further extended the expiration of the interest-only period and the deadline for drawing down the Fourth Loan Tranche to May 1, 2023. The First Amendment was determined to be a modification in accordance with FASB ASC Topic 470, Debt and did not result in extinguishment.

On December 22, 2022, the Company entered into the Second Amendment to the Loan and Security Agreement (Second Amendment), which became effective as of December 31, 2022 (Second Amendment Effective Date). The Second Amendment, among other things, (i) extended the expiration of the period in which interest-only payments on borrowings under the Loan and Security Agreement are made from May 1, 2023 to May 1, 2024; (ii) extended the maturity date from October 1, 2023 to October 1, 2024 (Maturity Date); (iii) extended the availability of the Fourth Loan Tranche commitment of $20 million from May 1, 2023 to May 1, 2024; and (iv) amended the Prepayment Charge (as defined therein) to equal 0.75% of the amount prepaid during the 12-month period following the Second Amendment Effective Date, and 0% thereafter. The ability to draw the Fourth Loan Tranche remains conditioned on approval by the Lenders' investment committee. In addition, a supplemental end of term charge of $292,500 (Supplemental End of Term Charge) shall be due on the earlier of (A) the Maturity Date, as amended, or (B) repayment of the aggregate amount of advances under the Loan and Security Agreement. The existing end of term charge of $1,042,500 (End of Term Charge) remained due on the earlier of (A) October 1, 2023 or (B) repayment of the aggregate amount of advances under the Loan and Security Agreement, and was paid on October 2, 2023. Repayment of the aggregate outstanding principal balance of the term loan, in monthly installments, commences in May 2024 upon expiration of the interest-only period and continues through the Maturity Date, as amended. The Second Amendment was determined to be a modification in accordance with FASB ASC Topic 470, Debt and did not result in extinguishment.

In connection with the Hercules Credit Facility, the Company incurred a commitment charge of $25,000, transaction costs of $273,186, a fee of $375,000 upon closing, the End of Term Charge, which was paid in October 2023, and the Company will be required to pay the Supplemental End of Term Charge. The Company paid the End of Term Charge on October 2, 2023 in the amount of $1,042,500. The fees and transaction costs are amortized to interest expense from 2019 through the Maturity Date using the effective interest method. The End of Term Charge was amortized to interest expense from 2019 through October 2023, and the Supplemental End of Term Charge is amortized to interest expense from December 2022 through the Maturity Date, both using the effective interest method. The effective interest rate was 13.2% at December 31, 2023. At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus all fees and other amounts due under the Loan and Security Agreement as of the date of such prepayment, including a prepayment charge equal to 0.75% of the principal amount being prepaid during the 12-month period following the Second Amendment Effective Date, and 0% thereafter.

Following the effective time of the First Amendment and the Second Amendment and as of December 31, 2023, an aggregate of $35 million, subject to the terms and conditions of the Loan and Security Agreement, may be made available to the Company for borrowing, $15 million of which was funded prior to the date of the First Amendment.

Long-term debt consisted of the following:

	December 31, 2023	December 31, 2022
Term loan payable	$ 15,000,000	$ 15,000,000
End of term charge	173,646	911,763
Unamortized debt issuance costs	(27,100)	(76,910)
Less: current portion	(15,146,546)	(911,763)
Total long-term debt	$ —	$ 14,923,090

Future principal payments, including the End of Term Charge, are as follows for the years ending December 31:

2024	15,292,500
Total	$ 15,292,500

The Loan and Security Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company. As of December 31, 2023, the Company was in compliance with all covenants of the Hercules Credit Facility in all material respects. In addition, subject to the terms of the Loan and Security Agreement, the Company granted the Lender the right to purchase up to an aggregate of $2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in financings upon the same terms and conditions afforded to such other investors.

10. STOCKHOLDERS' EQUITY

Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2023, a total of 5,868,816, 5,707,730, and 2,345,426, shares of common stock were reserved for issuance upon (i) the exercise of outstanding stock options, (ii) the issuance of stock awards under the Company's 2023 Equity Plan, and (iii) the issuance of shares under the 2016 ESPP, respectively.

2021 Jefferies Sales Agreement

In March 2021, the Company entered into an Open Market Sales Agreement℠ with Jefferies LLC (Jefferies), as sales agent (2021 Jefferies Sales Agreement), pursuant to the 2021 Jefferies Sales Agreement, the Company may offer and sell, from time to time through Jefferies, shares of common stock providing for aggregate sales proceeds of up to $100.0 million. The Company has no obligation to sell any shares under the 2021 Jefferies Sales Agreement, and could at any time suspend solicitations and offers under the 2021 Jefferies Sales Agreement. No sales had been made pursuant to the 2021 Jefferies Sales Agreement as of December 31, 2023.

11. INCOME TAXES

No current or deferred tax provision expenses for federal and state income taxes have been recorded as the Company has incurred losses since inception for tax purposes. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

In assessing the realizability of net deferred taxes in accordance with Accounting Standards Codification (ASC) 740, Income Taxes (ASC 740), the Company considers whether it is more likely than not that some portion or all the deferred tax assets will not be realized. Based on the weight of available evidence, primarily the incurrence of net losses since inception, anticipated net losses in the near future, reversals of existing temporary differences and expiration of various federal and state attributes, the Company does not consider it more likely than not that some or all of the net deferred taxes will be realized. Accordingly, a 100% valuation allowance has been applied against net deferred tax assets.

As of December 31, 2023, the Company had federal and state income tax net operating loss (NOL) carryforwards of approximately $250.6 million and $242.5 million, respectively. Federal NOL carryforwards generated through December 31, 2017 and state NOL carryforwards will expire at various dates through 2043. The federal NOL carryforwards generated during the year ended December 31, 2018 and thereafter will carryforward indefinitely. As of December 31, 2023, the Company had federal and state research and development tax credit carryforwards of approximately $10.1 million and $2.1 million, respectively, which will expire at various dates through 2043. Additionally, as of December 31, 2023, the Company had a federal orphan drug tax credit carryforward of approximately $2.1 million that expires in 2043.

On August 16, 2022 President Biden signed into law the Inflation Reduction Act (IRA). From a tax perspective, the IRA provisions includes a new corporate alternative minimum tax (CAMT) of 15% on adjusted financial statement income (AFSI) for corporations with over $1 billion in profits, a new excise tax on corporate stock buybacks and increased funding for IRS enforcement. A company's AFSI can be reduced by net operating losses, foreign tax credits, general business credits and depreciation for property under Section 197. To determine its US federal income tax liability, a company will need to compute taxes under both systems — the regular tax system and the CAMT system. The company then will pay the larger amount as its tax liability in any given year. The Company does not expect to fall into the CAMT system. The IRA provisions have no impact on the Company's financial statements for the period ended December 31, 2023.

Significant components of the Company's deferred tax assets and liabilities at December 31, 2023 and 2022 are as follows:

	Years ended December 31,	
	2023	2022
Deferred Tax Assets		
Federal & state NOL carryforward	$ 67,953,701	$ 64,840,595
Federal & state R&D credit carryforward	13,794,138	12,110,003
Deferred costs	1,012,032	342,210
Intangibles – net	78,378	78,378
Accounts payable and accrued expenses	2,135,899	2,004,737
Reserves	28,396	28,396
Stock options	3,323,000	4,042,117
Capitalized R&D expenses	16,489,741	11,151,910
Other items	167,126	98,552
Gross deferred tax assets	104,982,411	94,696,898
Valuation allowance	(104,842,857)	(94,628,799)
Deferred tax assets, net	$ 139,554	$ 68,099
Deferred Tax Liabilities		
Right of use asset	(139,554)	(68,099)
TOTAL	$ —	$ —

The change in valuation allowance of $10.2 million from December 31, 2022 to December 31, 2023 was primarily the result of an increase in capitalized R&D expenses, net operating losses, and tax credits.

The components of the income tax benefit for the years ended December 31, 2023 and 2022, are as follows:

	Years ended December 31,	
	2023	2022
Deferred Taxes		
Federal	$ —	$ —
State	—	—
Total income tax benefit	$ —	$ —

Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). Transactions involving the Company's common stock within the testing period, even those outside the Company's control such as purchases or sales by investors, could result in an ownership change. A limitation on the Company's ability to utilize some or all its NOLs or credits could have a material adverse effect on the Company's results of operations and cash flows. The Company believes, prior to December 31, 2021 that four ownership changes occurred since inception. Management believes that its aggregate Section 382 and 383 limitation (including the additional limitation for recognized "built-in gains") is sufficient so that no current impairment of its pre-ownership change tax attributes is required. Management believes there were no ownership changes from December 31, 2021 through December 31, 2023, based on a review of the Company's equity history during that period. Any future ownership changes, including those resulting from any recent or future financing activities, may cause our existing tax attributes to have additional limitations.

As of December 31, 2023, the Company is subject to tax in the U.S. (Federal and Massachusetts). The Company is open to examination for the tax years ended December 31, 2022, 2021, and 2020. In addition, any loss years remain open to the extent that losses are available for carryover to future years.

A reconciliation of the federal statutory tax rate of 21% to the Company's effective income tax rates are as follows:

	Years ended December 31,	
	2023	2022
Statutory tax rate	21.00 %	21.00 %
State taxes, net of federal benefits	5.20 %	6.05 %
Federal research and development credits	4.50 %	4.12 %
Change in valuation allowance	(27.21)%	(28.66)%
Stock-based compensation	(3.45)%	(2.53)%
Other	(0.04)%	0.02 %
Effective tax rate	0.00 %	0.00 %

12. STOCK INCENTIVE PLAN

The Company approved the 2013 Equity Incentive Plan in October 2013. On June 30, 2023, the 2013 Equity Incentive Plan was replaced by the 2023 Equity Incentive Plan (2023 Equity Plan). Prior to its replacement by the 2023 Equity Plan, the 2013 Equity Incentive Plan was amended in June 2016 and June 2018, (Amended 2013 Plan). The Amended 2013 Plan provides for the granting of stock options, restricted stock units (RSU), stock appreciation rights, and stock units to certain employees, members of the board of directors and consultants of the Company. The aggregate number of common shares that previously could have been issued under the Amended 2013 Plan automatically increase on the first business day of each year by a number of shares equal to the lower of (a) 6% of the total number of shares of common stock outstanding on the last calendar day of the prior fiscal year, or (b) a number of shares of common stock determined by the Company's board of directors. As of December 31, 2023, options to purchase 5,724,105 shares of common stock at a weighted average exercise price of $6.35 per share and 944,497 shares of common stock underlying restricted stock units remained outstanding under the Amended 2013 Plan.

In May 2023, the Company's Board of Directors authorized the 2023 Equity Plan to replace the Amended 2013 Plan. On June 30, 2023, the Company's stockholders approved the 2023 Equity Plan at the Company's 2023 annual meeting of stockholders. Pursuant to the 2023 Equity Plan, the Company will not make any further grants under the Amended 2013 Plan following June 30, 2023, though awards previously granted under the Amended 2013 Plan will remain outstanding. The 2023 Equity Plan is effective for a period of ten years after June 30, 2023, and a total of 5,450,000 additional shares of the Company's common stock, in addition to shares of the Company's common stock that are subject to awards granted under the Amended 2013 Plan that are outstanding as of such date and that are subsequently forfeited, cancelled or expire before being exercised or settled in full and thereupon become available for grant under the 2023 Equity Plan, are authorized for issuance under the 2023 Equity Plan. As of December 31, 2023, options to purchase 144,711 shares of common stock at a weighted average exercise price of $8.39 per share remained outstanding under the 2023 Equity Plan. As of December 31, 2023, there were 5,707,730 shares of common stock available for grant under the 2023 Equity Plan.

In 2020 and 2022 the Company granted cash awards under its Management Cash Incentive Plan, as amended (the Management Cash Incentive Plan). The Management Cash Incentive Plan provides its participants with the opportunity to earn cash incentive awards for the achievement of goals relating to the performance of the Company and was adopted in 2016. The cash awards vest in four annual installments from the date of grant and entitle the employees to receive a cash payment, on the earlier of (i) four years from the date of grant or (ii) a change of control, equal in value to the amount by which the then value of the Company's common stock exceeds the base value. As of December 31, 2023, $0.3 million was accrued as compensation expense for vested cash awards. There was no unrecognized expense as of December 31, 2023.

In 2022, the Company granted performance cash settled bonus awards (CSBUs) under its Management Cash Incentive Plan. Subject to and conditioned upon the acceptance by the FDA of the Company's submission of an NDA for reproxalap (Performance Criteria), the awards will vest in four annual installments from the date of grant and entitle the employees to receive a cash payment for each vested CSBU, on the earlier of (i) four years from the date of grant or (ii) a change of control, equal in value of the closing price per share of the Company's common stock on the Nasdaq Capital Market on the payment date. As of December 31, 2023, $1.5 million was accrued as compensation expense for CSBUs as the Performance Criteria was deemed probable and was met in February 2023. There was no unrecognized expense as of December 31, 2023.

The Company recognizes stock-based compensation expense over the requisite service period. The Company's share-based awards are accounted for as equity instruments, except for cash awards and CSBUs, which are accounted for as liabilities. The amounts included in the consolidated statements of operations relating to stock-based compensation associated with the two equity incentive plans, cash awards, CSBUs, and Helio founders' shares are as follows:

	Years ended December 31,	
	2023	2022
Research and development expenses	$ 3,076,048	$ 4,087,073
General and administrative expenses	2,676,723	4,201,903
Total stock-based compensation expense	$ 5,752,771	$ 8,288,976

Stock Options

Terms of stock option agreements, including vesting requirements, are determined by the board of directors or its compensation committee, subject to the provisions of the respective plan from which they were granted. Options granted by the Company typically vest over a four-year period. The options are subject to acceleration of vesting in the event of certain change of control transactions. The options may be granted for a term of up to ten years from the date of grant. The exercise price for options granted under the Amended 2013 Plan and the 2023 Equity Plan must be at a price no less than 100% of the fair market value of a common share on the date of grant.

The following table summarizes option activity under the incentive plans for the year ended December 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value(a)
Outstanding at December 31, 2022	5,403,982	$ 5.90	6.56	$ 10,506,953
Granted	1,172,775	6.96		—
Forfeited	(300,769)	6.16		226,418
Exercised	(306,328)	0.63		2,006,635
Expired	(100,844)	4.37		32,077
Outstanding at December 31, 2023	5,868,816	$ 6.40	6.44	$ 3,996
Exercisable at December 31, 2023	4,353,141	$ 6.36	5.69	$ 2,143

(a) The aggregate intrinsic value in this table was calculated on the positive difference, if any, between the closing price per share of the Company's common stock on December 31, 2023 of $3.51 and the per share exercise price of the underlying options. The total intrinsic value of stock options exercised was $2.0 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively.

The Company records stock-based compensation related to stock options granted at fair value. During the years ended December 31, 2023 and 2022, the Company used the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The weighted-average grant date fair value of options granted was $5.07 and $2.92 for the years ended December 31, 2023 and 2022, respectively. The assumptions used in determining fair value of the employee stock options for the years ended December 31, 2023 and 2022, are as follows:

	December 31, 2023	December 31, 2022
Expected dividend yield	0%	0%
Anticipated volatility	83.58% - 83.63%	84.82% - 85.21%
Stock price	$6.76 - $8.39	$3.49 - $4.52
Exercise price	$6.76 - $8.39	$3.49 - $4.52
Expected life (years)	5.50 - 6.02	5.50 - 6.08
Risk free interest rate	4.09% - 4.12%	1.47% - 3.26%

The dividend yield of zero is based on the fact that the Company has never paid cash dividends and have no present intention to pay cash dividends. Expected volatility is estimated using the historical volatility of the Company. The Company has estimated the expected life of its employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option for service-based awards since the Company doesn't have sufficient historical or implied data of its own. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon United States Treasury securities.

At December 31, 2023, there is approximately $6.2 million of unrecognized compensation cost relating to stock options outstanding, which the Company expects to recognize over a weighted average period of 2.22 years. Total unrecognized compensation cost will be adjusted for future forfeitures, if necessary.

Restricted Stock Units

Terms of RSUs agreements, including vesting requirements, are determined by the board of directors or its compensation committee, subject to the provisions of the Amended 2013 Plan and the 2023 Equity Plan. RSUs granted by the Company typically vest over a four year period stock share price on the date of grant to estimated fair value. In the event that the employees' employment with the Company terminates any unvested shares are forfeited and revert to the Company. RSUs are not included in issued and outstanding common stock until the shares are vested and released. The table below summarizes activity relating to RSUs for the year ended December 31, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	1,184,603	$ 4.95
Granted	238,750	6.76
Forfeited	(101,672)	4.72
Exercised/Released	(70,904)	4.72
Vested	(306,280)	5.42
Outstanding at December 31, 2023	944,497	$ 5.30

The weighted-average fair value of RSUs granted was $6.76 and $4.64 per share for the years ended December 31, 2023 and December 31, 2022, respectively. The total fair value of RSUs vested was $2.0 million and $1.3 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the outstanding RSUs had unamortized stock-based compensation of $3.6 million with a weighted-average remaining recognition period of 2.53 years and an aggregate intrinsic value of $3.3 million.

Employee Stock Purchase Plan

In March 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (2016 ESPP), which became effective in June 2016 following the approval of the Company's stockholders. The 2016 ESPP initially authorized the issuance of up to a total of 414,639 shares of the Company's common stock to participating employees. The number of shares reserved for issuance under the 2016 ESPP automatically increases on the first business day of each fiscal year, commencing in 2017, by a number equal to the lower of (i) 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (ii) the number of shares determined by the Company's Board of Directors. Unless otherwise determined by the administrator of the 2016 ESPP, two offering periods of six months' duration will begin each year on January 1 and July 1. Participating employees purchase stock under the 2016 ESPP at a price equal to the lower of 85% of the closing price on the applicable offering commencement date or 85% of the closing price on the applicable offering termination date. The fair value of the purchase rights granted under this plan was estimated on the date of grant using the Black-Scholes option-pricing model using assumptions as shown below:

	December 31, 2023	December 31, 2022
Expected dividend yield	0%	0%
Anticipated volatility	83.61% - 91.33%	84.04% - 84.99%
Stock price	$6.96 - $7.98	$3.80 - $4.27
Exercise price	$6.96 - $7.98	$3.80 - $4.27
Expected life (years)	0.50	0.50
Risk free interest rate	4.77% - 5.26%	0.22% - 4.76%

At December 31, 2023, the Company has 2,345,426 shares available for issuance under the 2016 ESPP. The number of shares available for issuance under the 2016 ESPP was increased as of January 2, 2024 by 588,897 shares. A summary of the weighted-average grant-date fair value, shares issued and total stock-based compensation expense recognized related to the 2016 ESPP for the years ended December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
Weighted-average grant-date fair value per share	$ 2.90	$ 1.57
Total shares issued	26,168	28,485
Total stock-based compensation expense	$ 44,022	$ 57,413

13. COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the officer's or director's lifetime. Through December 31, 2023, the Company had not experienced any losses related to these indemnification obligations and no material claims were outstanding. The Company currently does not expect significant claims related to these indemnification obligations, and consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

In-License Agreements

MEEI Agreement

The Company is developing ADX-2191 pursuant to an Exclusive License Agreement with Massachusetts Eye and Ear Infirmary (MEEI) originally entered into in July 2016 between MEEI and Helio Vision, Inc., as amended, (MEEI Agreement). The Company assumed the MEEI Agreement in connection with its 2019 acquisition of Helio Vision.

Pursuant and subject to the MEEI Agreement, the Company obtained an exclusive, worldwide license from MEEI to develop and commercialize ADX-2191 under certain patents and patent applications, and other licenses to intellectual property (MEEI Patent Rights). The Company has agreed to use commercially reasonable efforts, to develop ADX-2191 and to meet certain specified effort and achievement benchmarks by certain dates.

In consideration for the rights licensed under the MEEI Agreement, Helio Vision issued MEEI a number of shares of its preferred stock and Helio Vision agreed to pay non-creditable non-refundable license maintenance fees to MEEI of $15,000 on each of the second and third anniversary of the MEEI Agreement, $25,000 on each of the fourth and fifth anniversary of the MEEI Agreement and $35,000 on the sixth and each subsequent anniversary of the MEEI Agreement during the term of such agreement. In addition, Helio Vision was obligated to make future sales-dependent milestone payments to MEEI of up to the low seven figures in the aggregate, as well as royalty payments to MEEI at a rate which, as a percentage of net sales, is in the low single digits for products that incorporate or use the MEEI Patent Rights in the United States and as a percentage in the low single digits for products that incorporate or use the MEEI Patent Rights outside the United States. The Company is also obligated under the MEEI Agreement to pay MEEI a percentage of certain sublicense revenue that it receives in connection with entering into any sublicensing arrangements with any third parties, at a percentage rate which tiers downward from low-double digits to mid-single digits based on the date of the sublicense. Following the Company's acquisition of Helio Vision, the Company became obligated to make any future payments owed under the MEEI Agreement. There is no additional equity consideration issuable under the MEEI Agreement.

The MEEI Agreement will remain in effect until the expiration date of the last to expire patent licensed under the MEEI Agreement. The Company may terminate the MEEI Agreement with timely written notice to MEEI. MEEI has the right to terminate the MEEI Agreement if it, subject to certain specified cure periods, ceases all business operations with respect to licensed products, fails to pay amounts due under the MEEI Agreement, fail to comply with certain due diligence obligations, defaults in our obligation to maintain insurance, one of our officers is convicted of a felony relating to the manufacture, use, sale or importation of licensed products, we materially breach any provisions of the MEEI Agreement or in the event of its insolvency or bankruptcy.

In the event of an early termination of the MEEI Agreement, all rights licensed and developed by the Company under the MEEI Agreement may revert back to MEEI. The Company has agreed to indemnify MEEI for certain claims that may arise under the MEEI Agreement.

Legal Proceedings

On July 31, 2023, a purported stockholder filed a putative class action lawsuit (the Securities Class Action) in the U.S. District Court for the District of Massachusetts, against the Company and certain current and former officers, captioned Juliana Paice v. Aldeyra Therapeutics, Inc., et al. (No. 23-cv-11737). On January 2, 2024, the lead plaintiff filed an amended complaint. The lawsuit alleges violations by the defendants of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. The plaintiff alleges that the defendants made false or misleading statements or failed to disclose certain information concerning (i) the New Drug Application (NDA) for and the prospects of ADX-2191 for the treatment of primary vitreoretinal lymphoma and (ii) the NDA for and the prospects of reproxalap for the treatment of dry eye disease. The lawsuit seeks, among other things, compensatory damages on behalf of herself and all persons and entities that purchased or otherwise acquired the Company's securities between January 7, 2021, and October 16, 2023, as well as attorneys' fees and costs. On March 4, 2024, defendants filed a motion to dismiss the amended complaint. The Company disputes the plaintiff's claims and intends to vigorously defend the suit. At this time, the Company cannot reasonably predict the outcome or estimate potential losses, if any, that could result from this matter.

On October 25, 2023, a purported stockholder of the Company filed a derivative complaint in Middlesex Superior Court of the Commonwealth of Massachusetts, captioned Evan Leglar v. Todd C. Brady, et al. (No. 2381-cv-02980), against certain of the Company's executive officers and directors, and naming the Company as a nominal defendant. The derivative complaint alleges, purportedly on behalf of the Company, breaches of fiduciary duty and unjust enrichment claims against all defendants. The claims are based on substantially identical allegations as the complaint in the Securities Class Action. The lawsuit seeks, among other things, an award of damages and

restitution in favor of the Company, certain changes to the Company's corporate governance, and attorneys' fees and costs. On November 14, 2023, the plaintiff voluntarily dismissed all claims without prejudice.

In addition, from time to time, the Company is subject to litigation and claims arising in the ordinary course of business but, except as stated above, the Company is not currently a party to any material legal proceedings and the Company is not aware of any pending or threatened legal proceedings against them that the Company believes could have a material adverse effect on the Company's business, operating results, cash flows, or financial condition.

14. LEASES

The Company currently leases an office used to conduct business. The Company regularly evaluates the renewal options and when they are reasonably certain of exercise, the Company includes the renewal period in its lease term. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. In November 2023, the Company entered into a lease amendment extending the lease by 12 months through December 31, 2024 and contains two options to extend the term of the lease for an additional 12 months each. Each option shall be exercisable, if at all, by giving a nine month written notice to the landlord. As of December 31, 2023 the Company believes it is probable that it will extend the option into December 2025, which had an immaterial impact to the balance sheet as of December 31, 2023. For the years ended December 31, 2023 and 2022, right of use assets obtained in exchange for lease obligations were $0.5 million and $0.2 million, respectively.

As of December 31, 2023, the Company maintained an unamortized Right-Of-Use asset with a corresponding operating lease liability of approximately $0.5 million based on the present value of the minimum rental payments in accordance with ASC Topic 842, *Leases*. The weighted average discount rate used for leases as of December 31, 2023 is 9.1%. The weighted average lease term as of December 31, 2023 is 2.0 years. The operating lease expense for the year ended December 31, 2023 was $0.3 million. Maturities and balance sheet presentation of our lease liabilities for all operating leases as of December 31, 2023 is as follows:

Remaining total lease payments	$ 561,060
Less: effect of discounting	(50,246)
Present value of lease liabilities	$ 510,814
Current operating lease liabilities	$ 239,183
Non-current operating lease liabilities	271,631
Total	$ 510,814

The Company's gross future minimum payments under all non-cancelable operating leases as of December 31, 2023 are:

	Total	2024	2025	2026	2027
Operating lease obligations	$ 561,060	$ 275,855	$ 285,205	$ —	$ —

15. SIGNIFICANT AGREEMENTS

AbbVie Option Agreement

On October 31, 2023 (the Option Agreement Effective Date), the Company entered into an exclusive option agreement (the Option Agreement) with AbbVie Inc. (AbbVie), pursuant to which we granted AbbVie an exclusive option (the Option) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with the Company to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by the Company in the field of ophthalmology relating to treating conditions of the ocular surface, and (d) a right to review data for any other compounds that are owned or otherwise controlled by the Company in the fields of ophthalmology and immunology before such data is shared with any other third party (the Collaboration Agreement). AbbVie has paid the Company a non-refundable payment of $1 million in consideration of the Option (the Option Payment).

On December 21, 2023, pursuant to the Option Agreement, AbbVie extended the period during which it may exercise the Option (the Exercise Period Extension) by paying the Company a non-refundable payment of $5 million (the Option Extension Fee). As a result of the Exercise Period Extension, AbbVie may exercise the Option by delivering written notice to the Company at any time during the period following the Option Agreement Effective Date until the earlier of (a) the tenth (10th) business day after the date, if any, that the Company receives approval from the U.S. Food and Drug Administration of the NDA for reproxalap in dry eye disease (the FDA Decision) and (b) the date that is eighteen (18) months after the Option Agreement Effective Date. If the Collaboration Agreement is entered into, the Option Payment and the Option Extension Fee will be credited against the upfront cash payment payable by AbbVie.

For the twelve months ended December 31, 2023, the Company recognized zero collaboration revenue and $6.0 million of deferred collaboration revenue related to the Option Agreement and Exercise Period Extension. The Company concluded, using ASC 606 by analogy for recognition considerations as the Option Agreement was not considered to be a vendor-customer relationship, that the transaction price is $6.0 million (the Transaction Price), and all other amounts are excluded from the Transaction Price as they relate to fees that can only be achieved subsequent to the exercise of the Option. The Transaction Price was allocated to the single unit of account, the Option to enter into a future Collaboration Agreement which is a material right, as the Option Extension Fee and the Option Payment are creditable against the upfront payments payable by AbbVie if the Collaboration Agreement is entered into. The Company concluded that all other performance obligations were immaterial promises in the context of the Option Agreement and did not represent additional units of account. The Company will begin to recognize revenue when the Option is exercised or when the Option expires.

Exhibit 10.14

FOURTH AMENDMENT TO LEASE

This Fourth Amendment to Lease ("Fourth Amendment") is dated as of November 22, 2023 by and between 131 Hartwell LLC, a Massachusetts limited liability company ("Landlord"), successor-in-interest to WLC Three VI, L.L.C., a Delaware limited liability company ("Original Landlord") and Aldeyra Therapeutics, Inc. ("Tenant"), a Delaware corporation.

WHEREAS, Original Landlord, and Tenant are parties to a lease dated September 20, 2017 ("Original Lease") regarding certain premises consisting of the "Original Premises" as defined therein; and

WHEREAS, Original Landlord and Original Tenant amended the Original Lease by First Amendment to Lease dated November 27, 2017 adding the "Phase III Premises" as defined therein, that increased the Premises to 9,351 RSF; and by Third Amendment to Lease dated August 21, 2021, extending the Term; and

WHEREAS, Landlord has acquired the interest of Original Landlord; and

WHEREAS, Landlord and Tenant desire to further amend the Lease as provided herein.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, the receipt and legal sufficiency of which are hereby acknowledged, the Landlord and Tenant agree as follows:

1. Defined Terms. Capitalized Terms used but not defined herein shall have the meaning set forth in the Lease. The Original Lease, as amended by the First Amendment, by the Second Amendment, and by the Third Amendment shall hereinafter be referred to as the "Lease".

2. Extension of Term. The Term of the Lease is hereby extended for a period commencing January 1, 2024 (the "Extended Term Commencement Date") through and including December 3 I, 2024 (the " Fourth Amendment Extended Term").

3. Base Rent. Commencing on the Extended Term Commencement Date, Tenant shall pay Base Rent in accordance with the terms of the Lease as follows;

Period	Annual Base Rent	Monthly Base Rent	Rent PSF
1/1/24-12/31/24	$275,854.50	$22,987.88	$29.50

In addition, Tenant shall pay all electricity used at the Premises in accordance with section 14 of the Lease.

4. Additional Options to Extend. Provided Tenant is not in default beyond applicable notice and cure periods under the Lease either at the time of giving notice of its exercise of an additional option to extend or, as applicable, at the end of the Fourth Amendment Extended Term or at the end of the Fourth Amendment First Additional Extended Term (as hereinafter defined), Tenant shall have two (2) options to extend the term of this Lease for periods of twelve (12) months each (the "Fourth Amendment First Additional Extended Term" and the "Fourth Amendment Second Additional Extended Term," respectively). Each such option shall be exercisable, if at all, by Tenant giving nine (9) month's written notice to Landlord prior to the then-current expiration date. If Tenant does not validly exercise its option for the Fourth Amendment First Additional Term, the Term of this Lease shall expire at the end of the Fourth Amendment Extended Term and Tenant shall have no further rights or options to extend the Tenn under this Section. If Tenant elects to exercise its option for the Fourth Amendment First Additional Extended Term, then Rent shall be calculated as provided in Section 3 above but at a rate per square foot equal to $30.50 during such Fourth Amendment First Additional Extended Term, and if Tenant elects to exercise its option for the Fourth Amendment Second Additional Extended Term, then Rent shall be calculated as provided in Section 3 above but at a rate per square foot equal to $31.50 during such Fourth Amendment Second Additional Extended Term.

5. Broker. Except for Cushman & Wakefield, each party represents and warrants to the other that they have not made any agreement or taken any action which may cause anyone to become entitled to a commission as a result of the transactions contemplated by this Amendment, and each will indemnify and defend the other from any and all claims, actual or threatened, for compensation by any such Second person by reason of such party's breach of their representation or warranty contained in this Amendment. Landlord will pay any commission due to the named brokers hereunder pursuant to a separate agreement subject to execution and delivery of this Amendment by Landlord and Tenant.

6. Miscellaneous.

(a) The Lease shall be modified such that each reference to the Lease contained therein shall be deemed to refer to the Lease as amended by this Fourth Amendment.

(b) Except as specifically modified or amended herein, the Lease remains unchanged and in full force and effect and is hereby ratified and confirmed in every respect.

(c) In the event of a conflict between this Fourth Amendment and the Lease, this Fourth Amendment shall control.

(d) This Fourth Amendment shall not be effective until it has been duly executed by the parties hereto.

(e) This Fourth Amendment may be executed in counterparts, which taken together shall constitute one and the same instrument.

7. Addresses for Notices. All notices sent by Landlord to Tenant shall be sent in accordance with the Lease to Tenant at the Premises.

All notices from Tenant to Landlord shall be sent in accordance with the Lease to:

131 Hartwell LLC
c/o Azad Legacy Partners
131 Hartwell A venue
Lexington, MA 02421
Attn: Robert Parsekian

With a copy to:
Rubin and Rudman
c/o Paul Baccari, Esq.
5 3 State Street
Boston, MA 02109

Executed as a sealed instrument this day of October 2023.

Landlord:
131 HARTWELL LLC

By: /s/ Charles P. Minasian
Charles P. Minasian
Authorized Person

Tenant:
Aldeyra Therapeutics, Inc.

By: /s/ Bruce Greenberg
Name: Bruce Greenberg
Title: Senior Vice President of Finance
and Interim Chief Financial Officer

Exhibit 10.26
Execution Version

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [****], HAS BEEN OMITTED BECAUSE IT IS (I) NOT MATERIAL AND (II) OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE OPTION AGREEMENT

This Exclusive Option Agreement (the "**Agreement**") is made and entered into as of October 31, 2023 (the "**Effective Date**") by and between Aldeyra Therapeutics, Inc., a Delaware corporation ("**Licensor**") and AbbVie Inc., a Delaware corporation ("**AbbVie**"). Licensor and AbbVie are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Licensor owns and controls certain intellectual property rights with respect to the Licensed Compounds and Licensed Products in the Territory;

WHEREAS, AbbVie has experience and capabilities to support the successful development, launch, and commercialization of the Licensed Products; and

WHEREAS, Licensor wishes to grant to AbbVie, and AbbVie wishes to take, an exclusive option (on the terms and conditions set forth herein) to obtain (a) a co-exclusive license in the United States to facilitate a collaboration to develop and commercialize Licensed Compounds and Licensed Products in the United States and (b) an exclusive license in the OUS Territory, in each case ((a) and (b)), under such intellectual property rights and on the terms and conditions set forth in the Co-Development, Co-Commercialization and License Agreement attached hereto as Exhibit A (the "**License Agreement**").

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

In addition to the terms defined elsewhere in this Agreement, the following terms have the meanings indicated below. Capitalized terms used, but not defined, herein shall have the meanings provided in the License Agreement.

1.1 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the term of this Agreement and applicable to a particular activity or country or other jurisdiction hereunder.

1.2 "**Executive Officer**" means, (a) with respect to Licensor, its [****], and (b) with respect to AbbVie, its [****].

1.3 "**Exercise Period**" means the period commencing on the Effective Date and ending at 11:59:59 p.m. Central Time on (a) if the FDA Decision Date occurs before December 15, 2023, then the tenth (10th) Business Day after the FDA Decision Date; (b) if the FDA Decision date does not occur before December 15, 2023, AbbVie has not delivered an Option Exercise Notice to Licensor and AbbVie pays the Option Extension Fee pursuant to Section 2.3, then the earlier of (i) the tenth (10th) Business Day after the

FDA Decision Date and (ii) the date that is eighteen (18) months after the Effective Date; and (c) if the FDA Decision date does not occur before December 15, 2023, AbbVie has not delivered an Option Exercise Notice to Licensor and AbbVie does not pay the Option Extension Fee pursuant to Section 2.3, then December 23, 2023.

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

1.5 "**FDA Approval**" means Regulatory Approval (for clarity, including labeling approval) from the FDA regarding the Pending New Drug Application.

1.6 "**FDA Decision Date**" means the date on which Licensor receives an FDA Approval.

1.7 "**License Agreement Execution Notice**" means a written notice from AbbVie to Licensor requiring the Parties to execute the License Agreement.

1.8 "**Option Period**" means the period commencing on the Effective Date and ending on the earliest of (a) expiration of the Exercise Period, if AbbVie does not deliver the Option Exercise Notice during the Exercise Period; (b) expiration of the Schedule Evaluation Period (if any), if AbbVie does not deliver a License Agreement Execution Notice during the Schedule Evaluation Period; (c) the date (if any) that AbbVie withdraws the Option Exercise Notice or withdraws a License Agreement Execution Notice; and (d) execution of the License Agreement.

1.9 "**Pending New Drug Application**" means New Drug Application number [****].

ARTICLE 2
PAYMENTS

2.1 **Option Payment**. In consideration of the rights granted by Licensor to AbbVie hereunder, no later than thirty (30) days following the Effective Date, AbbVie shall pay Licensor a non-refundable payment equal to One Million Dollars ($1,000,000) (the "**Option Payment**"). If the Parties execute the License Agreement, then the Option Payment shall be credited against the upfront payment under Section 6.1 of the License Agreement.

2.2 **Mode of Payment; Taxes**. The following provisions of the License Agreement are hereby incorporated by reference in their entirety, *mutatis mutandis*: (a) the first sentence of Section 6.7 (*Mode of Payment; Offsets*), (b) Section 6.8 (*Withholding Taxes*), (c) Section 6.9 (*Indirect Taxes*) and (d) Section 6.10 (*Interest on Late Payments*).

2.3 **Option Extension Fee**. If the FDA Decision Date does not occur before December 15, 2023 and AbbVie has not delivered an Option Exercise Notice to Licensor, then AbbVie shall have the right, until 11:59:59 p.m. Central Time on December 22, 2023, to pay Licensor a non-refundable payment equal to Five Million Dollars ($5,000,000) (the "**Option Extension Fee**") in consideration for extending the Exercise Period to the earlier of (a) the tenth (10th) Business Day after the FDA Decision Date and (b) the date that is eighteen (18) months after the Effective Date. If the Parties execute the License Agreement, then any Option Extension Fee paid to Licensor shall be credited against the upfront payment under Section 6.1 of the License Agreement.

ARTICLE 3
OPTION

3.1 **Option Grant to AbbVie**. In consideration for the Option Payment, Licensor, on behalf of itself and its Affiliates, hereby grants to AbbVie, during the Option Period, an exclusive option to enter into the License Agreement with the Licensor (the "**Option**").

3.2 **Schedule Updates**. Licensor shall, within [****] after the date that AbbVie delivers the Option Exercise Notice (within the Exercise Period) to Licensor, deliver to AbbVie in writing either (i) any updates to the schedules of the License Agreement required to make such schedules accurate as of the applicable date (any such update, a "**Schedule Update**"); or (ii) if there are no Schedule Updates as of the applicable date, a notice indicating that there are no Schedule Updates (any such notice, a "**No Update Notice**"). Licensor shall, on [****] basis, notify AbbVie of any information that would give rise to any Schedule Update. Licensor shall [****] deliver to AbbVie any information in the possession or control of Licensor or any of its Affiliates with respect to any Schedule Update (or any information that would give rise thereto) [****] requested by AbbVie during the Option Period; *provided* that if, during the Schedule Evaluation Period, more than [****] elapse between the time of AbbVie's request for any such information and the time of Licensor's delivery of such information to AbbVie, then the Schedule Evaluation Period shall be extended by [****] for each day during the period commencing on the date of AbbVie's request for such information and ending on the date of delivery of such information to AbbVie. Licensor shall not be required to disclose any information to AbbVie if such disclosure (x) would [****] or (y) is not possible due to [****].

3.3 **Exercise of the Option**.

3.3.1 **Option Exercise Notice**. AbbVie may exercise the Option at any time during the Exercise Period by delivering written notice of such exercise (the "**Option Exercise Notice**") to Licensor. If AbbVie delivers the Option Exercise Notice to Licensor within the Exercise Period, then the provisions of Section 3.3.2 shall apply. If AbbVie does not deliver the Option Exercise Notice to Licensor during the Exercise Period, then the Option shall automatically expire on the last date of the Exercise Period.

3.3.2 **After Delivery of the Option Exercise Notice**.

(a) **If Licensor Delivers a No Update Notice**. If, following delivery of the Option Exercise Notice to Licensor, Licensor delivers a No Update Notice to AbbVie, then, subject to Section 3.3.2(d), each Party shall execute the License Agreement at a mutually agreed time within [****] after AbbVie's receipt of the No Update Notice.

(b) **If Licensor Delivers Any Schedule Update**. If, following delivery of the Option Exercise Notice to Licensor, Licensor delivers any Schedule Update to AbbVie, then, within [****] after receipt of the last Schedule Update (the "**Schedule Evaluation Period**") (subject to extension under Section 3.2 or Section 3.5), AbbVie shall have the right, to either (i) deliver to Licensor a License Agreement Execution Notice and, subject to Section 3.3.2(d), each Party shall execute the License Agreement at a mutually agreed time within [****] after Licensor's receipt of the License Agreement Execution Notice or (ii) deliver to Licensor written notice indicating that AbbVie is withdrawing the Option Exercise Notice, which withdrawal shall be effective immediately upon Licensor's receipt of such written notice. For clarity, (A) if AbbVie does not deliver a License Agreement Execution Notice to Licensor during the Schedule Evaluation Period (if any), then the Option shall expire upon expiration of the Schedule Evaluation Period and (B) if AbbVie withdraws the Option Exercise Notice during the Schedule Evaluation Period, then the Option shall automatically expire upon the date of such withdrawal.

(c) **AbbVie's Right to Deliver a License Agreement Execution Notice**. AbbVie shall have the right, at any time during the Option Period, to deliver to Licensor a License Agreement Execution Notice and, subject to Section 3.3.2(d), each Party shall execute the License Agreement at a mutually agreed time within [****] after Licensor's receipt of the License Agreement Execution Notice.

(d) **Final Schedule Updates**. [****] prior to the time that the Parties mutually agree to execute the License Agreement in accordance with Section 3.3.2(a), Section 3.3.2(b) or Section 3.3.2(c), Licensor shall deliver to AbbVie in writing either (i) any Schedule Update or (ii) a No Update Notice. If Licensor provides any such Schedule Update, then (A) Licensor shall[****] (I) deliver to AbbVie any information in the possession or control of Licensor or any of its Affiliates with respect to such Schedule Update [****] requested by AbbVie and (II) meet with AbbVie (including making available to AbbVie any personnel of Licensor or its Affiliates as [****] requested by AbbVie) to discuss such Schedule Update ([****]); and (B) AbbVie shall have the right, within [****] after Licensor has both (I) provided all such information [****] requested by AbbVie and (II) attended all such meetings [****] requested by AbbVie, to (x) withdraw the Option Exercise Notice for purposes of Section 3.3.2(a) or (y) withdraw the License Agreement Execution Notice for purposes of Section 3.3.2(b) or Section 3.3.2(c) and, in each case ((x) and (y)), upon any such withdrawal, neither Party shall have any obligation to execute the License Agreement and the Option shall automatically expire upon the date of such withdrawal.

3.4 **Updates; Interactions with Regulatory Authorities**.

3.4.1 **Updates**. During the Option Period, Licensor shall [****] notify AbbVie of any material research, development, manufacturing or commercialization activities conducted with respect to the Licensed Compound and Licensed Products and any results thereof. Without limitation to the foregoing, if, at any time during the Option Period, Licensor or any of its Affiliates becomes aware of any new information related to the Licensed Compound or Licensed Products that could be [****] expected to adversely impact the development, manufacture or commercialization of the Licensed Compound or Licensed Products (including the timeline therefor) in any material respect, Licensor shall provide such information to AbbVie within [****] after Licensor becomes aware of such information.

3.4.2 **Interactions with Regulatory Authorities**. During the Option Period, Licensor shall:

(a) [****] deliver to AbbVie a copy of any material communication received by Licensor or any of its Affiliates from a Regulatory Authority with respect to the Licensed Compound or Licensed Products;

(b) deliver to AbbVie a draft of any material communication related to the Licensed Compound or Licensed Products that Licensor or any of its Affiliates intends to submit to a Regulatory Authority, at least [****] in advance of such submission;

(c) [****] notify AbbVie of any upcoming meeting with any Regulatory Authority to the extent related to the Licensed Compound or Licensed Products and, unless prohibited by such Regulatory Authority, allow [****] AbbVie to attend and observe any such meeting to the extent related to the Licensed Compound or Licensed Product; and

(d) notwithstanding the foregoing, notify AbbVie of the occurrence of the FDA Approval within [****] following Licensor's receipt thereof.

3.5 **Meetings**. During the Option Period, from time to time and [****] after AbbVie's [****] request, Licensor shall meet with AbbVie (including making available to AbbVie any personnel of Licensor or its Affiliates as [****] requested by AbbVie) to discuss any matters with respect to the Licensed Compound or Licensed Products [****] requested by AbbVie, including (a) any Schedule Update(s) ([****]) or information [****] requested by AbbVie with respect thereto, (b) any notification, results or information required to be provided by Licensor under Section 3.4.1, (c) any communication, draft or notification required to be provided by Licensor under Section 3.4.2 or (d) any meeting with any Regulatory Authority related to the Licensed Compound or Licensed Product; provided that if AbbVie [****] requests any such meeting with Licensor during the Exercise Period or Schedule Evaluation Period (if any) but Licensor is not able to meet until after the Exercise Period or Schedule Evaluation Period (as applicable) would otherwise expire, then the Exercise Period or Schedule Evaluation Period (as applicable) shall be extended to the date that is [****] after such meeting occurs.

3.6 **Electronic Data Room**. During the Option Period, Licensor shall continue to provide AbbVie with access to the existing electronic data room for the Licensed Compound and Licensed Product, including all documents uploaded to such electronic data room prior to the Effective Date.

ARTICLE 4
CONFIDENTIALITY

4.1 **Confidentiality Obligations**. At all times during the term of this Agreement and for a period of [****] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its Affiliates and each of its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party (except to the extent such disclosure is expressly permitted by the terms of this Agreement) and not use, directly or indirectly, for any purpose, any Confidential Information of the other Party; *provided* that AbbVie may use the Confidential Information of Licensor for purposes of deciding whether or not to exercise the Option, deliver a License Agreement Execution Notice or propose another transaction to Licensor. "**Confidential Information**" means any and all information provided orally, visually, in writing or other form that is disclosed or otherwise provided by or on behalf of one (1) Party to the other Party in connection with this Agreement or the Confidentiality Agreement, whether prior to, on or after the Effective Date, including the terms of this Agreement, information relating to any Licensed Compound or any Licensed Product (including any regulatory documentation with respect thereto) or any exploitation of any Licensed Compound or any Licensed Product and any information with respect to the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto).

4.2 **Exceptions**. Section 8.2 (*Exceptions*) of the License Agreement is hereby incorporated by reference in its entirety, *mutatis mutandis*, except that references therein to "Product Information or Joint Know-How" are changed to "the terms of this Agreement."

4.3 **Permitted Disclosures**. Section 8.3 (*Permitted Disclosures*) of the License Agreement (other than Section 8.3.3) is hereby incorporated by reference in its entirety, *mutatis mutandis*.

4.4 **Use of Name**. Subject to Section 4.5, Section 8.5 (*Use of Name*) of the License Agreement is hereby incorporated by reference in its entirety, *mutatis mutandis*.

4.5 **Public Announcements**. Neither Party shall issue any public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel,

required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit (a) the proposed disclosure in writing to the other Party [****] practicable (and in no event less than [****] prior to the anticipated date of disclosure) so as to provide a [****] opportunity to comment thereon and (b) the expected time and place the disclosure will be made; *provided* that if such required disclosure includes a disclosure of this Agreement or the License Agreement, the disclosing Party shall also submit a redacted form of the applicable agreement to the other Party and shall submit a confidential treatment request (or equivalent protection in a country other than the United States) in connection with such disclosure. The disclosing Party shall consider [****] any comments received from the other Party with respect to such disclosure. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or the License Agreement or any amendment hereto or thereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 4.5; *provided* that such information remains accurate as of such time of publication and provided the frequency and form of such disclosure are reasonable.

4.6 **Return of Confidential Information**. After the effective date of termination or expiration of this Agreement for any reason, in the event that the License Agreement is not executed, upon the written request of a Party, the non-requesting Party shall either, at the requesting Party's election: (a) [****] destroy all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party or its Affiliates (other than the terms of this Agreement) and confirm such destruction in writing to the requesting Party or (b) [****] deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party or its Affiliates (other than the terms of this Agreement). Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain (i) a single copy of such Confidential Information for archival purposes and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information so retained shall continue to be subject to the terms of this Agreement for the period set forth in Section 4.1.

ARTICLE 5
TERM

5.1 **Term**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and shall continue in full force and effect until expiration of the Option Period.

5.2 **Termination**.

5.2.1 **Termination by AbbVie**. AbbVie may terminate this Agreement in its entirety immediately upon written notice to Licensor.

5.2.2 **Termination by Licensor**. Licensor may terminate this Agreement in its entirety if AbbVie willfully or grossly negligently breaches any of its material obligations under this Agreement, and such breach has a material and adverse effect on Licensor, by providing [****] (the "Notice Period") prior written notice (the "Termination Notice") to AbbVie and specifying the breach and its claim of right to terminate; provided that (a) the termination shall not become effective at the end of the Notice Period if AbbVie cures the breach specified in the Termination Notice during the Notice Period (or, if such breach cannot be cured within the Notice Period, if AbbVie commences actions to cure such breach within the

Notice Period and [****] continues such actions, such termination shall not become effective for so long as AbbVie [****] continues such actions); and (b) if either Party initiates a dispute resolution procedure under Section 12.6 of the License Agreement (as incorporated by reference in Section 8.1) during the Notice Period to resolve the dispute for which termination is being sought and is pursuing such procedure [****], the Notice Period shall be suspended and the termination shall become effective only if such breach remains uncured for [****] after the final resolution of the dispute through such dispute resolution procedure (or, if the breach cannot be cured within such [****] period, if AbbVie commences actions to cure such breach within such period and thereafter [****] continues such actions, such termination shall not become effective for so long as the AbbVie [****] continues such actions). Notwithstanding anything in this Agreement to the contrary, Licensor shall not have the right to terminate this Agreement under this Section 5.2.2 as a result of AbbVie's breach of Section 8.6.

5.3 **Accrued Rights; Surviving Obligations**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that 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. Without limiting the foregoing, (a) Sections 4.1 (for the period set forth therein), 4.2 and 4.3 (in each case, for the period set forth in Section 4.1), 4.4 through 4.6, 6.1, 6.3 and this Section 5.3 and Articles 1 (to the extent necessary to construe the other surviving provisions), 7 and 8 (other than Section 8.6) of this Agreement shall survive the termination or expiration of this Agreement for any reason and (b) Sections 2.1 (last sentence only) and 2.3 (last sentence only) of this Agreement shall survive the expiration of this Agreement for any reason.

ARTICLE 6

REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1 **Mutual Representations and Warranties**. Licensor and AbbVie each represents and warrants to the other Party, as of the Effective Date, that:

6.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

6.1.2 the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

6.1.3 this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other Applicable Laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and

6.1.4 it is not under any obligation, contractual or otherwise, to any Person that conflicts with, or is inconsistent with, the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

6.2 **Covenant of Licensor**. Licensor hereby covenants to AbbVie, on behalf of itself and its Affiliates, that it shall not, and shall cause its Affiliates not to, enter into, discuss or negotiate any agreement (or amendment to any existing agreement) with any Person, written or oral, that would conflict with, be inconsistent with, limit or otherwise diminish (a) the rights granted to AbbVie under this Agreement or (b) the rights that would be granted to AbbVie under the License Agreement if AbbVie were to exercise the Option and the Parties were to enter into the License Agreement.

6.3 **Disclaimer**. EXCEPT AS OTHERWISE PROVIDED HEREIN (OR IN THE LICENSE AGREEMENT, IF THE PARTIES ENTER INTO THE LICENSE AGREEMENT), NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT OR TITLE.

ARTICLE 7
INDEMNITY

7.1 **Indemnification of Licensor**. AbbVie shall indemnify Licensor, its Affiliates and its and their respective directors, officers, employees and agents (individually and collectively, the "**Licensor Indemnitees**"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (individually and collectively, "**Third Party Claims**") incurred or sustained by or rendered against the Licensor Indemnitees arising from or occurring as a result of:

[****]; [****];

[****].

7.2 **Indemnification of AbbVie**. Licensor shall indemnify AbbVie, its Affiliates and its and their respective directors, officers, employees and agents (the "**AbbVie Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred or sustained by or rendered against the AbbVie Indemnitees arising from or occurring as a result of:

[****]

[****]

[****].

7.3 **Indemnification Procedures**. Section 10.4 (*Indemnification Procedures*) of the License Agreement is hereby incorporated by reference in its entirety, *mutatis mutandis*.

7.4 **Special, Indirect and Other Losses**. EXCEPT (A) FOR THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER [****], (C) AS PROVIDED UNDER [****] OR (D) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 7, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY

OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE 8
MISCELLANEOUS

8.1 **Incorporation by Reference**. The following provisions of the License Agreement are hereby incorporated by reference in their entirety, *mutatis mutandis*: Section 12.3 (*Export Control*), Section 12.5 (*Severability*), Section 12.6 (*Dispute Resolution*) (except for Section 12.6.3), Section 12.8 (*Notices*), Sections 12.12 (*Waiver and Non-Exclusion of Remedies*) through 12.14 (*Further Assurances*), and Sections 12.16 (*Relationship of the Parties*) through 12.19 (*Counterparts*).

8.2 **Assignment**. Without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided* that either Party shall have the right (and Licensor shall have the obligation) to assign this Agreement without the other Party's consent in its entirety to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates and such Party shall provide written notice to the other Party within [****] after such assignment. Any attempted assignment or delegation in violation of this Section 8.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Licensor or AbbVie, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of Licensor, and the obligations of AbbVie, including the payment obligations, shall run in favor of any such successor or permitted assignee of Licensor's benefits under this Agreement.

8.3 **Governing Law, Jurisdiction and Service**.

8.3.1 **Governing Law**. This Agreement and the performance, enforcement, breach or termination hereof shall be governed by and construed in accordance with the laws of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

8.3.2 **Service**. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 12.8 (*Notices*) of the License Agreement (as incorporated by reference in Section 8.1) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

8.4 **Entire Agreement; Amendments**. This Agreement, together with the attached Schedules and Exhibits, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter here and all prior agreements, understandings and representations, whether written or oral, with respect thereto, including the Confidentiality Agreement, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

8.5 **Equitable Relief**. Each Party acknowledges and agrees that the provisions of Article 3 and Article 4 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such provisions and that any breach or threatened breach of any provision of such Articles, notwithstanding anything to the contrary herein, will result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Each Party agrees to waive any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 8.5 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement. For clarity, and without limitation to the foregoing, (i) AbbVie shall be entitled to obtain specific performance of Licensor's obligations under Sections 3.2, 3.3.2(d), 3.4, 3.5 and 3.6, (ii) each Party shall be entitled to specific performance of the other Party's obligation to execute the License Agreement under Section 3.3.2(a) (but, for clarity, subject to Section 3.3.2(d)) and (iii) each Party shall be entitled to specific performance of the other Party's obligation to execute the License Agreement following delivery of a License Agreement Execution Notice under Sections 3.3.2(b) or 3.3.2(c) (but, in each case, for clarity, subject to Section 3.3.2(d)).

8.6 [****] From and after the Effective Date, during the Option Period, the Parties shall meet and discuss [****] whether and, if so, on what terms [****]; *provided* that the Parties shall not have any further obligations with respect to [****] beyond such meeting and discussion unless and until the Parties negotiate and execute [****].

[SIGNATURE PAGE FOLLOWS]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

ABBVIE INC.	**ALDEYRA THERAPEUTICS, INC.**
By: /s/ Nicholas J Donoghoe	By: /s/ Todd C. Brady, M.D., Ph.D.
Name: Nicholas J Donoghoe	Name: Todd C. Brady, M.D., Ph.D.
Title: EVP, Chief Business and Strategy Officer	Title: President and Chief Executive Officer

Exhibit A
License Agreement

CO-DEVELOPMENT, CO-COMMERCIALIZATION AND LICENSE AGREEMENT

between

ALDEYRA THERAPEUTICS, INC.

and

ABBVIE INC.

Dated as of [•]

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CO-DEVELOPMENT, CO-COMMERCIALIZATION AND LICENSE AGREEMENT

This Co-Development, Co-Commercialization and License Agreement (the "**Agreement**") is made and entered into as of **[ ]** (the "**Effective Date**") by and between Aldeyra Therapeutics, Inc., a Delaware corporation ("**Licensor**") and AbbVie Inc., a Delaware corporation ("**AbbVie**"). Licensor and AbbVie are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Licensor owns and controls certain intellectual property rights with respect to the Licensed Compounds (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein);

WHEREAS, AbbVie has experience and capabilities to support the successful Development, launch, and Commercialization of the Licensed Products; and

WHEREAS, Licensor wishes to grant to AbbVie, and AbbVie wishes to take, (a) a co-exclusive license in the United States to facilitate a collaboration to develop and commercialize Licensed Compounds and Licensed Products in the United States and (b) an exclusive license in the OUS Territory (as defined herein), in each case ((a) and (b)), under such intellectual property rights, in each case, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**AbbVie**" has the meaning set forth in the preamble hereto.

1.2 "**AbbVie Indemnitees**" has the meaning set forth in Section 10.2.

1.3 "**AbbVie Know-How**" means all Information that is (a) conceived, discovered, developed or otherwise made by or on behalf of AbbVie or any of its Affiliates under this Agreement, (b) not generally known and (c) necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, but excluding Joint Know-How and any Information that is published in an AbbVie Patent or Joint Patent.

1.4 "**AbbVie Patents**" means all Patents that are owned or Controlled by AbbVie or its Affiliates as of the Effective Date or during the Term that claim any AbbVie

Know-How and are necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, but excluding Joint Patents.

1.5 "**AbbVie US Product TM Quality Standards**" has the meaning set forth in Section 7.9.8(b).

1.6 "**AbbVie US Product Trademark**" means any US Product Trademark that is not a Scheduled Trademark.

1.7 "**Accounting Standards**" means, with respect to a Party, (a) United States Generally Accepted Accounting Principles or (b) International Financial Reporting Standards as issued by the International Accounting Standards Board, as applicable, in each case, consistently applied.

1.8 "**Acquired Program**" has the meaning set forth in Section 3.7.3(a).

1.9 "**Acquirer**" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates (as of the Change of Control or thereafter), other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.10 "**ADR**" has the meaning set forth in Section 12.6.2.

1.11 "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such first Person at any time during the Term for so long as such Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.12 "**Agreement**" has the meaning set forth in the preamble hereto.

1.13 "**Alliance Manager**" has the meaning set forth in Section 2.5.6.

1.14 "**Allowable Expenses**" means Development Expenses, Commercialization Expenses and Other Shared Expenses. For clarity, costs may not be included more than once in the calculation of Allowable Expenses, even if a particular cost satisfies the definition of more than one cost category included herein.

1.15 "**Annual Net Loss Threshold**" has the meaning set forth in Section 6.4.1(c).

1.16 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.17 "**Approved Subcontractor**" means each subcontractor for the applicable activities set forth on [****].

1.18 "**Audit Arbitrator**" has the meaning set forth in Section 6.12.2.

1.19 "**Board of Directors**" has the meaning set forth in the definition of "Change of Control."

1.20 "**Breaching Party**" has the meaning set forth in Section 11.2.1.

1.21 "**Business Day**" means a day other than: a Saturday or Sunday or a day on which banking institutions in Chicago, Illinois or Boston, Massachusetts are permitted or required to be closed.

1.22 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 or October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 and October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

1.23 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.24 "**Cessation Event**" has the meaning set forth in Section 11.2.4.

1.25 "**Change of Control**" with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

1.25.1 any "person" or "group" (as such terms are defined below) acquires or becomes the "beneficial owner" (as defined below), directly or indirectly, of (a) shares of capital stock or other interests (including partnership interests) of such Party (or any controlling Affiliate) then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party (or any controlling Affiliate) representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party (or any controlling Affiliate) or (b) the power to elect a majority of the members of the Party's (or any controlling Affiliate's) board of directors or similar governing body ("**Board of Directors**"); the Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less

than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity; or

1.25.2 such Party (or any controlling Affiliate) enters into a merger, consolidation or similar transaction with another Person (whether or not such Party (or any controlling Affiliate) is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party (or any controlling Affiliate) immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party (or any controlling Affiliate) or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party (or any controlling Affiliate) immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party (or any controlling Affiliate) representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party (or any controlling Affiliate) immediately prior to such transaction; or

1.25.3 such Party and its Affiliates sell or transfer to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of such Party's and its Affiliates' total assets to which this Agreement relates; or

1.25.4 the holders of capital stock of such Party (or any controlling Affiliate) approve a plan or proposal for the liquidation or dissolution of such Party (or any controlling Affiliate).

For the purpose of this definition of Change of Control, (a) "person" and "group" have the meanings given such terms under Section 13(d) or 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (b) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.26 "**Combination Product**" means any Licensed Product that is comprised of or contains one (1) or more Licensed Compounds as an active ingredient(s) together with one (1) or more other active ingredients that are not Licensed Compounds that is sold either as a fixed dose/unit or as separate doses/units in a single package for one (1) price. For clarity, Combination Products do not include any eye drops or other ophthalmic drugs regulated by the FDA as drug-device combination products unless such product contains more than one (1) active ingredient.

1.27 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of or sale of a Licensed Compound or Licensed Product, including activities related to marketing, promoting, distributing and importing and exporting such Licensed Compound or Licensed Product, and interacting with Regulatory Authorities regarding any of the foregoing and, for purposes of setting forth the rights and obligations of the Parties under this Agreement, shall be deemed to include conducting Phase IV Clinical Trials and Medical

Affairs Activities with respect to a Licensed Compound or Licensed Product. When used as a verb, "**to Commercialize**" and "**Commercializing**" mean to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.28 "**Commercialization Expansion Notice**" has the meaning set forth in Section 5.3.1(c).

1.29 "**Commercialization Expenses**" means, subject to the other provisions of this Agreement, (a) [****] Costs (charged in accordance with Section 6.4.3) incurred, and the [****] Costs recorded as an expense, in each case, by a Party or any of its Affiliates in accordance with Accounting Standards after the Effective Date pursuant to this Agreement that are specifically identifiable or reasonably allocable to the Commercialization of a Licensed Product during the Term for the United States in accordance with the Commercialization Plan (other than any [****] activities that constitute, or are performed in connection with, such Commercialization ([****])), including expenses incurred in (i) [****] the Licensed Products for the U.S., (ii) [****] activities for the U.S., (iii) [****] activities anticipated for the U.S., (iv) [****] for any Licensed Product for the U.S., (v) [****] in the U.S., (vi) [****] for Commercialization in the U.S., (vii) [****] strategy for the Licensed Products in the U.S., (viii) [****] activities, (ix) plans and strategies for [****] for the U.S., and (x) other Commercialization activities anticipated for the U.S., and (b) [****] Costs for Licensed Products used or intended to be used for sale or distribution in the United States (including [****], but excluding [****]); provided that (x) with respect to clause (a), such expenses shall, subject to permitted Overruns pursuant to Section 6.3.2, be included within "Commercialization Expenses" for a Licensed Product only to the extent consistent with the Commercialization Plan, (y) the foregoing shall exclude any Commercialization activity that is solely and specifically performed with respect to one (1) or more countries in the OUS Territory and (z) with respect to any Commercialization activity that is performed with respect to the United States and one (1) or more countries in the OUS Territory, the foregoing shall include the portion of [****] Costs and [****] Costs with respect to such activity that are reasonably allocable to Commercialization for the United States[****]. For clarity, costs may not be included more than once in the calculation of Commercialization Expenses, even if a particular cost satisfies the definition of more than one cost category included herein.

1.30 "**Commercialization Plan**" means a commercialization plan setting forth in reasonable detail (a) (i) general strategies for the promoting, detailing, marketing and distributing of the Licensed Products for the U.S.; (ii) [****] activities for the U.S. and the [****] in the U.S.; (iii) the sales, marketing and promotional activities anticipated for the U.S., including [****]; (iv) [****] for any Licensed Product for the U.S., (v) [****] in the U.S.; (vi) plans regarding [****] in the U.S.; (vii) the [****] for the Licensed Products in the U.S.; (viii) [****] activities (as distinguished from the [****] in clause (vii)); (ix) [****] for the U.S.; and (x) any other Commercialization activities anticipated for the U.S.; (b) the allocation of responsibility for each such Commercialization activity, including designating a Party as the operational lead for such activity; and (c) the budget for the Commercialization Expenses for such Commercialization activities

1.31 "**Commercially Reasonable Efforts**" means, with respect to the [****].

1.32 "**Committee**" means the JSC, JDC or JCC.

1.33 "**Competing Product**" means any [****] that is (a) being Developed for, or that has received Regulatory Approval for, use in treating conditions of the [****], and (b) is administered [****]. For clarity, a [****] must satisfy clause (a) and clause (b) of this definition to be a Competing Product.

1.34 "**Competitive Infringement**" has the meaning set forth in Section 7.5.2.

1.35 "**Competitive Program**" has the meaning set forth in Section 3.7.2(a).

1.36 "**Compound-Specific Licensor Patent**" means any Licensor Patent that (a) discloses in its specification and claims (i) any Licensed Compound or Licensed Product or (ii) any uses or formulations of, or methods of making, any Licensed Compound or Licensed Product; and (b) does not disclose in its specification or claim (i) any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound or (ii) any uses or formulations of, or methods of making, any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound, including the Patents listed on **Schedule 1.36**. For the purposes of clarity, a Compound-Specific Licensor Patent discloses in its specification no RASP Inhibitor other than a Licensed Compound.

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

1.38 "**Confidentiality Agreement**" has the meaning set forth in Section 8.1.

1.39 "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license, covenant not to sue or otherwise (other than by operation of the license and other grants in Section 3.1 or Section 3.2), to grant a license, sublicense or other right (including a covenant not to sue or the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any item of Information, Regulatory Documentation, material, Patent or other intellectual property right that is owned or in-licensed by an Acquirer except (a) with respect to any such Information, Regulatory Documentation, material, Patent or other intellectual property right conceived, discovered, developed or otherwise made by or on behalf of such Acquirer (or its Affiliates or its or their respective (sub)licensees/Sublicensees) under or in connection with this Agreement after such Change of Control; (b) to the extent that any such Information, Regulatory Documentation, material, Patent or other intellectual property right (i) is included in or used in furtherance of this Agreement by or on behalf of Licensor or (ii) was generated through any use of, or access to any AbbVie Know-How, AbbVie Patents, Licensor Know-How, Licensor Patents, Joint Patents, Joint Know-How or any Confidential Information of AbbVie; provided, that the foregoing exclusion of Information, Regulatory Documentation, material, Patent or other intellectual property from Licensor's Control shall only apply for so long as Licensor complies with its obligations under Section 12.2.2.

1.40 "**Convicted Individual**" or "**Convicted Entity**" has the meaning set forth in Section 9.4.1(d).

1.41 "**Current MA Holder**" has the meaning set forth in Section 5.1.2(d).

1.42 "**Data Breach**" has the meaning set forth in Section 9.3.5.

1.43 "**Data Security and Privacy Laws**" means all Applicable Laws relating to the privacy, Processing and security of Personal Data.

1.44 "**Debarred Entity**" has the meaning set forth in Section 9.4.1(b).

1.45 "**Debarred Individual**" has the meaning set forth in Section 9.4.1(a).

1.46 "**Defense Proceeding**" means, with respect to any Patent, any opposition, re-issuance, post-grant review, inter-partes review, reexamination request, nullity action, interference or other similar post-grant proceedings and any appeals therefrom.

1.47 "**Deferral Notice**" has the meaning set forth in Section 6.4.1(c).

1.48 "**Deferral Option**" has the meaning set forth in Section 6.4.1(c).

1.49 "**Deferred Net Losses**" has the meaning set forth in Section 6.4.1(c).

1.50 "**Designated Country**" means (a) the first [****] of the following countries in which the MA Holder for such country files a Drug Approval Application for a Licensed Product in such country: [****] and (b) any other country designated by [****] as a "Designated Country".

1.51 "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. Notwithstanding the foregoing, "Development" shall be deemed to exclude Phase IV Clinical Trials. When used as a verb, "**to Develop**" and "**Developing**" means to engage in Development and "**Developed**" has a corresponding meaning.

1.52 "**Development Expenses**" means, subject to the other provisions of this Agreement, the (a) [****] Costs (charged in accordance with Section 6.4.3) incurred and the [****] Costs recorded as an expense, in each case, by a Party or any of its Affiliates in accordance with Accounting Standards after the Effective Date pursuant to this Agreement that are specifically identifiable or reasonably allocable to the Development of a Licensed Product during the Term for the United States in accordance with the Development Plan (other than any regulatory affairs activities that constitute, or are performed in connection with, such Development (including submissions to and communications with Regulatory Authorities and obtaining and maintaining Regulatory Approvals)) and (b) [****] Costs for Licensed Products used or intended to be used for the performance of such Development; provided that (x) with respect to clause (a), such expenses shall, subject to permitted Overruns pursuant to Section 6.3.2, be included within "Development

Expenses" for a Licensed Product only to the extent consistent with the applicable Development Plan, and (y) the foregoing shall exclude any Development activity that is solely and specifically intended to support or maintain Regulatory Approval in one (1) or more countries in the OUS Territory. For clarity, costs may not be included more than once in the calculation of Development Expenses, even if a particular cost satisfies the definition of more than one cost category included herein.

1.53 "**Development Plan**" means a development plan setting forth in reasonable detail the specific clinical studies and other Development activities to be performed by or on behalf of either Party or its Affiliates with respect to a Licensed Compound or Licensed Product that are intended to support or maintain Regulatory Approval in the United States and the budget for the Development Expenses for such Development activities, which plan shall allocate responsibility for such clinical studies and other Development activities between the Parties.

1.54 "**Dispute**" has the meaning set forth in Section 12.6.1.

1.55 "**Divest**" means the sale or transfer of all rights to a Competitive Program to a Third Party such that neither Licensor nor any of its Affiliates (including the Pre-Existing Entities) has any further right to perform or be involved in any Exploitation of such Competitive Program or receive a continuing share of profit or other economic interest in the success of such Competitive Program; provided that if such transfer is effected by way of one or more licenses or sublicenses, Licensor shall be entitled to receive license fees, milestones and royalties on sales of products in the Competitive Program so Divested.

1.56 "**Dollars**" or "**$**" means United States Dollars.

1.57 "**Drug Approval Application**" means a New Drug Application, as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.58 "**Drug Product Manufacturing Process**" has the meaning set forth in Section 4.1.2.

1.59 "**Drug Substance Manufacturing Process**" has the meaning set forth in Section 4.1.2.

1.60 "**Effective Date**" has the meaning set forth in the preamble.

1.61 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.62 "**European Union**" means the economic, scientific and political organization of member states as its membership may be constituted from time to time.

1.63 "**Excluded Acquirer IP**" has the meaning set forth in Section 3.7.5.

1.64 "**Excluded Individual**" or "**Excluded Entity**" has the meaning set forth in Section 9.4.1(c).

1.65 "**Exclusive ROFN Product Negotiation Period**" has the meaning set forth in Section 3.9.4.

1.66 "**Executive Officer**" means, (a) with respect to Licensor, its Chief Executive Officer, and (b) with respect to AbbVie, (i) with respect to Development matters, its Chief Medical Officer and (ii) with respect to all other matters, including any Commercialization matter, its President, US Eyecare.

1.67 "**Existing Agreements**" means any agreement existing as of the Effective Date by and between Licensor or any of its Affiliates, on the one hand, and one (1) or more Third Parties, on the other hand, related to the Commercialization or Manufacture of one (1) or more Licensed Compounds or Licensed Products or the Exploitation thereof.

1.68 "**Existing Patents**" has the meaning set forth in Section 9.2.1.

1.69 "**Existing Regulatory Documentation**" means the Regulatory Documentation owned or controlled by Licensor or any of its Affiliates as of the Effective Date.

1.70 "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, product or process.

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

1.72 "**Federally Funded Invention**" means any invention or discovery that (a) was conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof; (b) is a "subject invention" as that term is described in 35 U.S.C. § 201(e); (c) is otherwise subject to the provisions of the Bayh Dole Act; or (d) is the subject of any licenses, options or other rights of any other governmental authority, within or outside the United States, due to such governmental authority's funding of research and development or otherwise (other than the right to receive payments or any law of general application that applies to personal property generally, e.g., takings laws).

1.73 "**FFDCA**" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.74 "**Field**" means all human and non-human diagnostic, prophylactic and therapeutic uses, including the prevention, treatment or control of any disease, disorder or condition.

1.75 "**Firewall Procedures**" means [****] technical and administrative safeguards established by Licensor to (a) ensure that all activities of the Pre-Existing Entities (including with respect to any Competitive Program) or Acquired Program, as applicable, are kept separate from the activities performed (and the personnel conducting such activities) under or in connection with this Agreement, (b) ensure that no employees of Licensor who have or have had access to, the AbbVie Know-How, AbbVie Patents, Licensor Know-How, Licensor Patents, Joint Patents, Joint Know-How or any Confidential Information of AbbVie, perform any activities with respect to the Exploitation of such Competitive Program for such Pre-Existing Entity or Acquired Program, as applicable and (c) prevent any AbbVie Know-How, AbbVie Patents, Licensor Know-How, Licensor Patents, Joint Patents, Joint Know-How or any Confidential Information of AbbVie from being disclosed by Licensor to, or otherwise used or accessed by, any Pre-Existing Entity or personnel of Licensor who are [****] participating in an Acquired Program, as applicable; provided that the foregoing clause (c) shall not apply to excluding any personnel at or above the level of Senior Vice President who are not involved in the day-to-day conduct of the Acquired Program or the decision-making with respect to the day-to-day conduct of the Acquired Program.

1.76 "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such country after all Regulatory Approvals for such Licensed Product have been obtained in such country. [****] shall not be construed as a First Commercial Sale.

1.77 "**First Look Field**" means each of (a) the Ophthalmology Field (excluding treating conditions of the [****] by [****]) or (b) the Immunology Field.

1.78 "**First Look Period**" has the meaning set forth in Section 3.8.4.

1.79 "**First Look Product**" means any [****] that is owned or otherwise controlled by Licensor or any of its Affiliates for which there are data supporting the use of such [****] in a First Look Field.

1.80 "**First Look Product Transaction**" means, with respect to a First Look Product and a First Look Field, the license, sale or other grant or transfer, including by option, to any Person of any rights to [****] such First Look Product in such First Look Field in any country(ies) in the world.

1.81 "**First Look Data Package**" means, with respect to each First Look Product and each First Look Field, a data package consisting of: (a) the complete results of all development activities conducted by or on behalf of Licensor or its Affiliates or its or their (sub)licensees related to such First Look Product in such First Look Field, (b) copies of all regulatory documentation submitted to or received from regulatory authorities related to such First Look Product in such First Look Field, (c) any commercial analyses for such First Look Product in such First Look Field conducted by or on behalf of Licensor or any of its Affiliates, including market research, competitive analyses, forecasted sales and anticipated commercialization activities, (d) a description of any and all obligations that Licensor or any of its Affiliates has to a Third Party, financial or otherwise, with respect to the development, manufacture or commercialization of such First Look Product in the applicable country(ies) in such First Look Field and (e) copies of any and all agreements pursuant to which Licensor or any of its Affiliates in-licenses or otherwise

obtains rights to any Information, Patent or other intellectual property with respect to such First Look Product in the applicable country(ies) in such First Look Field, in each case ((a) through (e)), that are in the control of Licensor or any of its Affiliates at the time of preparation of the data package and in the form in which such information is held by Licensor or any of its Affiliates.

1.82 "**FTE**" means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [****] hours per Calendar Year) of work performing Development, Manufacture, Commercialization or other Exploitation activities for a Licensed Compound or Licensed Product or other activities under this Agreement. No additional payment shall be made with respect to any person who works more than [****] hours per Calendar Year and any person who devotes less than [****] hours per Calendar Year (or such other number as may be agreed by the JSC) shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [****].

1.83 "[****] **Costs**" means with respect to [****] under this Agreement for any period, the product of (a) the number of [****]during such period and (b) the [****].

1.84 "[****]" means [****], as adjusted pursuant to [****].

1.85 "**Generic Product**" means, with respect to a Licensed Product, any product that is approved in reliance, in whole or in part, on the prior Regulatory Approval (or on safety or efficacy data submitted in support of the prior Regulatory Approval) of such Licensed Product as determined by the applicable Regulatory Authority, including any product authorized for sale (a) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), (b) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision) or (c) in any other country or jurisdiction pursuant to all equivalents of such provisions, including any amendments and successor statutes with respect to any of the foregoing.

1.86 "**Immunology Field**" means the prevention, treatment or control of any autoimmune or inflammatory disease, disorder or condition.

1.87 "**Improvements**" means any invention, discovery, development or modification licensed, acquired, conceived, discovered, developed or otherwise made by or on behalf of AbbVie or its Affiliates or its or their Sublicensees with respect to a Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any delivery system or enhancement thereto) or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Compound or Licensed Product or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product.

1.88 "**Included** [****] **Costs and Expenses**" means the sum of (a) all costs and expenses for [****], (b) a pro rata allocation of [****] and (c) other [****], in any case ((a), (b) or

(c)), whether internal costs and expenses or amounts paid to Third Parties and allocated in accordance with [****] applied across its product portfolio.

1.89 "**IND**" means an application filed with a Regulatory Authority for authorization to commence clinical studies, including (a) an Investigational New Drug Application as defined in the FFDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States Investigational New Drug Application in other countries or regulatory jurisdictions (e.g., clinical trial application (CTA)) and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.90 "**Indemnification Claim Notice**" has the meaning set forth in Section 10.4.1.

1.91 "**Indemnified Party**" has the meaning set forth in Section 10.4.1.

1.92 "**Indemnitee**" has the meaning set forth in Section 10.4.1.

1.93 "**Indirect Taxes**" has the meaning set forth in Section 6.9.

1.94 "**Information**" means all information and data of a technical, scientific, business or other nature, including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, results, analyses, non-clinical and clinical data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, information regarding reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.95 "**Infringement**" has the meaning set forth in Section 7.5.2.

1.96 "**Initial Licensed Compound**" has the meaning set forth in the definition of "Licensed Compound."

1.97 "**Initial Licensed Product**" means the Licensed Product containing the Initial Licensed Compound as its sole active ingredient for which Licensor has submitted a Drug Approval Application in the United States as of the Effective Date.

1.98 "**IP Group**" has the meaning set forth in Section 7.1.1.

1.99 "**IRA**" means 42 U.S.C. §§ 1320f et seq. and all its subsequent amendments and replacements.

1.100 "**JCC**" has the meaning set forth in Section 2.3.

1.101 "**JDC**" has the meaning set forth in Section 2.2.

1.102 "**Joint Intellectual Property Rights**" has the meaning set forth in Section 7.2.2.

1.103 "**Joint Know-How**" has the meaning set forth in Section 7.2.2.

1.104 "**Joint Patents**" has the meaning set forth in Section 7.2.2.

1.105 "**JSC**" has the meaning set forth in Section 2.1.

1.106 "**Knowledge**" means the [****] of Licensor or any personnel holding positions equivalent to such job titles[****]; provided, that [****] investigation shall not include any requirement to [****] but Licensor shall be deemed to have Knowledge of [****].

1.107 "**Licensed Compound**" means the compound reproxalap (as set forth in the World Health Organization's *International Nonproprietary Names for Pharmaceutical Substances*; CAS No. 916056-79-6) (the "**Initial Licensed Compound**") and [****].

1.108 "**Licensed Product**" means any product containing a Licensed Compound, alone or in combination with one (1) or more other active ingredients, in any and all forms, presentations, delivery systems, dosages and formulations.

1.109 "**Licensor**" has the meaning set forth in the preamble hereto.

1.110 "**Licensor Commercialization Percentage**" has the meaning set forth in Section 5.3.1(c).

1.111 "**Licensor Indemnitees**" has the meaning set forth in Section 10.1.

1.112 "**Licensor Know-How**" means all Information that is (a) Controlled by Licensor or its Affiliates as of the Effective Date or during the Term, (b) not generally known and (c) necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, but excluding Joint Know-How and any Information that is published in a Licensor Patent or Joint Patent.

1.113 "**Licensor Patents**" means all Patents that are Controlled by Licensor or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, including the Existing Patents, but excluding Joint Patents.

1.114 "**Life Sciences Entity**" means any pharmaceutical, biotechnology, medical device or diagnostic company, including any Affiliate or any venture capital subsidiary or venture capital organization or division of any pharmaceutical, biotechnology, medical device or diagnostic company.

1.115 "**Losses**" has the meaning set forth in Section 10.1.

1.116 "**MA Holder**" means, (a) with respect to the United States, [****] and (b) with respect to each country in the OUS Territory, [****].

1.117 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of any Licensed Compound, any Licensed Product or any intermediates and components thereof, including regulatory affairs with respect to the foregoing, product characterization, quality assurance and quality control.

1.118 "**Manufacturing Cost**" with respect to a Licensed Compound or Licensed Product has the meaning set forth on **Schedule 1.118**.

1.119 "**Manufacturing Working Group**" has the meaning set forth in Section 2.4.2.

1.120 "**Medical Affairs Activities**" means the coordination of medical information requests and field based medical scientific liaisons with respect to Licensed Compounds or Licensed Products, including [****].

1.121 "**Mixed Specification with Mixed Claims Licensor Patent**" means any Licensor Patent that discloses in its specification and claims (a) (i) any Licensed Compound or Licensed Product or (ii) any uses or formulations of, or methods of making, any Licensed Compound or Licensed Product; and (b) (i) any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound or (ii) any uses or formulations of, or methods of making, any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound, including those set forth on **Schedule 1.121**.

1.122 "**Mixed Specification with Specific Claims Licensor Patent**" means any Licensor Patent that (a) discloses in its specification (i) (A) any Licensed Compound or Licensed Product or (B) any uses or formulations of, or methods of making, any Licensed Compound or Licensed Product, and (ii) (A) any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound or (B) any uses or formulations of, or methods of making, any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound; and (b) (i) claims (A) any Licensed Compound or Licensed Product or (B) any uses or formulations of, or methods of making, any Licensed Compound or Licensed Product and (ii) does not claim (A) any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound or (B) any uses or formulations of, or methods of making, any RASP Inhibitor other than a Licensed Compound or any product containing a RASP Inhibitor other than a Licensed Compound, including those set forth on **Schedule 1.122**.

1.123 "**Mono Product**" has the meaning set forth in the definition of "Net Sales."

1.124 "**NDA Transfer Date**" means the date [****] that the role of MA Holder in the United States transfers from the Current MA Holder to the New MA Holder.

1.125 "**Net Profits**" and, with correlative meaning, "**Net Losses**", means, [****].

1.126 "**Net Sales**" means [****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****].

1.127 "**New MA Holder**" has the meaning set forth in Section 5.1.2(d).

1.128 "**Non-Breaching Party**" has the meaning set forth in Section 11.2.1.

1.129 "**Non-MA Holder Party**" means, with respect to any country, at any time, the Party that is not the MA Holder for such country at such time.

1.130 "**Notice Period**" has the meaning set forth in Section 11.2.1.

1.131 "**Ophthalmology Field**" means the prevention, treatment or control of any disease, disorder or condition of any part of the human eye, which includes the cornea, iris, fovea, lens, macula, optic nerve, retina, pupil, sclera, and vitreous, and all periocular, periorbital and other

accessory structures that support human eye homeostasis, including conjunctiva, tissues of upper and lower eyelids, and fornices, meibomian glands, lacrimal glands and extraocular muscles.

1.132 "**Opt-In**" means opting into the jurisdiction of Unified Patent Court, such as through withdrawal under Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01) of the Opt-Out of a Patent.

1.133 "**Option Agreement**" has the meaning set forth in Section 8.1.

1.134 "**Opt-Out**" means opting out of the jurisdiction of Unified Patent Court, such as the opt-out of a Patent from the exclusive competence of the Unified Patent Court under Article 83(3) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01).

1.135 "**Other Shared Expenses**" means [****]:

[****];

[****];

[****];

[****];

[****];

[****];

[****];

[****].

1.136 "**OUS Product Trademarks**" has the meaning set forth in Section 7.9.2.

1.137 "**OUS Territory**" means the Territory, excluding the U.S.

1.138 "[****] **Costs**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards consistently applied) by a Party (or its Affiliate) directly incurred in the conduct of any applicable activities under this Agreement, including costs for independent contractors engaged as permitted under this Agreement; provided that [****] Costs shall not include costs for general overhead, postage, communications, photocopying, printing or internet expense, professional dues, operating supplies, printers, photocopiers, fax machines or other office equipment, laboratory equipment, computers or computer service charges, or any costs that are otherwise subsumed within the definition of [****] Costs and Expenses.

1.139 "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

1.140 "**Patents**" means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patents and patent applications claiming priority to such patents and patent applications in (a), including divisionals, continuations, continuations-in-part, and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.141 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.142 "**Personal Data**" means all information identifying, or in combination with other information, identifiable to an individual, including pseudonymized (key-coded) clinical data containing such information, and to the extent not covered in the foregoing, any information that is considered to be "personal information", "personally identifiable information" or similar under Data Security and Privacy Laws.

1.143 "**Phase IV Clinical Trial**" means a product support human clinical trial, or other test or study, of a Licensed Product for an indication that is commenced after receipt of the initial Regulatory Approval for such indication in the country for which such trial is being conducted and that is conducted within the parameters of the Regulatory Approval for the Licensed Product for such indication. Phase IV Clinical Trials may include [****].

1.144 "**Pre-Existing Entities**" has the meaning set forth in Section 3.7.2(a).

1.145 "**Privacy and Security Obligations**" has the meaning set forth in Section 9.2.20.

1.146 "**Processing**" (or its conjugates) means any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.147 "**Product Information**" has the meaning set forth in Section 8.1.

1.148 "**Product Labeling**" means, with respect to a Licensed Product in the U.S., (a) the full prescribing information for such Licensed Product in the United States, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a

carton, container, wrapper, or any package insert utilized with or for such Licensed Product in the United States.

1.149 "**Publication Policies**" has the meaning set forth in Section 8.7.

1.150 "**RASP**" (an acronym for Reactive Aldehyde Species) means pro-inflammatory molecules resulting from a variety of processes, including lipid peroxidation, alcohol peroxidation or polyamine or glucose metabolism.

1.151 "**RASP Inhibitor**" means any molecular entity that binds, scavenges or otherwise inhibits the biologic activity of a RASP.

1.152 "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Compound or Licensed Product in such country, including, where applicable, (a) satisfactory pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

1.153 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Licensed Compounds or Licensed Products in the Territory, including the FDA in the United States and the EMA in the European Union.

1.154 "**Regulatory Documentation**" means: all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotional documents, adverse event files and complaint files; in each case ((a) and (b)), relating to a Licensed Compound or a Licensed Product.

1.155 "**Regulatory Exclusivity**" means, with respect to a Licensed Product in any country or other jurisdiction in the Territory, an additional market protection, other than Patent protection, granted by a Regulatory Authority in such country or other jurisdiction that confers an exclusive Commercialization period during which AbbVie or its Affiliates or its or their Sublicensees have the exclusive right to market and sell such Licensed Product in such country or other jurisdiction for all indications.

1.156 "**Representatives**" has the meaning set forth in Section 8.1.

1.157 "**Reversion Product**" means any Licensed Product that is being Exploited by AbbVie pursuant to this Agreement on the applicable effective date of termination, in the form that such Licensed Product or Improvement exists on the effective date of termination.

1.158 "**ROFN Product**" means any Competing Product that is owned or otherwise controlled by Licensor or any of its Affiliates [****].

1.159 "**ROFN Product Data Package**" means, with respect to each ROFN Product a data package consisting of: (a) the complete results of all development activities conducted by or on behalf of Licensor or its Affiliates or its or their (sub)licensees related to such ROFN Product in the Ophthalmology Field, (b) copies of all regulatory documentation submitted to or received from regulatory authorities related to such ROFN Product in the Ophthalmology Field, (c) any [****] for such ROFN Product in the Ophthalmology Field conducted by or on behalf of Licensor or any of its Affiliates, including [****], (d) a description of any and all obligations that Licensor or any of its Affiliates has to a Third Party, financial or otherwise, with respect to [****] and (e) copies of any and all agreements pursuant to which Licensor or any of its Affiliates [****] in each case ((a) through (e)), that are in the control of Licensor or any of its Affiliates at the time of preparation of the data package and in the form in which such information is held by Licensor or any of its Affiliates. For purposes of this definition, [****] shall mean [****] that are the subject of the proposed ROFN Product Transaction.

1.160 "**ROFN Product Data Package Delivery Date**" means, with respect to each ROFN Product Data Package delivered by Licensor under this Agreement, the later of (a) the date of delivery of the complete version of such ROFN Product Data Package by Licensor to AbbVie and (b) if, in accordance with Section 3.9.3, AbbVie reasonably requests [****] additional material Information relating to the applicable ROFN Product in order to make an informed decision regarding whether to exercise its rights with respect to such ROFN Product, the date that such additional material Information is provided to AbbVie pursuant to Section 3.9.3.

1.161 "**ROFN Product Exercise Notice**" has the meaning set forth in Section 3.9.4.

1.162 "**ROFN Product Exercise Period**" has the meaning set forth in Section 3.9.4.

1.163 "**ROFN Product Negotiations**" has the meaning set forth in Section 3.9.2.

1.164 "**ROFN Product Transaction**" has the meaning set forth in Section 3.9.2.

1.165 "**ROFN Product Transaction Agreement**" has the meaning set forth in Section 3.9.5.

1.166 "**ROFN Product Transaction Notice**" has the meaning set forth in Section 3.9.2.

1.167 "**Royalty Term**" means, with respect to each Licensed Product and each country or other jurisdiction in the OUS Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country or other jurisdiction, and ending on the latest to occur of (a) the first date that there is no Valid Claim of any Licensor Patent (subject to Section 7.5.2) or Joint Patent that claims (i) the Licensed Compound contained in such Licensed Product as a [****] or (ii) a [****] in such country or other jurisdiction, (b) the first date that such Licensed Product is not subject to Regulatory Exclusivity in such country or other jurisdiction and

(c) the [****] of the First Commercial Sale of the first Licensed Product in such country or other jurisdiction.

1.168 "**Scheduled TM Quality Standards**" has the meaning set forth in Section 7.9.8(a).

1.169 "**Scheduled Trademarks**" means the Trademarks set forth on **Schedule 1.169**.

1.170 "**Sensitive AbbVie Information**" has the meaning set forth in Section [****].

1.171 "**Settlement Proceeds**" means, with respect to a Licensed Product, any amounts actually received by AbbVie or any of its Affiliates from any Settlement Sublicensee to the extent attributable to any Settlement Sublicense attributable to such Licensed Product, minus the costs and expenses incurred by AbbVie and its Affiliates in connection with the applicable settlement.

1.172 "**Settlement Sublicense**" has the meaning set forth in Section 1.173.

1.173 "**Settlement Sublicensee**" means any Third Party to which AbbVie or its Affiliate grants a sublicense with respect to a Generic Product (a "**Settlement Sublicense**") to settle or avoid litigation or any Patent claim or dispute related to the alleged non-infringement, invalidity or unenforceability of or challenge against any Patent covering or claiming a Licensed Product.

1.174 "**SOFR**" means the Secured Overnight Financing Rate for a thirty (30)-day term published by US Federal Reserve Bank of New York, as adjusted from time to time on the first New York business day of each month.

1.175 "**Special Claims**" has the meaning set forth in Section 10.6.

1.176 "**Special Patents**" means the Patents set forth on **Schedule 10.6**.

1.177 "**Sublicensee**" means a Third Party, other than a distributor, that is granted a sublicense by AbbVie or its Affiliate under the grants in Section 3.1, as provided in Section 3.4, except for a Settlement Sublicensee.

1.178 "**Term**" has the meaning set forth in Section 11.1.

1.179 "**Termination Notice**" has the meaning set forth in Section 11.2.1.

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

1.181 "**Third Party**" means any Person other than Licensor, AbbVie and their respective Affiliates.

1.182 "**Third Party Claims**" has the meaning set forth in Section 10.1.

1.183 "**Third Party Infringement Claim**" has the meaning set forth in Section 7.7.

1.184 "**Third Party Payments**" has the meaning set forth in Section 7.8.4.

1.185 "**Third Party Right**" means any Patent, trade secret or other intellectual property right of a Third Party in any country in the Territory that is necessary or reasonably useful for the Exploitation of a Licensed Compound or Licensed Product by AbbVie or any of its Affiliates or any of its or their Sublicensees, distributors or customers.

1.186 "**TM Competitive Infringement**" has the meaning set forth in Section 7.9.7(b).

1.187 "**TM Infringement Claim**" has the meaning set forth in Section 7.9.7(b).

1.188 "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design, business symbol, domain name, URL, social media tag or handle, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.189 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.190 "**US Product Trademarks**" has the meaning set forth in Section 7.9.1.

1.191 "**Valid Claim**" means a claim of (a) any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer; or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal; or (b) a pending patent application that has not been finally abandoned or finally rejected or expired and that has been pending for [****] from the date of filing of the earliest patent application to which such pending patent application is entitled to claim priority.

1.192 "**Voting Stock**" has the meaning set forth in the definition of "Change of Control."

1.193 "**Withholding Amount**" has the meaning set forth in Section 6.8.

1.194 "**Withholding Party**" has the meaning set forth in Section 6.8.

1.195 "**Working Group**" has the meaning set forth in Section 2.4.1.

ARTICLE 2
COLLABORATION MANAGEMENT

2.1 Joint Steering Committee. Within [****] after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") with overall responsibility for the oversight and coordination of the transfers outlined in Article 4 and the Development, Manufacture, Commercialization and other Exploitation of Licensed Compounds and Licensed Products in the Field for the United States as more fully described in this Article 2. The JSC shall perform the following functions:

2.1.1 oversee the Development, Manufacture, Commercialization and other Exploitation of Licensed Compounds and Licensed Products for the U.S.;

2.1.2 coordinate the Parties' activities under this Agreement, including oversight of the JDC, JCC and any Working Group;

2.1.3 serve as an initial forum for discussion of, and attempt to resolve, any issues or disputes that may arise in the JDC, JCC or any Working Group or otherwise under this Agreement;

2.1.4 oversee and coordinate the transfers outlined in Article 4; and

2.1.5 perform such other functions that are expressly assigned to the JSC under this Agreement or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

For clarity, the JSC shall not have any authority beyond the specific matters set forth in this Section 2.1, and in particular shall not have any power to (a) amend or modify the terms of this Agreement, (b) waive a Party's compliance with this Agreement, (c) decide or resolve any issues other than those specifically subject to JSC approval in this Section 2.1, (d) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement, or (e) impose any other obligations on either Party without the prior written consent of such Party.

2.2 Joint Development Committee. Within [****] after the Effective Date, the Parties shall establish a joint development committee (the "**JDC**") with the responsibility to oversee, review and coordinate the Development, including regulatory activities, of Licensed Products in the Field in the Territory (other than any Development activity that is solely and specifically intended to support or maintain Regulatory Approval in [****]. Subject to the oversight of the JSC, the JDC shall perform the following functions:

2.2.1 oversee and monitor the regulatory and other Development activities (including with respect to Manufacturing) in support of obtaining Regulatory Approval for the Licensed Products in the Field in [****];

2.2.2 discuss any additional clinical studies or other Development activities to be conducted with respect to the Licensed Compounds or Licensed Products in the Field in [****];

2.2.3 develop and approve the initial Development Plan (if any) and review and approve any amendments thereto;

2.2.4 oversee and monitor the implementation of the Development Plan and the cost incurred with respect thereto;

2.2.5 determine whether to designate any country other than the countries in clause (a) of the definition of Designated Country as a Designated Country;

2.2.6 review and approve any Product Labeling with the FDA for the Initial Licensed Product;

2.2.7 [****];

2.2.8 determine which Party should hold and maintain the global safety database for the Licensed Products;

2.2.9 develop and approve the Publication Policies; and

2.2.10 perform such other functions that are expressly assigned to the JDC under this Agreement or by the JSC or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

For clarity, the JDC shall not have any authority beyond the specific matters set forth in this Section 2.2, and in particular shall not have any power to (a) amend or modify the terms of this Agreement (b) waive a Party's compliance with this Agreement, (c) decide or resolve any issues other than those specifically subject to JDC approval in this Section 2.2, (d) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement or (e) impose any other obligations on either Party without the prior written consent of such Party.

2.3 Joint Commercialization Committee. Within [****] after the Effective Date, the Parties shall establish a joint commercialization committee (the "**JCC**") with the responsibility to oversee, review and coordinate the Commercialization of Licensed Products in the Field for the United States. Each Party shall use [****] reasonable efforts to support the operation of the JCC, including by designating [****] qualified personnel to serve on the JCC. Subject to the oversight of the JSC, the JCC shall perform the following functions:

2.3.1 develop and approve the initial Commercialization Plan and review and approve any updates or amendments thereto, [****];

2.3.2 oversee and monitor the implementation of the Commercialization Plan and the costs incurred with respect thereto;

2.3.3 periodically (no less often than [****], or as the Parties may mutually agree in writing) review and discuss the Commercialization Plan and any updates or amendments thereto;

2.3.4 review and approve the budget for any [****] Costs that are included in Other Shared Expenses;

2.3.5 with respect to any Commercialization activity for the Licensed Products performed with respect to the [****]; and

2.3.6 perform such other functions that are expressly assigned to the JCC under this Agreement or by the JSC or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

For clarity, the JCC shall not have any authority beyond the specific matters set forth in this Section 2.3, and in particular shall not have any power to (a) amend or modify the terms of this Agreement, (b) waive a Party's compliance with this Agreement, (c) decide or resolve any issues other than those specifically subject to JCC approval in this Section 2.3, (d) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement, or (e) impose any other obligations on either Party without the prior written consent of such Party.

2.4 Working Groups.

2.4.1 Formation. In addition to the Manufacturing Working Group, from time to time, each Committee may establish one (1) or more working groups (each, a "**Working Group**") to oversee particular projects or activities within the scope of such Committee's responsibilities. Working Groups may be established on an ad hoc basis for purposes of a specific project, for the term of the applicable Committee or on such other basis as the applicable Committee may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the Committee that established such Working Group. In no event shall the authority of any Working Group exceed that specified for the Committee that established such Working Group.

2.4.2 Manufacturing Working Group. Within [****] after the Effective Date, the Parties shall establish a manufacturing Working Group (the "**Manufacturing Working Group**"). The Manufacturing Working Group is deemed established by the JSC. Subject to the oversight of the JSC, the Manufacturing Working Group shall perform the following functions:

(a) serve as a forum for discussing the Manufacturing activities, including manufacturing process or Development, design and optimization, change control, quality matters, and commercial supply of the Licensed Compounds and Licensed Products;

(b) discuss and manage the operative aspects of Manufacturing, including Regulatory Approval-related matters and whether to establish any [****] supply arrangements, which may include establishing a [****] source of Licensed Compounds or Licensed Products, which [****] source may be a Party or a Third Party;

(c) determining when to transfer the Drug Product Manufacturing Process and the Drug Substance Manufacturing Process to AbbVie or its designee pursuant to Section 4.1.2 and coordinate the activities with respect to any such transfer; and

(d) perform such other functions as are expressly assigned to the Manufacturing Working Group under this Agreement or by the JSC or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.5 General Provisions Applicable to Committees and Working Groups.

2.5.1 Composition. Each Committee shall initially consist of [****] representatives from each Party; provided that each Party may, in its sole discretion, decrease the number of its representatives on each Committee. Each Committee representative shall have the requisite experience and seniority to enable such representative to make decisions on behalf of the Party it represents with respect to the issues falling within the jurisdiction of the applicable Committee. Each Party shall appoint at least [****] to each Working Group and shall have the right, but not the obligation, to appoint the same number of representatives to any Working Group as are appointed by the other Party to such Working Group. From time to time, each Party may substitute [****] or more of its representatives to any Committee or Working Group on written notice to the other Party, which notice may be given by e-mail sent to the other Party's representatives on such Committee or Working Group. Each Committee will have [****] co-chairpersons, [****] designated by each Party and each co-chairperson shall be entitled to call meetings. From [****], each Party may change its representative who will serve as co-chairperson of any Committee on written notice to the other Party, which notice may be given by e-mail sent to the other Party's co-chairperson of the applicable Committee.

2.5.2 Meetings and Minutes. Each Committee shall meet [****], or as otherwise agreed to by the Parties; provided that in the event there are no relevant issues for discussion by the applicable Committee in a given [****], the Parties may mutually agree to cancel the meeting scheduled for such [****]. The location of each Committee meeting shall alternate between locations designated by Licensor and locations designated by AbbVie (which, for clarity, may include videoconference), with the location of the first meeting of each Committee being designated by AbbVie. The co-chairpersons of each Committee shall be responsible for calling meetings on no less than [****] notice or such [****] duration as agreed between the Parties. Each Party shall make all proposals for agenda items and shall provide all appropriate Information with respect to such proposed items at least [****] in advance of the applicable meeting or such shorter duration as agreed between the Parties (which agreement shall not be unreasonably withheld, conditioned or delayed); provided that under exigent circumstances requiring input by a Committee, a Party may provide its agenda items to the other Party within a [****] period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The co-chairpersons shall coordinate with the Alliance Managers to prepare and circulate an agenda in advance of each meeting and prepare and issue final minutes within [****] thereafter. Such minutes will not be finalized until the co-chairperson from each Party reviews and confirms in writing (e-mail to suffice) the accuracy of such minutes. The minutes of each meeting shall, among other things, record all matters acted upon and approved or disapproved by the Committee, and any matters the Committee failed to resolve.

2.5.3 Procedural Rules. Each Committee and Working Group shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules

are not inconsistent with this Agreement. A quorum of each Committee and Working Group shall exist whenever there is present at a meeting [****] appointed by each Party. Representatives of the Parties on a Committee or Working Group may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Each Committee and Working Group shall take action (a) by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance or (b) by a written resolution signed by [****] appointed by each Party. Alliance Managers and other employees of either Party that are not representatives of the Parties on a Committee or Working Group may attend meetings at the invitation of a representative on such Committee or Working Group; provided that such attendees (x) shall not vote or otherwise participate in the decision-making process of such Committee or Working Group, and (y) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article 8; provided further that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party and obtain written agreement of the other Party (e-mail to suffice), and such Party shall also ensure that such Third Party is bound by obligations of confidentiality and non-use equivalent to those set forth in Article 8.

2.5.4 Dispute Resolution. If a Working Group cannot, or does not, reach consensus on an issue at a meeting, then either Party may refer the dispute to the Committee that established such Working Group for resolution and a special meeting of such Committee may be called for such purpose. If a Committee (other than the JSC) cannot, or does not, reach consensus on an issue at a meeting, then either Party may refer the dispute to the JSC for resolution and a special meeting of the JSC may be called for such purpose. If the JSC cannot, or does not, reach consensus on an issue, including any dispute arising in another Committee or Working Group, then within [****] after such matter was brought to the JSC for resolution, the dispute shall first be referred to the Executive Officers, who shall confer [****] on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers in writing shall be conclusive and binding on the Parties and deemed a consensus of the JSC. If the Executive Officers are not able to agree on the resolution of any such issue within thirty [****] after such issue was first referred to them, then such dispute shall be resolved as follows: (a) Licensor shall have the right to finally and definitively resolve any JSC dispute regarding the portion of the Commercialization Plan addressing the pricing and market access strategy for the Licensed Products in the United States and (b) AbbVie shall have the right to finally and definitively resolve any other JSC disputes; provided that [****]. Notwithstanding the foregoing, any Committee dispute regarding whether or not to form a Working Group shall not be escalated and no such Working Group shall be formed without consensus of the applicable Committee. Disputes arising between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith that are outside of the jurisdiction of the JSC shall be resolved pursuant to Section 12.6.

2.5.5 Limitations on Authority. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in any Committee or Working Group unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

2.5.6 Alliance Manager. Within [****] after the Effective Date, each Party shall appoint (and notify (e-mail to be sufficient) the other Party of the identity of) an employee of the notice-providing Party who has the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) who shall oversee contact between the Parties for all matters between meetings of the Committees and shall have such other responsibilities as the Parties may agree in writing after the Effective Date, which person(s) may be replaced at any time by notice in writing to the other Party (each, an "**Alliance Manager**"). The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

2.6 Discontinuation of Committees and Working Groups. Each Committee and Working Group shall continue to exist until the Parties mutually agree to disband each such Committee or Working Group. Notwithstanding anything herein to the contrary, once a Committee or Working Group has been disbanded in accordance with this Agreement, such Committee or Working Group shall be terminated and shall have no further rights or obligations under this Agreement, and, unless otherwise agreed by the Parties, thereafter any requirement of Licensor to provide Information or other materials to such Committee or Working Group shall be deemed a requirement to provide such Information or other materials to AbbVie and AbbVie shall have the right to solely decide, without consultation with Licensor, all matters that are subject to the review or approval by such Committee or Working Group hereunder.

2.7 Interactions Between the Committees and Internal Teams. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article shall prevent a Party from making routine day-to-day decisions relating to the conduct of those activities for which it has a performance obligation or other obligations hereunder, provided they are made, in a manner consistent with the terms and conditions of this Agreement.

2.8 Expenses. Each Party shall be responsible for all costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, any Committee or Working Group, which costs and expenses shall not be included in Allowable Expenses.

ARTICLE 3
GRANT OF RIGHTS

3.1 Grants to AbbVie. Subject to Section 3.4 and Section 3.5, Licensor (on behalf of itself and its Affiliates) hereby grants to AbbVie and its Affiliates:

3.1.1 a license (or sublicense), with the right to grant sublicenses in accordance with Section 3.4, under the Licensor Patents, the Licensor Know-How, the Scheduled Trademarks and Licensor's interests in the Joint Patents and the Joint Know-How, to (a) Develop, Manufacture, Commercialize and otherwise Exploit the Licensed Compounds, Licensed Products

and any Improvement with respect thereto, in all cases, in the Field in the Territory and (b) otherwise exercise AbbVie's rights in accordance with Article 7, which license shall be (x) co-exclusive (with Licensor and its Affiliates) with respect to the Development, Manufacture, Commercialization and other Exploitation of the Licensed Compounds, Licensed Products and any Improvement with respect thereto in the Field for the United States and (y) otherwise exclusive (even as to Licensor and its Affiliates); and

3.1.2 at any time while [****] in the United States, a license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 3.4, under the Regulatory Approvals and the Regulatory Documentation Controlled by Licensor with respect to the United States to Develop, Manufacture, Commercialize and otherwise Exploit the Licensed Compounds, Licensed Products and any Improvement with respect thereto in the Field in the Territory, which license shall be (a) co-exclusive (with Licensor and its Affiliates) with respect to the Development, Manufacture, Commercialization and other Exploitation of the Licensed Compounds, Licensed Products and any Improvement with respect thereto in the Field for the United States and (b) otherwise exclusive (even as to Licensor and its Affiliates).

3.2 Grants to Licensor. Subject to Section 3.4 and Section 3.5, AbbVie (on behalf of itself and its Affiliates) hereby grants to Licensor and its Affiliates:

3.2.1 a co-exclusive, royalty-free, non-sublicensable license under the AbbVie Patents, the AbbVie Know-How, any AbbVie US Product Trademarks and AbbVie's interests in the Joint Patents and the Joint Know-How to perform the activities allocated to Licensor under the Development Plan (if any) or the Commercialization Plan or to Manufacture any Licensed Compound or any Licensed Products to extent the Manufacturing Working Group approves Licensor as a [****] source of such Licensed Compound or Licensed Product; and

3.2.2 at any time while [****] in the U.S., a co-exclusive, royalty-free, non-sublicensable license and right of reference under the Regulatory Approvals and the Regulatory Documentation Controlled by AbbVie with respect to the U.S. to perform the activities allocated to Licensor under the Development Plan (if any) or the Commercialization Plan.

3.3 Co-Exclusive. For purposes of Section 3.1 and Section 3.2, "co-exclusive" means that Licensor and AbbVie shall collectively have all of the rights, and no Third Party shall have any rights, under the applicable intellectual property rights or Regulatory Documentation, as applicable, to perform the activities that are the subject of the applicable grant, and neither Party shall grant to any Third Party, without the prior written consent of the other Party, a license (or sublicense) or right of reference (or further right of reference) under such rights to conduct such activities, except as provided in Section 3.4.

3.4 Sublicenses. AbbVie shall have the right to grant sublicenses and further rights of reference, through multiple tiers, under the licenses and rights of reference granted in Section 3.1, to its Affiliates and other Persons; provided that any such sublicenses shall be consistent with the terms and conditions of this Agreement. Licensor shall not, and shall cause its Affiliates, not to grant any further licenses (or sublicenses) under the Licensor Know-How or

Licensor Patents or rights of reference (or further rights of reference) under the Regulatory Approvals and the Regulatory Documentation Controlled by Licensor.

3.5 Retention of Rights.

3.5.1 Except as expressly provided herein, Licensor grants no other right or license, including any rights or licenses to the Licensor Patents, the Licensor Know-How, Licensor's interest in the Joint Patents or the Joint Know-How or any other Patent or intellectual property rights, not expressly granted herein. Notwithstanding any other provision of this Agreement, for the purposes of the license grants under Section 3.1 with respect to any Licensed Product that is a Combination Product, in no event is a license granted hereunder with respect to any intellectual property right that is specific to any active ingredients of a Combination Product that are not Licensed Compounds; provided that the foregoing exclusion does apply to any intellectual property right specific to such Combination Product (e.g., intellectual property regarding combining a Licensed Compound with a class of such other active ingredient).

3.5.2 Except as expressly provided herein, AbbVie grants no other right or license, including any rights or licenses to AbbVie Patents, the AbbVie Know-How, AbbVie's interest in the Joint Patents and the Joint Know-How or any other Patent or intellectual property rights, not expressly granted herein.

3.6 Confirmatory Patent License. Licensor shall, if requested to do so by AbbVie, [****] enter into confirmatory license agreements in such form as may be [****] requested by AbbVie for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as AbbVie considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Licensor and AbbVie shall have the same rights in respect of the Licensor Patents and be under the same obligations to each other in all respects as if said confirmatory licenses had been executed.

3.7 Exclusivity.

3.7.1 Exclusivity. Licensor shall not, and shall cause its Affiliates not to, (a) directly or indirectly, clinically develop, commercialize or manufacture any Competing Product in any country or other jurisdiction in the Territory, or (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, clinically develop, commercialize or manufacture any Competing Product in any country or other jurisdiction in the Territory, except, in each case ((a) and (b)), for the performance of activities allocated to Licensor under the Development Plan (if any) or the Commercialization Plan under and in accordance with this Agreement.

3.7.2 Exception for Change of Control.

(a) Subject to the remainder of this Section 3.7.2, if during the Term, Licensor is acquired by a Third Party through a Change of Control and such Third Party or any of its Affiliates prior to such Change of Control (collectively, the "**Pre-Existing Entities**") is then engaged in activities that would otherwise constitute a breach of Licensor's obligations under Section 3.7.1 (a "**Competitive Program**"), Licensor shall not be in violation of Section 3.7.1 if and for so long as Licensor complies with Section 12.2.2.

(b) If Licensor fails to comply with Section 12.2, including if at any time Licensor fails to establish, maintain or implement Firewall Procedures, then (i) if such failure was with respect to any AbbVie Know-How or Confidential Information of AbbVie that is related to the Commercialization of any Licensed Product, Licensor shall be deemed to be in material breach of this Agreement and AbbVie shall have the right to [****] terminate this Agreement pursuant to Section 11.2.1 or modify this Agreement pursuant to Section 11.5 without any further opportunity for Licensor to cure such material breach or (ii) with respect to any other such failure, Licensor shall be deemed to be in material breach of this Agreement unless it can demonstrate that such failure was not material, and if Licensor cannot demonstrate that such failure was not material, then AbbVie shall have the right to [****] terminate this Agreement pursuant to Section 11.2.1 or modify this Agreement pursuant to Section 11.5 without any further opportunity for Licensor to cure such material breach.

3.7.3 Exception for Acquired Programs.

(a) Subject to the remainder of this Section 3.7.3, if during the Term, Licensor or its Affiliate acquires a Third Party (by merger, sale, consolidation, reorganization, or other transaction) so that such Third Party becomes an Affiliate of Licensor, or Licensor or its Affiliate acquires all or substantially all of the assets of such Third Party (including any subsidiaries or divisions thereof), and as of [****], such Third Party has, or the acquired assets contain, a Competitive Program (an "**Acquired Program**"), Licensor shall not be in violation of Section 3.7.1 if Licensor: either (i) Divests its rights to such Acquired Program in accordance with Section 3.7.3(b) or (ii) contributes such Acquired Program to the collaboration under this Agreement on terms to be agreed to by the Parties; and in each case ((i) or (ii)), provides written notice to AbbVie within [****] after the closing of the acquisition of such Acquired Program and whether Licensor or its Affiliate, as applicable, is electing (i) or (ii); provided, further, that if neither Divestment pursuant to clause (i) nor contribution pursuant to clause (ii) is concluded within [****], then Licensor shall terminate such Acquired Program in accordance with Section 3.7.3(d).

(b) If Licensor elects to Divest its rights to an Acquired Program, then Licensor (and its Affiliates, if applicable) will Divest such Acquired Program within [****] following the closing of the applicable acquisition (provided that such period may be extended for up to [****] if Licensor and its Affiliates are using [****] reasonable efforts to Divest such Acquired Program); provided that for so long as Licensor or its Affiliates retain such Acquired Program the Acquired Program is segregated in accordance with Section 3.7.3(e).

(c) If Licensor elects to contribute such Acquired Program to the collaboration under this Agreement, then Licensor and AbbVie shall negotiate [****] the terms of such contribution for a period [****] or such other period as agreed by the Parties; provided that for so long as Licensor or its Affiliates retain such Acquired Program the Acquired Program is segregated in accordance with Section 3.7.3(e).

(d) If neither Divestment nor contribution of an Acquired Program is completed within [****] under Section 3.7.3(b) or Section 3.7.3(c), as applicable, then Licensor (and its Affiliates, if applicable) will cease activities under such Acquired Program as soon as [****] practicable after the end of such time period, giving due consideration to ethical

concerns and requirements under Applicable Law; provided that for so long such Acquired Program is active, the Acquired Program is segregated in accordance with Section 3.7.3(e).

(e) During [****], contribution or termination of an Acquired Program pursuant to Section 3.7.3(b), 3.7.3(c) or Section 3.7.3(d) as applicable, Licensor may conduct such Acquired Program; provided that, promptly following the acquisition of the Acquired Program, Licensor establishes, maintains and implements the Firewall Procedures with respect to such Acquired Program.

(f) If Licensor fails to provide such notice as required within the period set forth in Section 3.7.3(a) or having provided such notice, fails to carry out the Divestiture, contribution or termination, as the case may be, within [****] under Section 3.7.3(b), Section 3.7.3(c) or Section 3.7.3(d), as applicable, then, unless the Parties agree otherwise, Licensor shall be deemed to be in material breach of this Agreement and AbbVie shall have the right to terminate this Agreement in accordance with Section 11.2.1 or modify this Agreement pursuant to Section 11.5.

3.7.4 Acknowledgement. Licensor acknowledges and agrees that (a) this Section 3.7 has been negotiated by the Parties, (b) the limitations on activities set forth in this Section 3.7 are reasonable, valid and necessary in light of the Parties' circumstances and necessary for the adequate protection of the business of the Licensed Products and (c) AbbVie would not have entered into this Agreement without the protection afforded it by this Section 3.7. If, notwithstanding the foregoing, a court of competent jurisdiction determines that the restrictions set forth in this Section 3.7 are too broad or otherwise unreasonable under Applicable Law, including with respect to duration or space, the court is hereby requested and authorized by the Parties to revise this Section 3.7 to include the maximum restrictions allowable under Applicable Law.

3.7.5 Excluded Acquirer IP. Licensor shall cause each Acquirer to refrain from filing a claim or commencing a suit, action or proceeding based upon an assertion of infringement of any Excluded Acquirer IP against AbbVie or its Affiliates or its or their Sublicensees based upon AbbVie or its Affiliates or its or their Sublicensees exercising their rights or performing their obligations under this Agreement. For clarity, this Section 3.7.5 does not require Licensor to cause any Acquirer to refrain from filing a claim or commencing a suit, action or proceeding against AbbVie or its Affiliates or its or their Sublicensees that is not based upon such Person's exercising its rights or performing its obligations under this Agreement. "**Excluded Acquirer IP**" means [****].

3.8 First Look.

3.8.1 With respect to each First Look Product, Licensor shall not, and shall cause its Affiliates not to, license, sell or otherwise grant or transfer, including by option, to any Third Party any rights to [****] such First Look Product in any First Look Field in any country without first complying with this Section 3.8. For clarity, this Section 3.8 does not restrict Licensor's rights with respect to its [****] of First Look Products by itself or through any of its Affiliates or with respect to the license, sale or other grant or transfer, including by option, to any

Third Party of any rights to [****] any First Look Product outside each First Look Field in any country(ies) in the world.

3.8.2 With respect to each First Look Product in the [****] Field, Licensor shall update the JDC, in accordance with this Section 3.8.2, regarding the development of such First Look Product in the [****] Field, and any resulting data, (a) when such First Look Product in the [****] Field advances to a new development stage (specifically, in vitro studies, in vivo studies, toxicology studies, phase 1, phase 2, phase 2(b), phase 3, completion of a registration study or commercial stage) and (b) when there is otherwise a [****] event with respect to the development of such First Look Product in the [****] Field. Each such update and data shall be provided either (i) in writing prior to any meeting of the JDC occurring during [****] that such advancement or other material event occurs or (ii) at such meeting of the JDC; provided that if the JDC does not meet during [****] (or if such advancement or other material event occurs after the JDC meets during [****]), then Licensor shall provide such update and data to AbbVie in writing promptly after the end of [****].

3.8.3 With respect to each First Look Product, if Licensor's, or any of its Affiliate's, board of directors determines to pursue a First Look Product Transaction in a First Look Field in any country(ies), then, within [****] after such determination (and in any event prior to Licensor or any of its Affiliates engaging in any term sheet level discussions with, accepting any offer from, or entering into any agreement with any Third Party with respect to such a potential First Look Product Transaction or providing any confidential information to any Third Party in connection therewith), Licensor shall first provide AbbVie with a First Look Data Package, and with electronic access to all Information included or referenced therein, and wait until expiration of the First Look Period before pursuing such First Look Product Transaction.

3.8.4 Commencing upon AbbVie's receipt of a First Look Data Package, AbbVie will have [****] period to review such First Look Data Package (the "**First Look Period**") and determine whether AbbVie would like to enter into a First Look Product Transaction with Licensor or its Affiliate with respect to the applicable First Look Product in the applicable First Look Field and country(ies). Upon (but not earlier than) the expiration of the First Look Period for a First Look Product in a First Look Field and country(ies), Licensor shall be free to engage in discussions and negotiations with Third Parties for a First Look Product Transaction for such First Look Product in such First Look Field in such country(ies) with no further obligation to AbbVie under this Section 3.8 with respect to such First Look Product in such First Look Field in such country(ies). For clarity, AbbVie shall only have the rights specified under this Section 3.8 [****] per First Look Product for a First Look Field in each country.

3.9 AbbVie Competing Product ROFN.

3.9.1 AbbVie ROFN. With respect to each ROFN Product, Licensor shall not, and shall cause its Affiliates not to, license, sell or otherwise grant or transfer, including by option, to any Third Party any rights to [****] such ROFN Product in any country without first complying with this Section 3.9. For clarity, this Section 3.9 does not restrict Licensor's rights with respect to its [****] of ROFN Products by itself or through any of its Affiliates or with respect to the license, sale or other grant or transfer, including by option, to any Third Party of any rights to [****] any ROFN Product outside the [****] Field in any country(ies) in the world.

3.9.2 Transaction Notice and Data Package. With respect to each ROFN Product, if Licensor or any of its Affiliates desire to license, sell or otherwise grant or transfer, including by option, to any Third Party any rights to [****] such ROFN Product in any country(ies) in the world (such transaction, a "**ROFN Product Transaction**"), then Licensor must provide written notice to AbbVie describing the scope of rights that are the subject of such proposed ROFN Product Transaction in reasonable detail (a "**ROFN Product Transaction Notice**") prior to Licensor or any of its Affiliates [****], any Third Party with respect to such proposed ROFN Product Transaction or providing any confidential information to any Third Party in connection with any proposed ROFN Product Transaction (collectively, "**ROFN Product Negotiations**") and provide AbbVie the applicable ROFN Product Data Package with respect to such ROFN Product and with electronic access to all Information included or referenced therein. For clarity, "ROFN Product Transaction" includes any transaction in which Licensor or any of its Affiliates desire to license, sell or otherwise grant or transfer, including by option, to any Third Party any rights to [****] a ROFN Product.

3.9.3 Additional Information. If AbbVie believes [****] that any of the Information required to be included in a ROFN Product Data Package is missing, then AbbVie shall have the right within [****] after receipt of such ROFN Product Data Package to request in writing that Licensor provide AbbVie any such missing Information, and, to the extent such Information is in Licensor's possession and control ([****]), Licensor shall deliver a revised and complete ROFN Product Data Package within [****] after the receipt of such request from AbbVie. In addition, Licensor promptly shall make available to AbbVie such other Information relating to the applicable ROFN Product that is in the possession or control of Licensor or any of its Affiliates ([****]) as AbbVie may [****] request within [****] after receipt of the complete ROFN Product Data Package in order to make an [****] decision regarding whether to exercise its ROFN with respect to such ROFN Product.

3.9.4 Exercise. With respect to each ROFN Product, if AbbVie wishes to enter into exclusive negotiations with Licensor to obtain the rights that Licensor wishes to grant with respect to such ROFN Product in the applicable country(ies) and field (as described in the applicable ROFN Product Transaction Notice), AbbVie shall provide Licensor with notice thereof (a "**ROFN Product Exercise Notice**") within [****] after the later of receipt of the applicable ROFN Product Transaction Notice and the ROFN Product Data Package Delivery Date for such ROFN Product (such [****] period, the "**ROFN Product Exercise Period**"). If AbbVie timely delivers a ROFN Product Exercise Notice within the applicable ROFN Product Exercise Period, the Parties will engage in [****] negotiations for a period of [****] after delivery of such ROFN Product Exercise Notice (an "**Exclusive ROFN Product Negotiation Period**") in an attempt to agree upon a definitive agreement containing the terms and conditions pursuant to which AbbVie would receive a license, assignment, option or other grant or transfer of rights in and to, including any rights to further [****], such ROFN Product in the applicable country(ies).

3.9.5 No Exercise or No Agreement During Exclusive ROFN Product Negotiation Period. If AbbVie does not deliver a ROFN Product Exercise Notice during the applicable ROFN Product Exercise Period or provides written notice that it does not intend to provide a ROFN Product Exercise Notice or the Parties fail to reach mutual agreement during the Exclusive ROFN Product Negotiation Period on such definitive agreement, then, in each case, Licensor shall thereafter be free to engage in ROFN Product Negotiations with Third Parties for

an agreement for such proposed ROFN Product Transaction (such agreement, a "**ROFN Product Transaction Agreement**") and enter into ROFN Product Transaction Agreements with Third Parties with respect to such ROFN Product in the applicable country(ies); provided that (a) during the [****] after the end of the Exclusive ROFN Product Negotiation Period if applicable, Licensor shall not enter into a ROFN Product Transaction Agreement for such ROFN Product in the applicable country(ies) on terms and conditions that, taken as a whole, are less favorable to Licensor than the terms and conditions last proposed by Licensor to AbbVie, if any, during the applicable Exclusive ROFN Product Negotiation Period, (b) if Licensor or its Affiliate, as applicable, does not enter into a ROFN Product Transaction Agreement with respect to such ROFN Product within [****] after the end of the ROFN Product Exercise Period or the Exclusive ROFN Product Negotiation Period, as applicable, and later Licensor intends to engage in ROFN Product Negotiations or enter into a ROFN Product Transaction Agreement in the applicable country(ies), then Licensor must so notify AbbVie and comply again with all of the terms of this Section 3.9; provided that the time period in this subsection (b) shall be extended for up [****] for any ROFN Product Transaction Agreement and a Third Party that was in active negotiations at the end of such [****] period as demonstrated by [****] if such ROFN Product has not advanced to a new development stage, (c) if Licensor or its Affiliate, as applicable, intends to engage in ROFN Product Negotiations based on new data generated after the expiration of the ROFN Product Exercise Period or the Exclusive ROFN Product Negotiation Period, as applicable, that causes the classification of such ROFN Product to be advanced to a new development stage (specifically, in vitro studies, in vivo studies, toxicology studies, phase 1, phase 2, phase 2(b), phase 3, completion of a registration study or commercial stage), then Licensor must so notify AbbVie and comply again with all of the terms of this Section 3.9; and (d) Licensor shall not enter into a ROFN Product Transaction Agreement for rights (as distinguished from terms and conditions, which are addressed in subsection (a) above) with respect to such ROFN Product in the applicable country(ies) that are materially different than those set forth in the applicable ROFN Product Transaction Notice without again complying with this Section 3.9. With respect to each ROFN Product for which AbbVie delivered a ROFN Product Exercise Notice during the applicable ROFN Product Exercise Period and Licensor entered into a ROFN Product Transaction Agreement for such ROFN Product, Licensor shall provide to AbbVie a summary of the material financial terms of such ROFN Product Transaction Agreement promptly after execution thereof.

3.9.6 JDC Updates. Licensor shall update the JDC regarding the development of any ROFN Product, and any resulting data, at each JDC meeting; provided that if the JDC does not meet in any [****], then Licensor will provide a high-level written summary of the development of any ROFN Product, and any resulting data, to AbbVie promptly after the end of such [****].

ARTICLE 4
TRANSFER ACTIVITIES

4.1 Technology Transfer. Promptly after the Effective Date, Licensor shall (and shall cause its Affiliates to) cooperate with AbbVie (and its designees) and provide [****] assistance and technology transfers to AbbVie (and its designees) to enable AbbVie (and its designees) to Develop, Manufacture, Commercialize and otherwise Exploit the Licensed Compounds and Licensed Products in the Territory, including by (a) providing AbbVie (and its designees) [****] assistance with respect to Development (including regulatory) and

Manufacturing matters related to such Licensed Compounds and Licensed Products, and (b) providing AbbVie (and its designees) with [****] access by teleconference or in person (as requested by AbbVie) to Licensor personnel (and personnel of its Affiliates and Third Party subcontractors) involved in the Exploitation of Licensed Compounds or Licensed Products to assist AbbVie (and its designees) with Development (including regulatory) and Manufacturing matters and to answer questions related to such Licensed Compounds and Licensed Products. For clarity, Licensor shall retain access to all Licensor Know-How and Regulatory Documentation as necessary to Develop, Manufacture, Commercialize and otherwise Exploit the Licensed Products in accordance with this Agreement. Without limiting the foregoing:

4.1.1 Disclosure of Know-How and Regulatory Documentation. Licensor shall, and shall cause its Affiliates to, disclose or make available to AbbVie, to the extent not previously provided, in such form and format as AbbVie may reasonably request (including by providing copies thereof, which copies must be true, complete and correct), all data and Information in Licensor's or any of its Affiliates' possession and Control that constitutes Licensor Know-How, Joint Know-How or Regulatory Documentation or any other material Information that relates, directly or indirectly, to a Licensed Compound or Licensed Product or the Exploitation thereof (a) that is in existence as of the Effective Date, [****], but in no event more than [****], after the Effective Date or (b) that comes into existence after the Effective Date, promptly, but in no event more [****], after the earliest of the conception, discovery, development or other making of such Licensor Know-How, Joint Know-How, Regulatory Documentation or other Information. Without limiting the foregoing, Licensor shall, within [****] after the Effective Date, disclose or make available to AbbVie (x) (i) all non-clinical and clinical data for the Licensed Compounds and Licensed Products; provided that [****]. Licensor shall provide AbbVie with all [****] assistance required in order to transfer to AbbVie such Information and Regulatory Documentation required to be produced pursuant to this Section 4.1.1 in a [****] manner, and shall make available to AbbVie those of Licensor's representatives as AbbVie may [****] request for purposes of transferring such Information and Regulatory Documentation to AbbVie or for purposes of AbbVie acquiring expertise on the practical application of such Licensor Know-How and Regulatory Documentation. For clarity, nothing in this Section 4.1.1 shall require assignment or other transfer of ownership of Licensor Know-How or Regulatory Documentation, and ownership and transfer of Regulatory Documentation shall be governed by Section 5.1.2(d).

4.1.2 Transfer of Manufacturing Processes. Without limiting Section 4.1.1, at the Manufacturing Working Group's direction, Licensor shall, and shall cause its Affiliates and Third Party manufacturers to, (a) transfer to AbbVie or its designee all Licensor Know-How relating to the Manufacture of the Initial Licensed Product using the Initial Licensed Compound as of the time of such transfer (the "**Drug Product Manufacturing Process**") and (b) transfer to AbbVie or its designee all Licensor Know-How relating to the current Manufacture of the Initial Licensed Compound as drug substance as of the time of such transfer (the "**Drug Substance Manufacturing Process**") and provide such support as may be necessary or [****] useful to AbbVie or its designee to use and practice the Drug Product Manufacturing Process or the Drug Substance Manufacturing Process, as applicable, including by (x) causing all appropriate employees of Licensor and its Affiliates to, and [****] to cause the relevant Representatives (other than employees) or Third Party manufacturers of Licensor or its Affiliates, to meet with employees or representatives of AbbVie (or its designee) at the applicable manufacturing facility at mutually convenient times to (i) assist with the working up and use of the Drug Product Manufacturing

Process or the Drug Substance Manufacturing Process, as applicable, and with the training of the personnel of AbbVie (or its designee) to the extent necessary or reasonably useful to enable AbbVie (or its designee) to use and practice the Drug Product Manufacturing Process or the Drug Substance Manufacturing Process, as applicable, and (ii) support and execute the transfer of all applicable analytical methods and the validation thereof (including all applicable Licensor Know-How, methods, validation documents and other documentation, materials and sufficient supplies of all primary and other reference standards) and (y) making available documentation constituting material support, performance advice, shop practice, standard operating procedures, specifications as to materials to be used and control methods, in each case, that are necessary or reasonably useful to enable AbbVie (or its designee) to use and practice the Drug Product Manufacturing Process or the Drug Substance Manufacturing Process, as applicable; provided that (A) if, notwithstanding Licensor's use of [****] efforts or [****], as applicable, to provide all such Licensor Know-How related to the Drug Product Manufacturing Process or Drug Substance Manufacturing Process, if Licensor [****] fails to deliver to AbbVie any such Licensor Know-How but thereafter [****] delivers to AbbVie such Licensor Know-How upon its realization or receipt of AbbVie's notification of such failure, such initial failure shall not be deemed a breach under this Agreement and (B) AbbVie shall not seek any remedies under this Agreement with regard to any such failure without first notifying Licensor. Licensor shall use [****] to complete the transfer of the Drug Product Manufacturing Process and Drug Substance Manufacturing Process as set forth in this Section 4.1.2 within [****] after the Manufacturing Working Group directs Licensor to undertake such transfer. For a period of [****] following completion of such transfer, Licensor and its Affiliates shall provide such assistance as AbbVie (or its Affiliate or designated Third Party manufacturer, as applicable) may [****] request to enable AbbVie or any of its Affiliates or Third Party supplier(s) to use and practice the applicable Drug Product Manufacturing Process or Drug Substance Manufacturing Process. Licensor shall provide up to [****] FTE hours of consultation and assistance with qualified personnel in connection with the technology transfer activities set forth in this Section 4.1.2 at [****] cost to AbbVie (including with respect to any related [****] Costs), and during the period that Licensor provides such FTE hours at [****] cost to AbbVie, AbbVie shall bear its own internal and [****] Costs in connection with such technology transfer activities. Licensor shall [****] notify AbbVie in writing after Licensor has provided [****] FTE hours of consultation and assistance in connection with the technology transfer activities set forth in this Section 4.1.2, and thereafter the [****] Costs and [****] Costs of each Party for such technology transfer activities shall be deemed to be included in Other Shared Expenses.

4.1.3 Transfer of Existing Agreements. To perform the Manufacturing activities specified in Section 5.4, upon AbbVie's request, with respect to each Existing Agreement, Licensor shall (a) subject to any necessary consent(s) from any Third Party, assign to AbbVie such Existing Agreement (including any Existing Agreement with any Third Party manufacturer), (b) use [****] to facilitate, cooperate with and assist AbbVie in entering into its own agreement with the applicable Third Party counterparty or (c) terminate such Existing Agreement to the extent related to the Licensed Compounds and Licensed Products; provided that to the extent that the assignment by Licensor of any Existing Agreement pursuant to this Section 4.1.3 requires the separation of such agreement into an agreement that is retained by Licensor or such Affiliate and an agreement that is assignable to (or entered into by) AbbVie, the Parties will [****] cooperate to negotiate such separation as soon as practicable; provided that neither AbbVie nor any of its Affiliates shall be required to make any payments or agree to any [****] undertakings in connection therewith that are specific to activities prior to the separation, and until such

separation is executed, the Parties will [****] cooperate to provide to AbbVie the benefits under such agreement to the extent applicable to the rights granted to AbbVie under this Agreement; provided, further, that if any such Existing Agreement is required for Licensor to perform its obligations under this Agreement, (x) if AbbVie requests termination of such Existing Agreement in accordance with clause (c), Licensor shall not be obligated to terminate such Existing Agreement unless and until [****] and (y) if such Existing Agreement is assigned to AbbVie, the Parties will [****] cooperate to provide to Licensor the benefits under such agreement to the extent required for Licensor to perform such obligations.

ARTICLE 5
REGULATORY, DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURING ACTIVITIES

5.1 Regulatory.

5.1.1 Ownership of Regulatory Documentation. With respect to each country in the Territory, all Regulatory Documentation relating to the Licensed Compounds or Licensed Products in such country shall be owned by, and held in the name of, the MA Holder for such country or its designee.

5.1.2 United States. The provisions of this Section 5.1.2 shall apply with respect to regulatory activities for the Licensed Compounds and Licensed Products in the United States:

(a) The MA Holder for the United States shall have the sole right to prepare, obtain and maintain all Regulatory Documentation (including all INDs, Drug Approval Applications and Regulatory Approvals) and to prepare other submissions to, and conduct communications with, FDA, in each case, for the Licensed Compounds and Licensed Products in the United States in accordance with this Section 5.1.2; provided that [****]. The MA Holder for the United States shall use [****] to obtain and maintain Regulatory Approval of the Initial Licensed Product in the United States; provided that, [****].

(b) The MA Holder for the United States shall (i) provide the Non-MA Holder Party for the United States with an opportunity to review and comment on all material regulatory filings (including INDs and any amendments and supplements thereto) to, and material communications with, FDA and (ii) provide access to interim drafts of such filings and communications to the Non-MA Holder Party for the United States via the access methods (such as secure databases) mutually agreed by the Parties, and the Non-MA Holder Party for the United States shall provide its comments on the final drafts of such filings or communications within [****] (or [****] for Drug Approval Applications), or such other period of time mutually agreed to by the Parties. If FDA establishes a response deadline for any such filings or material communications shorter than such [****] period, the Parties shall work cooperatively to ensure that the Non-MA Holder Party for the United States has a [****] opportunity for review and comment within such deadlines. The MA Holder shall, and shall cause its Affiliates and Sublicensees to, consider [****] any timely comments of the Non-MA Holder Party.

(c) (i) The MA Holder shall provide the Non-MA Holder Party with prior written notice of any scheduled meeting, conference, inspection or discussion (including any advisory committee meeting) with the FDA relating to a Licensed Compound or Licensed Product, [****] after the MA Holder first receives notice of the scheduling of such meeting, conference or discussion; (ii) the Non-MA Holder Party shall have the right to have [****] of its employees attend and observe all such meetings, conferences, inspections and discussions to the extent related to a Licensed Compound or Licensed Product; (iii) the MA Holder will include the Non-MA Holder Party, to the extent practical, in any [****] meetings, conferences, inspections and discussions with the FDA concerning any pending IND, Drug Approval Application or any [****] regulatory matters relating to a Licensed Compound or Licensed Product in the United States; (iv) the Non-MA Holder Party shall attend and observe any meetings, conferences, inspections and discussions with the FDA as may be [****] requested by the MA Holder; and (v) the MA Holder for the United States shall provide the Non-MA Holder Party with copies of the minutes or summaries of all such meetings, conferences and discussions with the FDA to the extent provided by or to the FDA.

(d) **United States – NDA Transfer Date.** If and when the JDC decides that the MA Holder for the United States changes from one Party (the "**Current MA Holder**") to the other Party (the "**New MA Holder**"), then the Current MA Holder shall transfer all Regulatory Documentation in the United States owned by and held in the name of Current MA Holder to the New MA Holder, so that, as between the Parties, as of the NDA Transfer Date, the New MA Holder or its designee will be the owner and holder of all Regulatory Documentation in the United States. The Current MA Holder shall, at its sole cost and expense, provide all assistance to the New MA Holder to effectuate such transfer, including executing and delivering to the New MA Holder all necessary documents as may be reasonably requested by the New MA Holder for the United States in connection with such transfers.

5.1.3 OUS-Territory. The provisions of this Section 5.1.3 shall apply with respect to regulatory activities for the Licensed Compounds and Licensed Products in the OUS Territory:

(a) With respect to each country in the OUS Territory, the MA Holder for such country shall have the sole right to prepare, obtain and maintain all Regulatory Documentation (including all INDs, Drug Approval Applications and Regulatory Approvals) and to prepare other submissions to, and conduct communications with, all Regulatory Authorities, in each case, for the Licensed Compounds and Licensed Products in such country. The Non-MA Holder Party shall support the MA Holder, as may be [****] requested by the MA Holder, in obtaining and maintaining Regulatory Approvals for the Licensed Products in such country and supporting activities, including providing all documents or other materials as may be necessary or reasonably useful for the MA Holder to obtain and maintain Regulatory Approvals for the Licensed Products in such country and attending meetings with Regulatory Authorities with respect thereto in such country.

(b) With respect to each Designated Country, (i) the MA Holder for such Designated Country shall provide the Non-MA Holder Party for such Designated Country with an opportunity to review and comment on all [****] regulatory filings (including INDs and any amendments and supplements thereto) to, and [****] communications with, Regulatory

Authorities in such Designated Country and (ii) the MA Holder for such country shall provide access to interim drafts of such filings and communications to the Non-MA Holder Party for such country via the access methods (such as secure databases) mutually agreed by the Parties, and the Non-MA Holder Party for such Designated Country shall provide its comments on the final drafts of such filings or communications [****] (or [****] for Drug Approval Applications), or such other longer period of time mutually agreed to by the Parties. If any Regulatory Authority establishes a response deadline for any such filings or material communications shorter than such [****] period, the Parties shall work cooperatively to ensure that the Non-MA Holder Party for the applicable Designated Country has a [****] opportunity for review and comment within such deadlines. With respect to each Designated Country, the MA Holder shall, and shall cause its Affiliates and Sublicensees to, consider [****] any timely comments of the Non-MA Holder Party for such country.

(c) With respect to each Designated Country, (i) the MA Holder for such Designated Country shall provide the Non-MA Holder Party for such Designated Country with prior written notice, to the extent the MA Holder for such Designated Country has sufficient advance notice, of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with any Regulatory Authority in such Designated Country relating to a Licensed Compound or Licensed Product, within [****] after the MA Holder for such Designated Country first receives notice of the scheduling of such meeting, conference or discussion (or, if such meeting, conference or discussion will take place within [****] after it receives such notice, as soon as [****] practicable after the MA Holder for such Designated Country receives notice of the scheduling of such meeting, conference or discussion); (ii) the Non-MA Holder Party for such country shall have the right to have [****] of its employees attend as an observer all such meetings, conferences, and discussions to the extent related to a Licensed Compound or Licensed Product; (iii) the MA Holder for such Designated Country will include the Non-MA Holder Party for such Designated Country, to the extent practical, in any [****] meetings, conferences, and discussions with any Regulatory Authority in such country concerning any pending IND, Drug Approval Application or any [****] regulatory matters relating to a Licensed Compound or Licensed Product in such Designated Country; (iv) the Non-MA Holder Party shall attend and observe any meetings, conferences, and discussions with the FDA as may be [****] requested by the MA Holder; and (v) the MA Holder for such Designated Country shall provide the Non-MA Holder Party for such country with copies of the minutes or summaries of all such meetings, conferences, and discussions with any Regulatory Authority in such Designated Country to the extent provided by or to such Regulatory Authorities.

5.1.4 Recalls, Suspensions or Withdrawals.

(a) With respect to the United States, (i) the MA Holder for the United States shall use [****] efforts to notify the Non-MA Holder Party for the United States promptly (but in no event later than [****]) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the United States, and shall include in such notice the reasoning behind such determination, and any supporting facts; and (ii) the MA Holder for the United States shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in United States; provided that prior to any implementation of such recall, market suspension or market withdrawal, the MA Holder for

the United States shall, to the extent practicable, consult with the Non-MA Holder Party for the United States and shall consider the Non-MA Holder Party's comments [****]. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the United States, the MA Holder shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 5.1.4(a), the MA Holder shall be solely responsible for the execution thereof, and the Non-MA Holder Party shall [****] cooperate in all such efforts. Without limiting Article 10, (x) if and to the extent that a recall, market suspension or market withdrawal resulted from a Party's or any of its Affiliate's material breach of its obligations hereunder, or from such Party's or any of its Affiliate's gross negligence or willful misconduct, such Party shall be responsible for the costs and expenses of such recall, market suspension or market withdrawal incurred by or on behalf of either Party and (y) except as set forth in the foregoing clause (x), [****].

(b) With respect to each country in the OUS Territory, the MA Holder for such country shall have the right to make the final determination whether to voluntarily implement any recall, market suspension or market withdrawal of a Licensed Product in such country. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 5.1.4(b), the MA Holder shall be solely responsible for the execution thereof, and the Non-MA Holder Party shall [****] cooperate in all such efforts. Without limiting Article 10, (i) if and to the extent that a recall, market suspension or market withdrawal resulted from a Party's or any of its Affiliate's material breach of its obligations hereunder, or from such Party's or any of its Affiliate's gross negligence or willful misconduct, such Party shall be responsible for the costs and expenses of such recall, market suspension or market withdrawal incurred by or on behalf of either Party and (ii) except as set forth in the foregoing clause (i), [****].

5.1.5 Global Safety Database and Pharmacovigilance Agreement. The JDC shall appoint one (1) Party to hold and maintain the global safety database for the Licensed Products. If and when the JDC determines that the other Party shall be responsible for all or part of the global safety database, the Party that is holding and maintaining the global safety database for the Licensed Products shall promptly transfer such global safety database to the other Party. Upon a mutually agreed timeframe after receipt of Regulatory Approval for the Initial Licensed Product in the United States, the Parties shall enter into a safety reporting agreement pursuant to which one Party will provide the other Party the information necessary for such other Party to comply with its pharmacovigilance responsibilities in the Territory with respect to the Licensed Products, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States), in each case, in the form [****] requested by such Party. [****].

5.2 Development.

5.2.1 Generally. The Parties acknowledge and agree that there are no clinical studies or other Development activities with respect to the Licensed Compounds or Licensed Products (other than the activities set forth on **Schedule 5.2.1**) ongoing as of the Effective Date.

5.2.2 United States.

(a) **Development Plan.** There is no Development Plan in effect as of the Effective Date. If at any time after the Effective Date, either Party desires to initiate any clinical studies or other Development activities (other than the preparation and submission of Drug Approval Applications and regulatory affairs with respect to the foregoing) with respect to the Licensed Compounds or Licensed Products that is intended, in whole or in part, to support or maintain Regulatory Approval in the United States, then such Party, through its representatives on the JDC may propose an initial Development Plan. If the JDC approves the Development Plan, then thereafter, each Party, through its representatives on the JDC, may propose amendments to the Development Plan. Neither Party shall perform any clinical studies or other Development activities (other than the preparation and submission of Drug Approval Applications and regulatory affairs with respect to the foregoing) with respect to the Licensed Compounds and Licensed Products useful to support or maintain Regulatory Approval in the United States that are not set forth in the Development Plan.

(b) **Diligence.** Each Party shall use [****] to perform the activities allocated to it under the Development Plan.

5.2.3 OUS Territory. As between the Parties, AbbVie shall have the sole right, at its sole cost and expense, to perform all Development activities with respect to the Licensed Compounds and Licensed Products that are solely and specifically intended to support or maintain Regulatory Approval in [****] countries in the OUS Territory and, for clarity, such Development shall not be included in the Development Plan.

5.2.4 Compliance. Each Party shall perform, and cause to be performed, any and all Development activities for which such Party is responsible pursuant to the Development Plan in good scientific manner and in compliance with all Applicable Law.

5.2.5 Records. Each of AbbVie and Licensor shall, and shall cause its Affiliates and any Third Party subcontractor to, maintain complete, current and accurate records of all Development activities performed by or on behalf of such Party, and all data and other Information resulting from such Development activities, which records shall (a) be in [****] detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law, (b) [****] reflect all work done and results achieved in the performance of such Development activities and (c) record only such Development activities and not include or be commingled with records of activities that are not conducted under this Agreement. AbbVie or Licensor, as the case may be, shall retain, or cause to the retained, such records for at least [****] after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law. Each Party shall have the right, during [****] and upon reasonable notice, to inspect and copy all records of the other Party maintained at such other Party's place of business pursuant to this Section 5.2.5. The inspecting Party shall maintain such records and the Information disclosed therein in confidence in accordance with Article 8.

5.2.6 Reports. The JDC shall determine what reports shall be generated in respect of Development activities, including the content and timing thereof. Each Party shall [****] share all such reports with the JDC.

5.3 Commercialization.

5.3.1 United States.

(a) **Commercialization Plan.** The Parties shall conduct the Commercialization of the Licensed Products for the United States pursuant to the Commercialization Plan. [****] after the Effective Date, the JCC shall develop and approve the initial Commercialization Plan for the Initial Licensed Product in the United States. The JCC shall review the Commercialization Plan at least [****], and shall make updates and amendments thereto with respect to the Commercialization of the Licensed Products for the United States. The Parties acknowledge and agree that the Initial Licensed Product has only been Developed for the United States. If the JSC determines to Develop and seek Regulatory Approval for another Licensed Product in the United States, then the JCC shall prepare a Commercialization Plan for such Licensed Product by and when directed by the JSC. Neither Party shall perform any Commercialization activities with respect to the Licensed Products for the United States that are not allocated to such Party in the Commercialization Plan.

(b) **Diligence.** Upon receipt of Regulatory Approval for a Licensed Product in the U.S., each Party shall use [****] to perform the activities allocated to it under the Commercialization Plan.

(c) **Commercialization Responsibilities.** Licensor shall have the right to expand the scope of its Commercialization activities to perform up to [****] of the aggregate Commercialization activities [****] with respect to the Licensed Products in the United States by providing [****] written notice of such election (a "**Commercialization Expansion Notice**"), which notice must specify the percentage of such aggregate Commercialization activities that Licensor elects to perform (such percentage, the "**Licensor Commercialization Percentage**"). Thereafter, [****] shall amend the Commercialization Plan to include Licensor's performance of such activities consistent with Section 2.5.4. For clarity, prior to delivering the Commercialization Expansion Notice [****], Licensor may perform Commercialization activities with respect to the United States to the extent allocated to Licensor in the Commercialization Plan [****].

5.3.2 OUS Territory. As between the Parties, AbbVie shall have the sole right, at its sole cost and expense, to perform all Commercialization activities that are solely and specifically performed with respect to [****] countries in the OUS Territory and, for clarity, such Commercialization shall not be included in the Commercialization Plan.

5.3.3 Booking of Sales; Distribution. AbbVie (or its designee(s)) shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Licensed Products in the Territory and to perform or cause to be performed [****] services; provided that all such activities, including [****], must be consistent with the pricing and market access strategy for the Licensed Products set forth in the Commercialization Plan. AbbVie shall be responsible for [****] with respect to the Licensed Products in the Territory.

5.3.4 Compliance. Each Party shall perform, and cause to be performed, any and all Commercialization activities for which such Party is responsible in compliance in all [****] respects with all Applicable Law.

5.3.5 Reports.

(a) **United States.** The JCC shall determine what reports shall be generated in respect of Commercialization activities set forth in the Commercialization Plan, including the content and timing thereof. Each Party shall [****] share all such reports with the JCC.

(b) **OUS Territory.** Until the [****] of the First Commercial Sale of a Licensed Product in the OUS Territory, within [****] following [****] of each [****], AbbVie shall provide to Licensor a high-level report on the status of the Commercialization with respect to the Licensed Compounds and Licensed Products in the [****] period ending [****] or [****], as applicable.

5.4 Manufacturing and Supply. AbbVie shall be responsible for the Manufacture of Licensed Compounds and Licensed Products for Development and Commercialization hereunder, subject to any [****] supply arrangements approved by the Manufacturing Working Group, which may include establishing a [****] source of Licensed Compounds or Licensed Products, which [****] source may be a Party or a Third Party.

5.5 Subcontracting. AbbVie shall have the right to subcontract any of its Development, Manufacturing, Commercialization or other Exploitation activities to a Third Party. Except as set forth in the Development Plan or Commercialization Plan, as applicable, Licensor shall not subcontract any of its Development, Manufacturing or Commercialization activities to a Third Party that is not an Approved Subcontractor for the applicable activities. Each Party shall (a) be responsible for the acts and omissions of its subcontractors and (b) ensure that its Third Party subcontractors comply with the applicable terms and conditions of this Agreement, including Article 8.

ARTICLE 6
PAYMENTS AND RECORDS

6.1 Upfront Payment. In partial consideration of the rights granted by Licensor to AbbVie hereunder and subject to the terms and conditions set forth in this Agreement, no later than [****] following the Effective Date, AbbVie shall pay Licensor a non-refundable, non-creditable upfront payment equal to One Hundred Million Dollars ($100,000,000) less any amounts paid by AbbVie to Licensor pursuant to the Option Agreement.

6.2 Milestones. In partial consideration of the rights granted by Licensor to AbbVie hereunder and subject to the terms and conditions of this Agreement (including Section 11.7), AbbVie shall pay to Licensor a non-refundable, non-creditable one-time milestone payment within [****] after the first achievement of the applicable milestone event with respect to a Licensed Product by or on behalf of AbbVie or its Affiliates or its or their Sublicensees, as follows:

Milestone Event	Milestone Payment
First receipt of Regulatory Approval for a Licensed Product in the U.S. for the treatment of the signs and symptoms of dry eye disease	One Hundred Million Dollars ($100,000,000)
[****] of the aggregate of commercial insurance patients and Medicare patients have access to the Initial Licensed Product that is covered by commercial insurance or Medicare, as applicable, as determined pursuant to the formulary data provided by Managed Markets Insights and Technology	[****]
Net Sales of all Licensed Products made by AbbVie or any of its Affiliates or its or their Sublicensees during any [****] ending on the last day of [****] period [****] following receipt of the first Regulatory Approval for a Licensed Product in the U.S. exceed [****]	[****]

Each milestone payment in this Section 6.2 shall be payable only upon the first achievement of such milestone event and no amounts shall be due for subsequent or repeated achievements of such milestone event, whether for the same or a different Licensed Product or for the same or a different indication. The maximum aggregate amount payable by AbbVie for all Licensed Products pursuant to this Section 6.2 is Three Hundred Million Dollars ($300,000,000).

6.3 Profit or Loss in the United States. The terms and conditions of this Section 6.3 shall govern each Party's rights and obligations with respect to Net Profits and Net Losses relating to the Licensed Products in the United States.

6.3.1 In General. Subject to Section 6.3.2 and Section 6.7, (a) Licensor shall receive forty percent (40%) of all Net Profits and bear forty percent (40%) of all Net Losses, as applicable, with respect to the Licensed Products in the United States, and (b) AbbVie shall receive sixty percent (60%) of all Net Profits and bear sixty percent (60%) of all Net Losses, as applicable, with respect to the Licensed Products in the United States. For clarity, Net Sales and Allowable Expenses that relate to the Exploitation of the Licensed Product during the Term but that are incurred after the Term shall continue to be shared by the Parties as provided in this Section 6.3.1.

6.3.2 Overruns. If the Development Expenses or Commercialization Expenses incurred by a Party for [****] exceed the aggregate amounts budgeted for such Party in the applicable Development Plan or Commercialization Plan, as applicable, for such [****] (and taking into account any amendments to such Development Plan or Commercialization Plan, as applicable, that may be approved during such [****]) by more than [****], such excess Development Expenses or Commercialization Expenses, as applicable (each, an "**Overrun**") shall be borne by the Party incurring the applicable Development Expenses or Commercialization Expenses, as applicable (for purposes of this Section 6.3.2, the "**Responsible Party**") and shall be excluded from "Development Expenses" or "Commercialization Expenses", as applicable, hereunder; provided that [****] shared by the Parties pursuant to Section 6.3.1.

6.4 Calculation and Payment of Net Profit or Net Loss Share.

6.4.1 Reports and Payments in General. Within [****] after the end of each [****], (i) AbbVie shall provide Licensor with a flash report setting forth AbbVie's [****] estimate of (A) the Net Sales of Licensed Products in the United States for such [****] and (B) the gross profits or losses in the United States for such [****] and (ii) each Party shall provide the other Party with a flash report setting forth such Party's [****] estimate of the Allowable Expenses incurred by such Party for Licensed Products for such [****]. Within [****] after the end of each [****], (x) AbbVie shall report to Licensor the Net Sales of Licensed Products in the United States for such [****] and (y) each Party shall report to the other Party Allowable Expenses incurred by such Party for Licensed Products for such [****], in each case, in a manner sufficient to enable the other Party to calculate Net Profits or Net Losses for such [****]. Such report shall specify in [****] detail all expenses included in Allowable Expenses, and, if requested by a receiving Party, any invoices or other supporting documentation for any payments to a Third Party that individually exceed [****] (or such other amount approved by the JSC) shall be promptly provided. Within [****]s after the end of each [****] (or for the last [****] in a [****], [****] after the end of such [****]), the Parties shall reconcile all Net Sales and Allowable Expenses to ascertain whether there is a Net Profit or Net Loss and payments shall be made as set forth in subsections (a) and (b) below, as applicable.

(a) If there is a Net Profit for such [****], then, no later than [****] after the end of such [****], AbbVie shall make a reconciling payment to Licensor to ensure that Licensor receives an amount equal to its percentage of the Net Profit set forth in Section 6.3.1 for such [****] (taking into account any Allowable Expenses incurred by Licensor in such [****]); or

(b) If there is a Net Loss for such [****], then, subject to Section 6.4.1(c), no later than [****] after the end of such [****], the Party that has borne less than its share of the Net Loss in such [****] (taking into account Net Sales of Licensed Products made by or on behalf of AbbVie in such [****]) shall make a reconciling payment to the other Party to ensure that each Party bears its respective percentage of such Net Loss as set forth in Section 6.3.1 during such [****].

(c) If, Licensor's share of aggregate Net Losses for any Calendar Year exceeds [****] (the "**Annual Net Loss Threshold**"), then Licensor shall have the option to defer paying its share of Net Losses for such [****] that exceed the Annual Net Loss Threshold (such right, a "**Deferral Option**" and such Net Losses, "**Deferred Net Losses**"). Licensor may exercise its Deferral Option with respect to any [****] by providing written notice of such exercise (a "**Deferral Notice**") during the [****] period commencing upon the reconciliation of all Net Sales and Allowable Expenses in which Licensor's share of Net Losses for such [****] would exceed the Annual Net Loss Threshold. With respect to each [****] for which Licensor timely provides a Deferral Notice, (i) Licensor shall not be obligated to make any reconciling payment pursuant to Section 6.4.1(b) with respect the Deferred Net Losses for such [****] and (ii) AbbVie shall have the right to offset an amount equal to such Deferred Net Losses plus interest accruing from the date of the Deferral Notice in accordance with Section 6.10 from amounts otherwise payable to Licensor under this Agreement.

6.4.2 Last [****]. No separate payment shall be made for Net Profits or Net Losses for the last [****] in any [****]. Instead, at the end of each such [****], a final reconciliation shall be conducted by comparing the share of Net Profit or Net Loss to which a Party is otherwise entitled for such [****] pursuant to Section 6.3 against the sum of all amounts (if any) previously paid or retained by such Party for prior [****] during such [****], and the Parties shall make reconciling payments to one another no later than [****] after the end of such [****], if and as necessary to ensure that each Party receives for such [****] its share of Net Profits or bears its share of Net Losses in accordance with Section 6.3.

6.4.3 [****] Records and Calculations. Except for the [****] hours of consultation and assistance with qualified personnel in connection with the technology transfer activities set forth in Section 4.1.2 to be provided by Licensor at [****] cost to AbbVie, neither Party shall be required to record the actual [****] hours worked and all [****] Costs shall be charged for the applicable [****] at the budgeted amount. Licensor shall maintain records of the [****] hours of consultation and assistance with qualified personnel in connection with the technology transfer activities set forth in Section 4.1.2 provided at [****] cost to AbbVie in the same manner as used for other products developed by Licensor.

6.4.4 Adjustment of [****] Rates. The [****] Rates applicable to activities undertaken by either Party are subject to adjustments effective on [****] of each [****], with the first such [****] adjustment to be made as of [****] based on the total percentage change in the all [****] cost index for total compensation for [****] published by the United States Department of Labor, Bureau of Labor Statistics (as reported on the Bureau of Labor Statistics website) over the [****] ending on the last [****] of the [****] of the immediately preceding [****], or as otherwise agreed to by the Parties.

6.5 Royalties in the OUS Territory.

6.5.1 Royalty Rate. As further consideration for the rights granted to AbbVie hereunder, subject to Section 6.5.2, Section 6.5.3 and Section 6.5.5, commencing upon the First Commercial Sale of a Licensed Product in the OUS Territory, AbbVie shall pay to Licensor a tiered royalty equal to the percentages of annual Net Sales on a Licensed Product-by-Licensed Product basis in the OUS Territory, as set forth below, calculated by multiplying the applicable royalty rate percentage by the corresponding portion of aggregate annual Net Sales for such Licensed Product in such [****]. For clarity, the royalty rates set forth below are intended to be tiered and incremental, and the higher incremental rate will only apply to that portion of the Net Sales of royalty-bearing Licensed Products that fall within the indicated range of sales. Notwithstanding the royalty rates set forth below, all royalties payable pursuant to this Section 6.5.1 are subject to reduction and offset, as further described in Section 6.5.3, Section 6.5.5 or as expressly stated elsewhere in this Agreement.

	Increments of Aggregate Annual Net Sales of each Licensed Product in the OUS Territory in a Calendar Year	Royalty Rate
(1)	Portion of Net Sales during [****] of such Licensed Product in the OUS Territory up to and including [****]	[****]
(2)	Portion of Net Sales during [****] of such Licensed Product in the OUS Territory greater than [****] and up to and including [****]	[****]
(3)	Portion of Net Sales during [****] of such Licensed Product in the OUS Territory greater than [****]	[****]

6.5.2 Royalty Term. AbbVie shall have no obligation to pay any royalty with respect to Net Sales of any Licensed Product in any country in the OUS Territory after the Royalty Term for such Licensed Product in such country has expired. With respect to each Licensed Product in each country in the OUS Territory, from and after [****] of the Royalty Term for such Licensed Product in such country, (a) the grants in Section 3.1 shall become unrestricted, fully-paid, royalty-free, perpetual and irrevocable with respect to such Licensed Product in such country and (b) Net Sales of such Licensed Product in such country shall be excluded for purposes of calculating the royalties in this Section 6.5.

6.5.3 Royalty Reductions. Notwithstanding Section 6.5.1 but subject to Section 6.6:

(a) in the event that, and in such case from and after the first [****] during which, a Licensed Product is Commercialized in a country in the OUS Territory and is not claimed by a Valid Claim of [****] in such country or other jurisdiction, then the royalty rate set forth in Section 6.5.1 with respect to such Licensed Product shall be reduced by [****] in such country;

(b) in the event that, and in such case from and after the first [****] during which Net Sales for a Licensed Product in a country are at least [****] less than the Net Sales for such Licensed Product in such country during the [****] preceding the [****] during which a Generic Product for such Licensed Product is first sold in such country, the royalty rate set forth in Section 6.5.1 with respect to such Licensed Product shall be reduced by [****] in such country; and

(c) if a court or a governmental agency of competent jurisdiction requires AbbVie or any of its Affiliates or its or their Sublicensees to grant a compulsory license to a Third Party permitting such Third Party to make and sell a Licensed Product in a country in the OUS Territory, then the royalty rate set forth in Section 6.5.1 with respect to such Licensed Product shall be reduced by [****] in such country.

6.5.4 Royalty Payments and Reports. Following the First Commercial Sale of any Licensed Product in the OUS Territory, AbbVie shall calculate all amounts payable to Licensor pursuant to Section 6.5 at the end of each [****], which amounts shall be converted to

Dollars, in accordance with Section 6.7. AbbVie shall provide Licensor with an estimate of royalty amounts that will be due for a [****] within [****] after the end of such [****]. AbbVie shall pay to Licensor the royalty amounts due with respect to a given [****] within [****] after the end of such [****]. Each payment of royalties due to Licensor shall be accompanied by a statement of the amount of Net Sales of each Licensed Product in the OUS Territory during the applicable [****] and a calculation of the amount of royalty payment due on such Net Sales for such [****].

6.5.5 Offset for Third Party Payments.

(a) AbbVie shall be entitled to deduct from any royalties payable under Section 6.5.1 (as may be adjusted pursuant to Section 6.5.3), [****] of all Third Party Payments to the extent [****] identifiable or [****] allocable to the Exploitation of a Licensed Product for the OUS Territory.

(b) Notwithstanding the foregoing, AbbVie shall be entitled to deduct from any royalties payable under Section 6.5.1 (as may be adjusted pursuant to Section 6.5.3), [****] of all Third Party Payments that are attributable to (i) a [****] or (ii) Licensor's [****] breach of its representations and warranties hereunder.

(c) AbbVie shall keep Licensor [****] informed regarding the negotiations of the agreement pursuant to which AbbVie would owe such Third Party Payments and any amounts offset by AbbVie pursuant to this Section 6.5.5 shall be considered in any calculation of damages with respect to applicable material breach by Licensor of its representations and warranties hereunder.

6.5.6 Aggregate Limitation on Reductions and Offsets. Notwithstanding Section 6.5.3 and Section 6.5.5, in no event will the combined effect of all reductions or offsets to the royalties payable to Licensor under Sections 6.5.3 and 6.5.5 combined reduce the royalty payable by AbbVie to Licensor under this Section 6.5 for any Licensed Product in any country during a [****] to less than [****] of the amount that would otherwise be due under Section 6.5.1, but for such reductions or offsets; provided, that the foregoing limitation does not apply to any reduction under Section 6.5.5 for Third Party Payments that are attributable to (a) [****] or (b) Licensor's [****] breach of its representations and warranties hereunder. Offsets or reductions not exhausted in any [****] may be carried into future [****], subject to the foregoing limitation.

6.6 Mechanics of Adjustments. Any adjustments pursuant to Section 6.5.3 shall apply only to the relevant Licensed Product in the relevant country in the OUS Territory and shall be allocated [****] across each of the royalty tiers in the relevant [****].

6.7 Mode of Payment; Offsets. All payments to a Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as such Party may from time to time designate by notice to the other Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), each Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or its or their Sublicensee's standard conversion methodology consistent with Accounting Standards. [****]

6.8 Withholding Taxes. Where any sum due to be paid to either Party hereunder is or would otherwise be subject to any withholding or similar tax, the Parties shall cooperate with each other and use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to secure any available exemption from, reduction in, or refund of such tax, including by taking advantage of any applicable double taxation agreement or treaty. In the event there is no applicable exemption from such withholding or similar tax, the payor shall remit such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of the payment of such withholding or similar tax. Any such amounts deducted by the payor in respect of such withholding or similar tax shall be treated as having been paid by the payor for purposes of this Agreement. In the event that a government authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and such Party (the "**Withholding Party**") remits such withholding or similar taxes to the government authority, including any interest and penalties that may be imposed thereon (together with the tax paid, the "**Withholding Amount**"), the Withholding Party will have the right (a) to offset the Withholding Amount against future payment obligations of the Withholding Party under this Agreement, (b) to invoice the other Party for the Withholding Amount (which shall be payable by the other Party [****] of its receipt of such invoice) or (c) to pursue reimbursement by any other available remedy. [****] upon entering into this Agreement, Licensor shall furnish to AbbVie a properly completed and validly executed Internal Revenue Service Form W-9 certifying that Licensor is not subject to backup withholding.

6.9 Indirect Taxes. All payments are exclusive of value added taxes, sales taxes, consumption taxes and other similar taxes (the "**Indirect Taxes**"). If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the other Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part subsequently determined not to have been chargeable, all necessary steps will be taken by the other Party to receive a refund of these undue Indirect Taxes from the applicable governmental authority or other fiscal authority and any amount of undue Indirect Taxes repaid by such authority to the other Party will be transferred to the paying Party within [****] of receipt.

6.10 Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at [****], such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

6.11 Financial Records. Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Net Sales (with respect to AbbVie), Allowable Expenses and any reimbursable costs or expenses hereunder in sufficient detail to calculate all amounts payable hereunder. Such books and records shall be retained by such Party and its Affiliates until the later of (a) [****] after the end of the period to which such books and

records pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

6.12 Audit.

6.12.1 Procedures. At the request of the other Party, each Party shall, and shall cause its Affiliates to, permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to Section 6.11 to ensure the accuracy of all reports and payments made hereunder. Such audits may not (a) be conducted for any [****] more [****] after the end of such [****], (b) be conducted more than once in any [****] period or (c) be [****]. The accounting firm shall disclose only whether the reports are correct or not and the specific details concerning any discrepancies. No other information shall be shared. Except as provided below, the cost of any audit shall be borne by the auditing Party, unless the audit reveals a variance of more than the greater of [****] from the reported amounts or [****] in which case the audited Party shall bear the cost of such audit. Unless disputed pursuant to Section 6.12.2, if such audit concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts (and, if such additional amounts are owed due to an error in an invoice or report provided by the audited Party, with interest thereon as provided in Section 6.10), or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments (and, if such excess payments were made due to an error in an invoice or report provided by the auditing Party, with interest thereon as provided in Section 6.10), in either case ((i) or (ii)), within [****] after the date on which such audit is completed by the auditing Party.

6.12.2 Audit Dispute. In the event of a dispute with respect to any audit under Section 6.12.1, Licensor and AbbVie shall work [****] to resolve such dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [****], such dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Audit Arbitrator**"). The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than [****] after such decision and in accordance with such decision, the audited Party shall pay the additional amounts (and, if such additional amounts are owed due to an error in an invoice or report provided by the audited Party, with interest thereon as provided in Section 6.10), or the auditing Party shall reimburse the excess payments (and, if such excess payments were made due to an error in an invoice or report provided by the auditing Party, with interest thereon as provided in Section 6.10), as applicable.

6.12.3 Confidentiality. The receiving Party shall treat all information subject to review under this Article 6 in accordance with the confidentiality provisions of Article 8, and (a) the auditing Party shall cause its independent accounting firm and (b) the Parties shall cause the Audit Arbitrator, in each case ((a) and (b)), to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

6.13 Third Party Obligations. Licensor shall be responsible for all payments owed to Third Parties under any license and other agreements regarding any intellectual property rights in-licensed by Licensor or its Affiliates, including any agreement pursuant to which Licensor or any of its Affiliates has rights with respect to any Licensed Compound or Licensed Product.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1 IP Group.

7.1.1 [****] after the Effective Date, the Parties shall establish an intellectual property group (the "**IP Group**") to provide a forum for the Parties to discuss and coordinate activities with respect to intellectual property matters related to this Agreement. The IP Group shall (a) discuss the Patent strategy for the Licensed Compounds and Licensed Product, (b) determine the US Product Trademarks, (c) determine the Scheduled TM Quality Standards and (d) make certain decisions as set forth in this Article 7. The IP Group shall consist of at least [****] from each Party. The IP Group shall meet as necessary or reasonably useful, with the location of such meetings to be determined by the IP Group. Decisions of the IP Group shall be made by consensus. The IP Group shall operate by consensus, except that if the IP Group cannot, or does not, reach consensus on a US Product Trademark issue at a meeting, then [****] shall have the right to finally and definitively resolve such issue; provided that the Parties acknowledge and agree that [****] right under Section [****] shall remain in place with respect to the [****] Trademarks. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in the IP Group unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The IP Group shall not have the power to amend, modify or waive compliance with this Agreement, which may only be amended or modified as provided in Section 12.9 or compliance with which may only be waived as provided in Section 12.12. For clarity, the IP Group is not a Working Group under Section 2.4.

7.2 Ownership of Intellectual Property.

7.2.1 Ownership of Technology. Subject to Section 7.2.2, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all: (a) Information, Improvements and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party (or its Affiliates or its or their respective (sub)licensees/Sublicensees) under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto, except to the extent that any such Information, Improvement or invention, or any Patent or intellectual property rights with respect thereto, is Joint Know-How or Joint Patents; and (b) other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants set forth in Section 3.1 or Section 3.2) by such Party or any of its Affiliates or its or their respective (sub)licensees/Sublicensees outside of this Agreement.

7.2.2 Ownership of Joint Patents and Joint Know-How. As between the Parties, the Parties shall each own an equal, undivided interest in any and all: (a) Information,

Improvements and other inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of Licensor or its Affiliates or its or their (sub)licensees, on the one hand, and AbbVie or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, whether or not patented or patentable (the "**Joint Know-How**"); and (b) Patents (the "**Joint Patents**") and other intellectual property rights with respect to the Information, Improvements and inventions described in clause (a) (together with Joint Know-How and Joint Patents, the "**Joint Intellectual Property Rights**"). Each Party shall [****] disclose to the other Party in writing and shall cause its Affiliates, and its and their (sub)licensees/Sublicensees to so disclose, the conception, discovery, development or making of any Joint Know-How or Joint Patents. Subject to the licenses and rights of reference granted under Section 3.1 and, in the case of Licensor, its obligations under Section 3.7.1 and with respect to Product Information under Article 8, (x) each Party shall have the right to practice, grant licenses under and transfer its interest in any Joint Intellectual Property Rights, (y) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any Joint Intellectual Property Rights by reason of joint ownership thereof and (z) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

7.2.3 United States Law. The determination of whether Information, Improvements and inventions are conceived, discovered, developed or otherwise made by or on behalf of a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs. In the event that such United States law does not apply to the conception, discovery, development or making of any Information, Improvements or other inventions hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information, Improvements and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, (a) the sole ownership provided for in Section 7.2.1 and (b) the joint ownership provided for in Section 7.2.2.

7.2.4 Assignment Obligation. Each Party shall cause all Persons who perform Development, Manufacturing or regulatory activities for such Party under this Agreement to be under an obligation to assign their rights in any Information, Improvements and other inventions resulting therefrom to such Party, except where Applicable Law requires otherwise (in which case a suitable license, or right to obtain such a license, shall be obtained). Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information, Improvements and other inventions, as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, (a) the sole ownership provided for in Section 7.2.1 and (b) the joint ownership provided for in Section 7.2.2.

7.3 Control of Intellectual Property. Licensor shall not enter into or amend any agreement with a Third Party, or include in any such agreement or amendment any restrictive provisions, with an intent to limit its Control of, or to not Control, any Information, Patent or other intellectual property right that would be subject to the license grants in Section 3.1 in the absence of such agreement, amendment or restrictive provisions. Further, when entering into any

agreement or amendment with a Third Party relating to any Information, Patents or other intellectual property rights that, if Controlled by Licensor or its Affiliates, would be subject to the license grants in Section 3.1, Licensor shall use [****] reasonable efforts to obtain Control of such Information, Patents and other intellectual property rights.

7.4 Maintenance and Prosecution of Patents.

7.4.1 Licensor Patents. As between the Parties, Licensor shall have the [****] right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain the [****] Patents, other than the [****] Patents, in the Territory, at its sole cost and expense. With respect to any pending claims of any [****] Patents, Licensor shall, to the extent procedurally able to do so in the relevant jurisdiction, within [****] after [****], amend such pending claims to claim solely any Licensed Compound or any of its uses or formulations or a method of making any Licensed Compound, thereby creating a [****] Patent. Licensor shall send instructions to foreign counsel/agents to accomplish the foregoing no later than [****] after [****]. After [****], Licensor shall not pursue or permit issuance of any [****] Patents. For clarity this Section 7.4.1 shall not apply to control of Defense Proceedings, which proceedings shall be governed by Section 7.6.

7.4.2 AbbVie Patents and Joint Patents. As between the Parties, AbbVie shall have (a) the [****] right, but not the obligation, to prepare, file, prosecute and maintain the [****] Patents in the Territory and (b) the [****] right, but not the obligation, to prepare, file, prosecute and maintain the [****] Patents and[****]Patents in the Territory, in each case ((a) and (b)), using counsel of its own choice, at AbbVie's sole cost and expense. For clarity this Section 7.4.2 shall not apply to control of Defense Proceedings, which proceedings shall be governed by Section 7.6.

7.4.3 Step-In. If, as between the Parties, the Party with the [****] right to prepare, file, prosecute or maintain any [****] Patent or [****] Patent in a country or other jurisdiction in the Territory decides not to do so, such Party shall provide [****] prior written notice to the other Party of such intention (which notice shall, in any event, be given no later than [****] prior to the next deadline for any action that may be taken with respect to such [****] Patent or [****] Patent in such country or other jurisdiction), and the other Party shall thereupon have the option to assume the control and direction of the preparation, filing, prosecution and maintenance of such [****] Patent or [****] Patent at its sole cost and expense in such country or jurisdiction; provided that (a) with respect to any [****] Patent, Licensor's exercise of such option shall be subject to [****] prior written consent (not to be unreasonably withheld, conditioned or delayed) and (b) with respect to any [****] Patent, AbbVie will only have the step-in rights set forth in this Section 7.4.3 with respect to [****] Patents, and AbbVie shall not pursue or permit issuance of any [****] Patent that includes any claims directed to or encompassing any RASP Inhibitor other than a Licensed Compound.

7.4.4 Cooperation.

(a) With respect to [****] Patents and [****] Patents, the prosecuting Party shall [****] inform the other Party of all material steps with regard to the preparation, filing, prosecution and maintenance of such [****] Patents and [****] Patents in the

Territory, including by providing the other Party with a copy of material communications to and from any patent authority in the Territory regarding such [****] Patents and [****] Patents and by providing the other Party drafts of any material filings or responses to be made to such patent authorities in the Territory in connection therewith sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the other Party to review and comment thereon. The prosecuting Party shall consider [****] the requests and suggestions of the other Party with respect to such drafts and with respect to strategies for filing and prosecuting such [****] Patents and [****] Patents in the Territory; provided that, unless otherwise agreed by [****], Licensor shall implement all requests and suggestions of AbbVie with respect to Licensor's activities under this Section 7.4 with respect to the [****] Patents.

(b) The Parties shall cooperate fully in the preparation, filing, prosecution and maintenance of the [****] Patents, [****] Patents and [****] Patents in the Territory under this Agreement; provided that, except with respect to the [****] Patents, the prosecuting Party shall reimburse the non-prosecuting Party for its [****] Costs incurred in connection with any cooperation activities requested by the prosecuting Party. Cooperation shall include:

(i) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (A) effectuate the ownership of intellectual property set forth in Section 7.2.1 and Section 7.2.2, as applicable; (B) enable the other Party to apply for and to prosecute Patent applications in the Territory; and (C) obtain and maintain any Patent extensions, supplementary protection certificates, and the like with respect to the [****] Patents, [****] Patents and [****] Patents in the Territory, in each case ((A), (B), and (C)), to the extent provided for in this Agreement;

(ii) consistent with this Agreement, assisting in any license registration processes with applicable governmental authorities that may be available in the Territory for the protection of a Party's interests in this Agreement; and

(iii) [****] informing the other Party of any matters coming to such Party's attention that may materially affect the preparation, filing, prosecution or maintenance of any such [****] Patents, [****] Patents or [****] Patents in the Territory.

7.4.5 Patent Term Extension and Supplementary Protection Certificate. As between the Parties, AbbVie shall have the [****] right, after consultation with the IP Group, to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the [****] Patents and [****] Patents, [****] Patents and any [****] Patents, in each case, including whether or not to do so. Licensor shall, and shall cause its Affiliates to, provide [****] assistance, as requested by AbbVie, including by taking such action as patent holder as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

7.4.6 Common Ownership Under Joint Research Agreements. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in

35 U.S.C. §100(h). Notwithstanding anything to the contrary in this Agreement, neither Party shall invoke this Agreement under 35 U.S.C. §102(c) to except any patent or patent application as prior art without the prior written consent of the other Party. If such written consent is granted, the Parties shall coordinate their activities with respect to all submissions under 35 U.S.C. §102(c).

7.4.7 Patent Listings. As between the Parties, after consultation with the IP Group, AbbVie shall have the [****] right to make all filings with Regulatory Authorities in the Territory with respect to the [****] Patents, [****] Patents and [****] Patents as required or allowed (a) in the United States, in FDA's Orange Book, (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, or (c) other international equivalents in the Territory.

7.4.8 UPC Opt-Out and Opt-In. As between the Parties, AbbVie shall have the right to make any decision regarding whether or not to elect Opt-Out or Opt-In with respect to any [****] Patents and [****] Patents, [****] Patents and [****] Patents; provided that AbbVie shall consider [****] Licensor's comments with respect thereto with respect to [****] Patents, [****] Patents and [****] Patents.

7.5 Enforcement of Patents.

7.5.1 Notice. Each Party shall [****] notify the other Party in writing of any alleged or threatened infringement of a [****] Patent or [****] Patent of which such Party becomes aware.

7.5.2 Enforcement of Infringement Actions. As between the Parties, AbbVie shall have the [****] right in the Territory, but not the obligation, to prosecute (a) any alleged or threatened infringement of the [****] Patents, [****] Patents, [****] Patents or [****] Patents by a product in the Field in any jurisdiction in the Territory (an "**Infringement**") or (b) any alleged or threatened infringement of the [****] Patents by a Competing Product, including any Generic Product (or the Exploitation thereof) in the Field in any jurisdiction in the Territory (a "**Competitive Infringement**"), including as a defense or counterclaim in connection with any Third Party Infringement Claim, at AbbVie's sole cost and expense, using counsel of its own choice. In the event AbbVie prosecutes any Infringement or Competitive Infringement, Licensor shall have the right to join as a party to such claim, suit or proceeding and participate with its own counsel at its sole cost and expense; *provided* that AbbVie shall retain control of the prosecution of such claim, suit or proceeding. If AbbVie or its designee does not take [****] reasonable steps to prosecute or settle an Infringement or Competitive Infringement (i) within [****] following the first notice provided above with respect to the Infringement or (ii) provided such date occurs after the first such notice of the Infringement is provided, [****] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensor may prosecute such Infringement or Competitive Infringement at its sole cost and expense; *provided* that Licensor's right to prosecute such Infringement or Competitive Infringement shall be subject to the approval of [****]. Licensor shall not institute any action or discussions with respect to an Infringement or Competitive Infringement without [****] approval. In the event of any alleged or threatened infringement of any [****] Patents, by a Third Party product in the Field that is not a Competitive Infringement in any jurisdiction in the Territory, AbbVie shall have the right to request that Licensor grant AbbVie the right to prosecute such infringement, which

Licensor agrees to consider [****]. Notwithstanding the definition of "Royalty Term," if AbbVie is unable to prosecute an Infringement or a Competitive Infringement of any [****] Patent due to [****], such [****] Patent shall (A) no longer be considered a [****] Patent for purposes of clause (b) of the definition of "Royalty Term" and (B) be deemed to be expired for purposes of Section 6.5.3(a).

7.5.3 Cooperation; Settlement. The Parties agree to cooperate fully in any infringement action pursuant to this Section 7.5. Where a Party controls an infringement action under this Section 7.5, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may [****] request from time to time, in connection with its activities set forth in this Section 7.5, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees available at reasonable business hours. Each Party shall be responsible for its own costs and expenses incurred in connection with its activities set forth in this Section 7.5; provided that if the controlling Party requests the cooperation of the other Party pursuant to this Section 7.5.3, the controlling Party shall reimburse such other Party for its [****] Costs incurred in connection therewith. Unless otherwise set forth herein, the Party entitled to bring an infringement action in accordance with this Section 7.5 shall have the right to settle such claim; provided that Licensor shall not have the right to settle any Infringement or Competitive Infringement under this Section 7.5 without [****] approval in the United States, not to be unreasonably withheld, delayed or conditioned. In the event that Licensor controls any Infringement or Competitive Infringement claim, suit or proceeding pursuant to this Section 7.5, Licensor shall (x) consult with AbbVie as to the strategy for the prosecution of such claim, suit or proceeding, (y) consider [****] any comments from AbbVie and (z) keep AbbVie [****] informed of any material steps taken and provide copies of all material documents filed in connection with such claim, suit or proceeding.

7.5.4 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement and except with respect to costs incurred by a Party that joins and participates in such claim, suit or proceeding at its sole cost and expense as set forth in this Section 7.5, any recovery realized as a result of such claim, suit or proceeding described above in this Section 7.5 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery. Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to bring the claim, suit or proceeding; provided, however, that (a) if AbbVie controls such claim, suit or proceeding, to the extent that any award or settlement (whether by judgment or otherwise) with respect to a [****] Patent, [****] Patent or [****] Patent is attributable to loss of sales or profits with respect to a Licensed Product, such amount shall be paid to or retained by AbbVie and treated as "Net Sales" in the [****] in which the money is actually received for purposes of calculating Net Profits pursuant to Section 6.3 and royalties pursuant to Section 6.5, as applicable and (b) if Licensor controls such claim, suit or proceeding, then the Parties shall negotiate [****] an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to the applicable Licensed Product.

7.6 Invalidity or Unenforceability Defenses or Actions.

7.6.1 Notice. Each Party shall [****] notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the [****] Patents, [****] Patents or [****] Patents by a Third Party of which such Party becomes aware.

7.6.2 Defense Actions. As between the Parties, AbbVie shall have (a) the [****] right, but not the obligation, to defend and control the defense (including any Defense Proceedings) of the validity and enforceability of the [****] Patents and (b) the [****] right, but not the obligation, to defend and control the defense (including any Defense Proceedings) of the validity and enforceability of the [****] Patents, [****] Patents and the [****] Patents, in each case ((a) and (b)), in the Territory, using counsel of its own choice, at AbbVie's sole cost and expense; provided that if the assertion of invalidity or unenforceability of such Patents is brought as a defense or counterclaim in connection with an infringement action initiated pursuant to Section 7.5, the applicable enforcing Party shall have the [****] right, but not the obligation, to defend and control the validity and enforceability of such Patents at its sole cost and expense. Nothing in this Section 7.6 will limit any indemnification rights or obligations of a Party under Article 10.

7.6.3 Step-In. If AbbVie elects not to defend or control the defense (including any Defense Proceedings) of the [****] Patents, [****] Patents or [****] Patents in a claim, suit or proceeding arising under this Section 7.6 brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, and, in either case, has not settled and is not actively pursuing settlement of such claim, suit or proceeding, then, with [****] prior approval (not to be unreasonably withheld, conditioned or delayed), Licensor may conduct and control the defense of any such claim, suit or proceeding in the Territory, at Licensor's sole cost and expense; provided that Licensor shall obtain the written consent of AbbVie prior to settling or compromising any such claim, suit or proceeding with respect to any [****] Patent.

7.6.4 Participation; Cooperation. The non-controlling Party may participate in any claim, suit or proceeding (including any Defense Proceedings) regarding the validity and enforceability of Licensor Patents or Joint Patents in the Territory with counsel of its choice at its sole cost and expense; provided that the controlling Party shall retain control of the defense in such claim, suit or proceeding (including any Defense Proceedings). The Parties agree to cooperate fully in any claim, suit or proceeding (including any Defense Proceedings) pursuant to this Section 7.6. Where a Party controls a claim, suit or proceeding (including any Defense Proceedings) under this Section 7.6, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may [****] request from time to time in connection with its activities set forth in this Section 7.6, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant records, documents and other evidence (including laboratory notebooks) and making inventors and other of its employees available at reasonable business hours; provided that if the controlling Party requests the cooperation of the non-controlling Party pursuant to this Section 7.6.4, the controlling Party shall reimburse such other Party for its [****] Costs incurred in connection therewith. In the event that Licensor controls any claim, suit or proceeding (including any Defense Proceedings) pursuant to this Section 7.6, Licensor shall (a) consult with AbbVie as to the strategy for such claim, suit or proceeding, (b) consider [****] any comments from AbbVie and (c) keep AbbVie [****] informed of any material steps taken and provide copies of all material documents filed in connection with such claim, suit or proceeding.

7.7 Infringement Claims by Third Parties. If the manufacture, sale, use or other Exploitation of a Licensed Compound or Licensed Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit or proceeding by a Third Party alleging infringement by AbbVie or any of its Affiliates or its or their Sublicensees, distributors or customers (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an enforcement action initiated pursuant to Section 7.5, the Party first becoming aware of such alleged Third Party Infringement Claim shall [****] notify the other Party thereof in writing. As between the Parties, AbbVie shall have the [****] right in the United States and the [****] right in the OUS Territory, but, in either case, not the obligation, to defend and control the defense of (including to settle) any such Third Party Infringement Claim at its sole cost and expense (but subject to Section 7.8.4 and Article 10), using counsel of its own choice. Licensor may participate in any such Third Party Infringement Claim with counsel of its choice at its sole cost and expense; provided that AbbVie shall retain control of such Third Party Infringement Claim. If AbbVie or its designee does not take [****] reasonable steps to defend or control the defense of any such Third Party Infringement Claim in the United States (a) within [****] following the first notice provided above with respect to the Third Party Infringement Claim or (b) provided such date occurs after the first such notice of the Third Party Infringement Claim is provided, [****] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensor, with the prior approval of [****] (not to be unreasonably withheld, delayed or conditioned), may defend or control the defense of any such Third Party Infringement Claim at its sole cost and expense. The Party defending or controlling the defense of any such Third Party Infringement Claim shall keep the other Party [****] informed of all material developments in connection with any Third Party Infringement Claim. The other Party shall, and shall cause its Affiliates to, assist and cooperate with the Party defending or controlling the defense of any such Third Party Infringement Claim, as such Party may [****] request from time to time, in connection with its activities set forth in this Section 7.7, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees available at reasonable business hours; provided that the Party defending or controlling the defense of any such Third Party Infringement Claim shall reimburse the other Party for its [****] Costs incurred in connection therewith (which reimbursement, for clarity, shall constitute a Third Party Payment). Nothing in this Section 7.7 will limit any indemnification rights or obligations of a Party under Article 10.

7.8 Third Party Rights.

7.8.1 If AbbVie determines that any Third Party Right is necessary for the Exploitation of a Licensed Compound or Licensed Product by AbbVie or any of its Affiliates or any of its or their Sublicensees, distributors or customers, then, as between the Parties, AbbVie shall have the [****] right, but not the obligation, to enter into a license or other agreement with such Third Party pursuant to which AbbVie or its Affiliate would acquire a license or other right under such Third Party Right as necessary for AbbVie or its Affiliates or its and their Sublicensees, distributors or customers to Exploit a Licensed Compound and Licensed Products in such country.

7.8.2 Prior to entering into any agreement for any Third Party Right that is [****] useful for the Exploitation of a Licensed Compound or Licensed Product by AbbVie or

any of its Affiliates or any of its or their Sublicensees, distributors or customers, Licensor shall notify AbbVie and [****] AbbVie's comments with respect to obtaining such agreement [****]. Licensor shall not enter into agreement for any Third Party Right that is [****] useful for the Exploitation of a Licensed Compound or Licensed Product by AbbVie or any of its Affiliates or any of its or their Sublicensees, distributors or customers without obtaining the right to grant AbbVie a sublicense under such Third Party Rights on terms consistent the terms of this Agreement.

7.8.3 If in the [****] opinion of AbbVie, a Third Party's Patent may relate to the Exploitation of any Licensed Compound or Licensed Product under this Agreement, AbbVie shall have the [****] right, but not the obligation, to challenge the patentability, validity or enforceability of any such Patent in any court of competent jurisdiction or before any supra-national, federal, national, regional, state, provincial or local governmental body of competent jurisdiction, including the United States Patent and Trademark Office and the European Patent Office. Licensor shall not challenge the patentability, validity or enforceability of such Patent in any court or governmental body without AbbVie's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed). Licensor shall assist and cooperate with AbbVie as AbbVie may [****] request from time to time in connection with the activities set forth in this Section 7.8.3.

7.8.4 In the event that (a) AbbVie owes upfront payments, milestone payments, royalties or other amounts under an agreement with a Third Party (i) in order to obtain a license or right under a Third Party Right pursuant to Section 7.8.1 (prior to the application of any stacking provision in any agreement with respect to such Third Party Right) or (ii) in connection with any [****], (b) AbbVie incurs any [****] Costs in settling any Third Party Infringement Claim or [****] (including pursuant to any settlement thereof or any adverse judgment in connection therewith) pursuant to Section 7.7 (clauses (a) and (b), "**Third Party Payments**"), in each case ((a) and (b)), such Third Party Payments (x) to the extent specifically identifiable or reasonably allocable to the Exploitation of a Licensed Product for the United States, [****]; provided that with respect to any such Third Party Payments that are attributable to Licensor's breach of its representations and warranties hereunder or to a [****], such Third Party Payments shall not constitute Other Shared Expenses, and Licensor shall be responsible, and shall reimburse AbbVie for, [****] of such Third Party Payments and (y) to the extent related to a [****] anywhere in the Territory or otherwise specifically identifiable or reasonably allocable to the Exploitation of a Licensed Product for the OUS Territory, shall be offsettable from royalty payments pursuant to Section 6.5.5.

7.9 Product Trademarks.

7.9.1 Determination of US Product Trademarks. [****] shall determine the Trademark(s) used or to be used by the Parties or their respective Affiliates or, with respect to AbbVie, its Sublicensees, for the Development, Manufacture, Commercialization or other Exploitation of Licensed Products in the United States, which may be one or more of the Scheduled Trademarks or any Trademark owned or controlled by AbbVie or any of its Affiliates, excluding each Party's and its Affiliates' trade names, corporate names and corporate logos and any Trademark that consists of or incorporates any of the foregoing (such Trademarks and any registrations thereof or any pending applications relating thereto, the "**US Product Trademarks**").

7.9.2 Determination of OUS Product Trademarks. AbbVie shall have the [****] right to determine the Trademark(s) used or to be used by AbbVie or its Affiliates or its or their Sublicensees for the Development or Commercialization of Licensed Products in the OUS Territory, which may be the foreign equivalents of one or more of the Scheduled Trademarks or any other Trademark owned or controlled by AbbVie or any of its Affiliates, excluding each Party's and its Affiliates' trade names, corporate names and corporate logos and any Trademark that consists of or incorporates any of the foregoing (such Trademarks and any registrations thereof or any pending applications relating thereto, the "**OUS Product Trademarks**").

7.9.3 Ownership of Product Trademarks. As between the Parties, (a) Licensor shall remain the [****] owner of the Scheduled Trademarks in the United States and AbbVie hereby acknowledges and agrees that all use of the Scheduled Trademarks by AbbVie, its Affiliates, and its and their sublicensees and distributors, in the United States and all goodwill generated in connection therewith, shall inure [****] for and to the benefit of Licensor and (b) AbbVie shall be the [****] owner of the AbbVie US Product Trademarks and the OUS Product Trademarks and all goodwill generated in connection therewith, shall inure [****] for and to the benefit of AbbVie (or its Affiliates, as applicable).

7.9.4 Licensor Covenants. Except for any Scheduled Trademarks that Licensor registers in the United States pursuant to this Agreement, Licensor shall not, and shall cause its Affiliates not to, use or seek to register any Trademark that contains or consists of the equivalent of, that is confusingly similar to, or that is a colorable imitation of, any US Product Trademark (including any variant, translation or transliteration thereof) or OUS Product Trademark (including any variant, translation or transliteration thereof), in either case, in the Territory.

7.9.5 Registration of Scheduled Trademarks in the United States.

(a) [****] shall determine which Party shall have the [****] right, but not the obligation, to control the registration, prosecution and maintenance of any registration or application for any Scheduled Trademark in the United States in the name of Licensor and the costs and expenses with respect thereto shall be Other Shared Expenses. If, as between the Parties, the Party with the [****] right to control the registration, prosecution and maintenance of any Scheduled Trademark in the United States decides not to do so, such Party shall provide [****] prior written notice to the other Party of such intention (which notice shall, in any event, be given no later than [****] prior to the next deadline for any action that may be taken with respect to such Scheduled Trademark), and the other Party shall thereupon have the option to assume the control and direction of the registration, prosecution and maintenance of such Scheduled Trademark in the United States and the costs and expenses with respect thereto shall be Other Shared Expenses.

(b) With respect to Scheduled Trademarks in the United States, the registering Party shall [****] inform the other Party of all material steps with respect to the registration, prosecution and maintenance of each Scheduled Trademark, including by providing the other Party with a copy of material communications to and from the United States Patent and Trademark Office regarding such Scheduled Trademarks and by providing the other Party drafts of any material filings or responses to be made to the United States Patent and Trademark Office

in connection therewith [****] in advance of submitting such filings or responses so as to allow for a [****] opportunity for the other Party to review and comment thereon. The registering Party shall consider [****] the requests and suggestions of the other Party with respect to such drafts and with respect to strategies for registering and prosecuting any Scheduled Trademarks in the United States.

(c) The Parties shall cooperate fully in the registration, prosecution and maintenance of the Scheduled Trademarks in the United States and the costs and expenses with respect thereto shall be Other Shared Expenses. Such cooperation shall include:

(i) executing all papers and instruments, including powers of attorney, to enable the other Party to register, prosecute and maintain any Scheduled Trademark in the United States;

(ii) providing any dates of first use and any necessary specimens of use or other evidence of use necessary to enable the other Party to register, prosecute and maintain any Scheduled Trademark in the United States; and

(iii) [****] informing the other Party of any matters coming to such Party's attention that may materially affect the registration, prosecution or maintenance of any Scheduled Trademark in the United States.

7.9.6 Registration of AbbVie US Product Trademarks and OUS Product Trademarks. As between the Parties, AbbVie shall have the [****] right, but not the obligation, to register, prosecute and maintain any registration or application for any AbbVie US Product Trademark in the United States and any OUS Product Trademark in the OUS Territory and (a) the costs and expenses with respect thereto for the AbbVie US Product Trademarks shall be Other Shared Expenses and (b) AbbVie shall be solely responsible for the costs and expenses with respect thereto for the OUS Product Trademarks.

7.9.7 Enforcement and Defense.

(a) Each Party shall provide to the other Party [****] written notice of any actual or threatened infringement of a Scheduled Trademark in the United States and of any actual or threatened Third Party claim that the use of a Scheduled Trademark in the United States violates the rights of any Third Party, in each case, of which such Party becomes aware, and [****] shall [****] discuss such notice and the potential enforcement strategies available.

(b) As between the Parties, AbbVie shall have the [****] right (but not the obligation) to (i) defend against any claim by any Third Party that the use of any of the Scheduled Trademarks in the United States by Licensor or by AbbVie (or any of its Affiliates, sublicensees or distributors) infringes, dilutes, misappropriates or otherwise violates any of such Third Party's Trademarks or constitutes unfair trade practices or another like offense (each, a "**TM Infringement Claim**") or (ii) take such action as AbbVie deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offence relating to, any Scheduled Trademark in the United States by such Third Party (a "**TM Competitive Infringement**"), using counsel of its own choice and the costs and expenses with respect thereto shall be Other Shared Expenses.

(c) If AbbVie exercises its right to defend against a TM Infringement Claim or to commence proceedings in relation to a TM Competitive Infringement, in each case, in accordance with Section 7.9.7(b), then Licensor shall have the right to join any such defense or infringement action, and participate with its own counsel, at its sole cost and expense; provided that, unless otherwise determined by the IP Group, AbbVie shall retain control of the defense or prosecution of such claim, suit or proceeding.

(d) If AbbVie decides not to commence proceedings in relation to a TM Competitive Infringement or not to control the defense of a TM Infringement Claim, in each case, in accordance with Section 7.9.7(b), then Licensor shall have the right (but not the obligation) to assume such defense or take such action as it deems necessary against the relevant Third Party, using counsel of its own choice and the costs and expenses with respect thereto shall be Other Shared Expenses.

(e) If AbbVie exercises its right to defend against a TM Infringement Claim or to commence proceedings in relation to a TM Competitive Infringement, in each case, in accordance with Section 7.9.7(b), Licensor shall [****] cooperate with AbbVie and provide such [****] assistance as AbbVie may [****] request, with respect to such enforcement or defense and the costs and expenses with respect thereto shall be Other Shared Expenses, including by (i) joining any lawsuit or proceeding as a party where such joinder is required under Applicable Law to enforce or so defend the applicable Scheduled Trademark in the United States, and (ii) executing and delivering to AbbVie such powers of attorney or other documents or instruments necessary for AbbVie to enforce or defend in Licensor's name.

(f) Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such action (whether by way of settlement or otherwise) shall be retained by or paid to AbbVie, as applicable, and treated as "Net Sales" in the [****] in which the money is actually received for purposes of calculating Net Profits pursuant to Section 6.3.

(g) As between the Parties, AbbVie shall have the [****] right (but not the obligation) to (i) defend against any claim by any Third Party that the use of any (A) AbbVie US Product Trademarks in the United States by Licensor or by AbbVie (or any of its Affiliates, sublicensees or distributors) or (B) OUS Product Trademark in the OUS Territory by AbbVie (or any of its Affiliates, sublicensees or distributors), in either case ((A) or (B)), infringes, dilutes, misappropriates or otherwise violates any of such Third Party's Trademarks or constitutes unfair trade practices or another like offense or (ii) take such action as AbbVie deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offence by such Third Party relating to any AbbVie US Product Trademarks in the United States or any OUS Product Trademarks in the OUS Territory, using counsel of its own choice and (1) the costs and expenses with respect thereto for the AbbVie US Product Trademarks shall be [****] and (2) AbbVie shall be solely responsible for the costs and expenses with respect thereto for the OUS Product Trademarks.

7.9.8 Quality Control.

(a) AbbVie agrees that (i) all of the Licensed Products Manufactured, Commercialized or otherwise Exploited in the United States by or on behalf of AbbVie under or in connection with any Scheduled Trademarks, if any, shall be of a standard of quality consistent with AbbVie's standards for similar products and shall comply with Applicable Law and (ii) all uses of the Scheduled Trademarks, if any, by or on behalf of AbbVie shall comply with and adhere to usage guidelines established by the IP Group and shall comply with all Applicable Laws (the "**Scheduled TM Quality Standards**"). Upon Licensor's request (not more than [****]) AbbVie shall make available to Licensor, representative samples of any Licensed Product, labels, packaging, webpage screenshots, advertising or promotional material or content, in each case, Manufactured, produced or created, as applicable, by or on behalf AbbVie or any of its Affiliates for the United States that display any Scheduled Trademarks. If Licensor [****] believes that AbbVie is not complying with the Scheduled TM Quality Standards, then Licensor may notify AbbVie of such non-compliance and the Parties shall coordinate [****] to determine any changes necessary for AbbVie to comply with the Scheduled TM Quality Standards. Furthermore, Licensor shall have the right, from time to time, but no more than [****], during regular business hours, upon [****] prior written notice, to inspect all facilities and business locations under AbbVie's, its Affiliates' or its or their Sublicensees' control used to Manufacture any Licensed Products or produce or create any labels, packaging, webpage screenshots, advertising or promotional material or content, in either case, for the United States that displays any Scheduled Trademark for the purposes of determining [****] whether such Licensed Products, labels, packaging, webpage screenshots, advertising or promotional material or content conform with the Scheduled TM Quality Standards.

(b) Licensor agrees that (i) all of the Licensed Products Manufactured, Commercialized or otherwise Exploited in the United States by or on behalf of Licensor under or in connection with any AbbVie US Product Trademarks, if any, shall be of a standard of quality consistent with AbbVie's standards for similar products and shall comply with Applicable Law and (ii) all uses of the AbbVie US Product Trademarks, if any, by or on behalf of Licensor shall comply with and adhere to usage guidelines provided by AbbVie to Licensor and shall comply with all Applicable Laws (the "**AbbVie US Product TM Quality Standards**"). Upon AbbVie's request (not more than [****]) Licensor shall make available to AbbVie, representative samples of any Licensed Product, labels, packaging, webpage screenshots, advertising or promotional material or content, in each case, Manufactured, produced or created, as applicable, by or on behalf of Licensor or any of its Affiliates for the United States that display any AbbVie US Product Trademarks. If AbbVie [****] believes that Licensor is not complying with the AbbVie US Product TM Quality Standards, then AbbVie may notify Licensor of such non-compliance and the Parties shall coordinate [****] to determine any changes necessary for Licensor to comply with the AbbVie US Product TM Quality Standards. Furthermore, AbbVie shall have the right, from time to time, but no more than [****], during regular business hours, upon [****] prior written notice, to inspect all facilities and business locations under Licensor's, its Affiliates' or its or their Sublicensees' control used to Manufacture any Licensed Products or produce or create any labels, packaging, webpage screenshots, advertising or promotional material or content, in either case, for the United States that displays any AbbVie US Product Trademark for the purposes of determining [****] whether such Licensed Products, labels, packaging, webpage screenshots, advertising or promotional material or content conform with the AbbVie US Product TM Quality Standards.

7.10 Inventor's Remuneration. Each Party shall be solely responsible for any remuneration that may be due such Party's employees or agents that are inventors under any applicable inventor remuneration laws.

ARTICLE 8
CONFIDENTIALITY AND NON-DISCLOSURE

8.1 Confidentiality Obligations. At all times during the Term and for a period of [****] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its Affiliates and each of its and their respective officers, directors, employees and agents (collectively, "**Representatives**") to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information of the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "**Confidential Information**" means any and all Information provided orally, visually, in writing or other form that is disclosed or otherwise provided by or on behalf of one (1) Party to the other Party in connection with this Agreement, that certain Confidentiality Agreement entered into by the Parties, dated [****], as amended (the "**Confidentiality Agreement**") or that certain Exclusive Option Agreement entered into by the Parties, dated October 31, 2023, as amended ("**Option Agreement**"), in each case, whether prior to, on or after the Effective Date, including the terms of this Agreement (and both of the foregoing agreements), information relating to any Licensed Compound or any Licensed Product (including the Regulatory Documentation), any Exploitation of any Licensed Compound or any Licensed Product, any Information with respect thereto developed by or on behalf of the disclosing Party or its Affiliates or its or their respective (sub)licensees/Sublicensees (including Licensor Know-How) and the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (a) (i) Confidential Information contained in Regulatory Documentation and (ii) Confidential Information constituting Joint Know-How and any other Information developed, owned or Controlled by Licensor or any of its Affiliates (including Licensor Know-How) primarily relating to any Licensed Compound or any Licensed Product or any Improvement thereto or the Exploitation of any of the foregoing in the Field ((i) and (ii) collectively, "**Product Information**") shall be deemed the Confidential Information of AbbVie (and AbbVie shall be deemed the disclosing Party and Licensor shall be deemed the receiving Party with respect thereto) until termination (but not expiration) of this Agreement and (b) any other Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto).

8.2 Exceptions. Notwithstanding the foregoing, the confidentiality and non-use obligations under Section 8.1 with respect to any Confidential Information shall not apply to any information that:

8.2.1 is or hereafter becomes generally available to the public by use, publication, general knowledge or the like, other than by breach by the receiving Party or any of its Representatives of this Agreement or, prior to the Effective Date, by the receiving Party of (a) the Option Agreement or (b) that certain Confidentiality Agreement entered into by the Parties, dated February 21, 2023, as amended;

8.2.2 is subsequently disclosed to the receiving Party by a Third Party, without restriction and without breach of any agreement between such Third Party and the disclosing Party or any of its Representatives with respect to such information;

8.2.3 was already in the possession of the receiving Party or any of its Representatives without restriction prior to receipt from the disclosing Party or any of its Representatives as shown in the written records of the receiving Party or its Representatives or by other competent evidence; provided that the foregoing exception shall not apply with respect to Product Information or Joint Know-How; or

8.2.4 is or was independently developed by the receiving Party or any of its Representatives without use or reference to or disclosure of the Confidential Information of the disclosing Party, as shown in the written records of the receiving Party or its Representatives or by other competent evidence; provided that the foregoing exception shall not apply with respect to Product Information or Joint Know-How.

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

8.3 Permitted Disclosures. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

8.3.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by law (other than by reason of filing with securities regulators, which shall be governed by Section 8.6); provided, however, that the receiving Party shall first have given [****] written notice (and to the extent possible, at least [****] notice) to the disclosing Party and given the disclosing Party [****] opportunity to take whatever action it deems necessary to protect its Confidential Information ([****]); and provided, further, that the Confidential Information disclosed in response to such court or governmental order or as required by law shall be limited to the information that is legally required to be disclosed in response to such court or governmental order or by such law;

8.3.2 made to its or its Affiliates' financial or legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, at least as restrictive as those set forth in this Agreement (but of shorter duration if customary under the circumstances); provided that the

receiving Party shall remain responsible for any failure by such financial and legal advisors to treat such Confidential Information as required under this Article 8; or

8.3.3 made by or on behalf of the receiving Party to a patent authority as may be necessary or reasonably useful for purposes of obtaining, defending or enforcing a Patent pursuant to this Agreement; provided, however, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information, to the extent such protection is available.

8.4 Additional Permitted Disclosures.

8.4.1 AbbVie and its Affiliates and its and their Sublicensees may disclose Confidential Information of Licensor [****] in connection with the Exploitation of the Licensed Compounds, the Licensed Products (including in connection with any filing, application or request for Regulatory Approval by or on behalf of AbbVie or any of its Affiliates or its or their Sublicensees) or otherwise in connection with the performance of its obligations or exercise of AbbVie's rights as contemplated by this Agreement, including to existing or potential distributors, Sublicensees, collaboration partners or acquirers; provided, however, that such distributors, Sublicensees, collaboration partners or acquirers shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 8 (but of shorter duration if customary under the circumstances).

8.4.2 Licensor and its Affiliates may disclose Product Information to any Third Parties as may be necessary to perform the activities allocated to Licensor under the Development Plan (if any) and the Commercialization Plan or in connection with any filing, application or request for Regulatory Approval by or on behalf of Licensor pursuant to this Agreement; provided, however, that such Third Parties shall be subject to obligations of confidentiality and non-use with respect to such Product Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 8 (but of shorter duration if customary under the circumstances).

8.4.3 Licensor and its Affiliates may disclose the terms of this Agreement and Confidential Information of AbbVie to any bona fide actual or prospective [****], in each case who have a need to know such Confidential Information, provided, however, that such Third Parties shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use set forth in this Article 8 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [****] from the date of disclosure for actual or prospective [****] and no less than [****] from the date of disclosure for other [****]); provided, that, Licensor shall not have any right to disclose any Sensitive AbbVie Information pursuant to this Section 8.4.3 to a prospective [****] without AbbVie's prior written consent. For purposes of this Section 8.4.3, "**Sensitive AbbVie Information**" means any Confidential Information of AbbVie related to the [****]).

8.5 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their respective (sub)licensees/Sublicensees (or any abbreviation or adaptation

thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 8.5 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted); provided that such Party shall, subject to Section 8.6, submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as [****] practicable (and in no event less than [****] prior to the anticipated date of disclosure) so as to provide a [****] opportunity to comment thereon.

8.6 Public Announcements. [****] following the Effective Date, the Parties will coordinate [****] to issue [****] mutually agreed press releases. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit (a) the proposed disclosure in writing to the other Party [****] practicable (and in no event less than [****] prior to the anticipated date of disclosure) so as to provide a [****] opportunity to comment thereon, (b) the reason such disclosure is, in the opinion of such Party's counsel, required by Applicable Law and (c) the expected time and place the disclosure will be made; provided that if such required disclosure includes a disclosure of this Agreement, the disclosing Party shall also submit a redacted form of this Agreement to the other Party and shall submit a confidential treatment request (or equivalent protection in a country other than the U.S.) in connection with such disclosure. The disclosing Party shall consider [****] any comments received from the other Party with respect to such disclosure. Notwithstanding the foregoing, AbbVie and its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Licensed Compounds and Licensed Products; provided that such disclosure is subject to the other provisions of this Article 8 with respect to Licensor's Confidential Information. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 8.6, provided that such information remains accurate as of such time of publication and provided the frequency and form of such disclosure are reasonable.

8.7 Publications. The Parties, through the JDC, shall develop policies and procedures ("**Publication Policies**") for any publication with respect to Development of any Licensed Compound or Licensed Product, including the results of any clinical studies and disclosure in applicable clinical trial registries. The Publication Policies shall be consistent with each Party's policies and procedures for the publication and disclosure of the results of clinical studies. Each Party recognizes that the publication of papers regarding results of, and other information regarding, activities under this Agreement, including oral presentations and abstracts, may be beneficial to both Parties; provided that such publications are subject to [****] controls to protect Confidential Information. In particular, the Parties intend to maintain the confidentiality

of any Confidential Information included in any invention disclosures or Patent application until such Patent application has been filed. Accordingly, AbbVie shall be free to publicly disclose the results of, and information regarding, activities under this Agreement in a manner consistent with Applicable Law and industry practices, as provided in this Section 8.7, subject to prior review by Licensor of any disclosure of Licensor's Confidential Information for issues of patentability and protection of such Confidential Information. Before publishing or disclosing any of Licensor's Confidential Information, AbbVie shall deliver a then-current copy of proposed abstracts, manuscripts or summaries of presentations to Licensor at [****] prior to submitting the paper to a publisher or an oral presentation is made. Licensor shall review any such paper and give its comments to AbbVie within [****] of the delivery of such paper to Licensor. With respect to oral presentation materials and abstracts, Licensor shall make [****] efforts to expedite review of such materials and abstracts, and shall return such items [****] practicable to AbbVie with [****] comments, [****], but in no event later [****] from the date of delivery to Licensor. Failure to respond within such [****] period shall be deemed approval to publish or present. Notwithstanding the foregoing, AbbVie shall comply with Licensor's request to delete references to Licensor's Confidential Information in any such paper or presentation and will withhold publication of any such paper or any such presentation for an [****] in order to permit Licensor to obtain Patent protection if Licensor deems it necessary. Any publication shall include recognition of the contributions of the Licensor according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Licensor shall not, and shall cause each of its Affiliates and its and their respective licensors and (sub)licensees not to, make any publications or public disclosures regarding the Licensed Compounds or Licensed Products or any Confidential Information of AbbVie without AbbVie's prior written consent.

8.8 Return of Confidential Information. After the effective date of termination (but not expiration) of this Agreement for any reason, upon the written request of a Party, the non-requesting Party shall either, at the requesting Party's election: (a) [****] destroy all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party, its Affiliates or its or their (sub)licensees/Sublicensees (other than Joint Know-How and the terms of this Agreement) and confirm such destruction in writing to the requesting Party or (b) [****] deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of the requesting Party's Confidential Information in the possession or Control of the non-requesting Party, its Affiliates or its or their (sub)licensees/Sublicensees (other than Joint Know-How and the terms of this Agreement). Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain (x) such Confidential Information to the extent necessary or [****] useful for purposes of performing any continuing obligations or exercising any ongoing rights and, in any event, a single copy of such Confidential Information for archival purposes and (y) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 8.1.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations and Warranties. Licensor and AbbVie each represents and warrants to the other Party, as of the Effective Date, that:

9.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

9.1.2 the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

9.1.3 this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other Applicable Laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and

9.1.4 it is not under any obligation, contractual or otherwise, to any Person that conflicts with, or is inconsistent with, the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.2 Additional Representations and Warranties of Licensor. Licensor further represents and warrants to AbbVie, as of the Effective Date, and covenants, as follows:

9.2.1 All existing Licensor Patents are listed on **Schedule 9.2.1** (the "**Existing Patents**"). All Existing Patents are subsisting and, [****], are not invalid or unenforceable, in whole or in part. All Existing Patents are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, and have been filed and maintained properly, diligently and correctly and all applicable fees have been paid on or before the due date for payment, and all relevant references, documents and information have been presented to the relevant patent examiner at the relevant patent office. Licensor and its Affiliates have not taken any action that would render unpatentable (including by means of the "on-sale bar" doctrine or prior publication) any invention claimed in the Existing Patents.

9.2.2 Licensor is the sole and exclusive owner of the entire right, title and interest in the Existing Patents and the Licensor Know-How, free of any encumbrance, lien or claim of ownership by any Third Party, except as set forth on **Schedule 9.2.2**. Licensor is entitled to grant the licenses specified herein.

9.2.3 All Existing Agreements are listed on **Schedule 9.2.3**. The rights and obligations of the Parties hereunder are fully consistent with, and are not limited in any material respect by, the Existing Agreements. None of Licensor, its Affiliates and, [****], any Third Party is in breach of any Existing Agreement.

9.2.4 There are no claims, judgments or settlements against, or amounts with respect thereto, owed by Licensor or any of its Affiliates relating to the Existing Regulatory Documentation, the Existing Patents or the Licensor Know-How. No claim or litigation has been brought or threatened in writing by any Person alleging, [****], whether or not asserted, that (a) the Existing Patents or the Licensor Know-How are invalid or unenforceable or (b) the Existing Regulatory Documentation, the Existing Patents or the Licensor Know-How, or the disclosing, copying, making, assigning or licensing of the Existing Regulatory Documentation, the Existing Patents or the Licensor Know-How, or the Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds or Licensed Products as contemplated herein, does or will violate, infringe, misappropriate or otherwise conflict or interfere with, any Patent or other intellectual property or proprietary right of any Person, and [****] no facts or circumstances exist that would [****] be expected to give rise to any such claims. Except as set forth on **Schedule 9.2.4**, [****] no Person (x) has infringed or is infringing or threatening to infringe any Existing Patent or (y) has misappropriated or is misappropriating or threatening to misappropriate the Licensor Know-How.

9.2.5 Licensor Controls all Information and Patents in its or its Affiliates' ownership or control that are necessary or [****] useful to Develop, Manufacture or Commercialize the Licensed Compounds and the Licensed Products as contemplated herein and, except as set forth on **Schedule 9.2.5**, such Information and Patents are not subject to any other license or agreement to which Licensor or any of its Affiliates is a party. The Existing Patents represent all Patents within Licensor's or its Affiliates' ownership or control relating to the Licensed Compounds or the Licensed Products or the Exploitation thereof in the Field. [****] there is no Information owned or controlled by Licensor or any of its Affiliates that relates to the Licensed Compounds or the Licensed Products or the Exploitation thereof in the Field that is not within the Licensor Know-How. [****] no rights or licenses are required under any Information, Patents or other intellectual property (other than the Licensor Know-How and Licensor Patents) for AbbVie or its Affiliates to Develop, Manufacture or Commercialize the Licensed Compounds or Licensed Products as contemplated herein.

9.2.6 Each Person who has or has had any rights in or to any Existing Patents or any Licensor Know-How has assigned and has executed an agreement assigning its entire right, title and interest in and to such Existing Patents and Licensor Know-How to Licensor (and, [****] at the time of such assignment, no such Person was under any conflicting obligation to assign any such Existing Patents or Licensor Know-How to any other Person), and to the extent any of Licensor's or its Affiliates' (sub)licensees, employees and agents participate in the Exploitation of the Licensed Compounds or Licensed Products during the Term, Licensor shall obtain such an assignment and such an agreement from such Persons, in each case, without payments beyond those required by Article 6. [****] no current officer, employee, agent or consultant of Licensor or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Licensor or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Licensor.

9.2.7 Except as set forth on **Schedule 9.2.5**, Licensor has obtained the right (including under any Patents and other intellectual property rights) to use all Information and all other materials (including any formulations and manufacturing processes and procedures)

developed or delivered by any Third Party under any agreements between Licensor and any such Third Party with respect to the Licensed Compounds or the Licensed Products and Licensor has the rights under each such agreement to transfer such Information or other materials to AbbVie and its designees and to grant AbbVie the right to use such Information or other materials in the Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds or the Licensed Products without restriction.

9.2.8 The Licensor Know-How has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality. [****] no breach of such confidentiality has been committed by any Third Party.

9.2.9 Licensor has made available to AbbVie: (a) the file wrapper and other documents and materials relating to the prosecution, defense, maintenance, validity or enforceability of the Existing Patents; (b) all Existing Regulatory Documentation; and (c) Licensor Know-How and other Information in its possession or Control regarding or related to the Licensed Compounds or the Licensed Products, including all material adverse information with respect to the safety and efficacy of the Licensed Compounds known to Licensor, and in each case ((a) through (c)), all such materials, Existing Regulatory Documentation, Licensor Know-How and other Information are true, complete and correct. After the Effective Date, Licensor will continue to make available to AbbVie true, complete and correct copies of any Regulatory Documentation, Licensor Know-How and other Information in its possession or Control regarding or related to the Licensed Compounds or the Licensed Products. Neither Licensor nor any of its Affiliates has any knowledge of any scientific or technical facts or circumstances that would adversely affect the scientific, therapeutic or commercial potential of the Licensed Compounds or Licensed Products. Neither Licensor nor any of its Affiliates is aware of anything that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for an IND or Regulatory Approval.

9.2.10 As of the Effective Date, Licensor has made Opt-Out elections with respect to the Existing Patents.

9.2.11 All applications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests to the FDA or other Regulatory Authority with respect to the Licensed Compounds and Licensed Products, when submitted by or on behalf of Licensor or any of its Affiliates to the FDA or other Regulatory Authority with respect to the Licensed Compounds or the Licensed Products, were true, complete and correct in all respects as of the date of submission by or on behalf of Licensor or such Affiliate, and any legally necessary or required updates, changes, corrections or modifications to such applications, submissions, information, claims, reports or statistics have been submitted to the FDA or any other Regulatory Authority. Without limiting the foregoing, neither Licensor nor any of its Affiliates, nor any of its or their respective officers, employees or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Compounds or the Licensed Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Compounds or the Licensed Products, or committed an act, made a statement or failed to make a statement with respect to the Development of the Licensed

Compounds or the Licensed Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

9.2.12 There is no on-going clinical trial of any Licensed Product sponsored by or on behalf of Licensor or any of its Affiliates.

9.2.13 Licensor and its Affiliates have conducted, and their respective contractors and consultants have conducted, all Development of the Licensed Compounds and the Licensed Products (including the generation, preparation, maintenance and retention of all Regulatory Documentation) that they have conducted prior to the Effective Date in accordance with good laboratory and clinical practice and Applicable Law. Licensor and its Affiliates have employed (and, with respect to such tests and studies that Licensor will perform, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and clinical studies with respect to the Licensed Compounds and Licensed Products.

9.2.14 Licensor and its Affiliates have conducted, and their respective contractors and consultants have conducted, all Manufacture of the Licensed Compounds and the Licensed Products in accordance with good manufacturing practice and Applicable Law. Licensor and its Affiliates have employed Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the Manufacturing activities with respect to the Licensed Compounds and Licensed Products. Licensor has made available to AbbVie copies of any and all written notices of inspectional observations, establishment inspection reports and any other documents received from any Regulatory Authority relating to the Licensed Compounds and the Licensed Products.

9.2.15 There are no amounts that will be required to be paid to a Third Party as a result of the Development, Manufacture, Commercialization or other Exploitation of Licensed Compounds or the Licensed Products that arise out of any agreement to which Licensor or any of its Affiliates is a party or, to Licensor's Knowledge, at all.

9.2.16 Except as set forth on **Schedule 9.2.16**, neither Licensor nor any of its Affiliates is Developing or has Developed any [****] for use in the [****] Field.

9.2.17 Neither Licensor nor any of its Affiliates has ever been involved in the research, development, manufacture, sale, marketing or promotion of opioids, opioid products or any pharmaceutical product that has been approved by the FDA and expressly indicated for the treatment of a specified opioid-induced side effect.

9.2.18 No officer or Vice President-level employee of Licensor or any of its Affiliates currently serves as a director, board member, officer, employee or agent of any entity that primarily engages in conduct that promotes opioids, opioid products or any pharmaceutical product that has been approved by the FDA and expressly indicated for the treatment of a specified opioid-induced side effect.

9.2.19 The inventions claimed or covered by the Existing Patents or that are within Licensor Know-How are not Federally Funded Inventions.

9.2.20 The Processing of Personal Data by Licensor (including any transfer of Personal Data across national borders) in connection with the Licensed Compounds and Licensed Products is and has been in compliance with Data Security and Privacy Laws in all countries and jurisdictions in the Territory and all privacy related consents and notices that apply to the Licensed Compounds and Licensed Products (collectively, the "**Privacy and Security Obligations**"). Licensor has provided all necessary privacy notices related to research participants and has an appropriate legal basis under Data Security and Privacy Laws to Process all Personal Data in connection with the Exploitation of the Licensed Compounds and Licensed Products, including pursuant to this Agreement. Licensor has developed, implemented and maintains a compliance program, policies and procedures and training programs to ensure ongoing compliance with the Privacy and Security Obligations. Licensor has [****] reasonable physical, technical, organizational and administrative security measures and policies in place to protect all Personal Data collected by it or on its behalf from and against unauthorized Processing. Licensor is and has complied in all material respects with all Privacy and Security Obligations relating to data breach reporting and notification obligations. In the last [****], Licensor has not received written notice of any alleged material violation from a Regulatory Authority or other Third Party of any Privacy and Security Obligations and has no Knowledge of facts that would give rise to such a violation. [****] Licensor is not under investigation by any Regulatory Authority for a violation of Data Security and Privacy Laws.

9.2.21 The execution, delivery and performance of this Agreement and the other agreements and instruments contemplated hereby, and the consummation of the transactions contemplated hereunder, complies with the Privacy and Security Obligations. Licensor has the full right and authority to provide to AbbVie the Personal Data Processed by Licensor in connection with the Licensed Compounds and Licensed Products for the purposes contemplated in this Agreement.

9.2.22 In the event the consummation of this Agreement and the transactions contemplated herein require Licensor to transfer Personal Data across national borders, Licensor and AbbVie shall take steps to ensure the lawful export of Personal Data, the terms of which may be outlined in a separate agreement between AbbVie and Licensor.

9.3 Data Privacy and Security.

9.3.1 For all Personal Data transmitted by Licensor to AbbVie with respect to one (1) or more Licensed Compounds or Licensed Products, including in the performance of its activities under this Agreement, Licensor shall:

(a) comply at all times with the Data Security and Privacy Laws;

(b) to the extent permitted by Applicable Law, notify AbbVie, as soon as practicable and in any event prior to making the relevant disclosure, if it is obliged to make a disclosure of the Personal Data under Applicable Law;

(c) make timely notification to, and obtain any necessary authorizations from, any applicable Regulatory Authority where required under applicable Data Security and Privacy Laws of its collection and other Processing of Personal Data in order to comply with its obligations under this Agreement;

(d) at all times, act in a manner such that it is not subject to any prohibition or restriction that prevents or restricts it from disclosing or transferring the Personal Data to AbbVie as required under this Agreement;

(e) ensure that all fair Processing and required notices have been obtained and are maintained and are sufficient in scope, and that Licensor has an appropriate legal basis under Data Security and Privacy Laws, to enable Licensor to Process the Personal Data as required in order to comply with its obligations under this Agreement (including the transfer of all applicable Personal Data to AbbVie), in each case, in accordance with the Data Security and Privacy Laws;

(f) implement and maintain [****] administrative, technical, and physical safeguards designed to (i) maintain the security and confidentiality of the Personal Data; (ii) protect against [****] anticipated threats or hazards to the security or integrity of the Personal Data; and (iii) protect against unauthorized access to or use of Personal Data;

(g) notify the AbbVie [****], and in any event within [****] of receipt of any correspondence from a data protection regulator in relation to the Processing of Personal Data related to this Agreement; and

(h) refrain from taking actions related to the Processing of the Personal Data that would be reasonably likely to damage or impair the other Party's reputation.

9.3.2 For all Personal Data transmitted by one Party to the other Party with respect to [****] or more Licensed Compounds or Licensed Products, including in the performance of its activities under this Agreement, the transmitting Party shall not prevent or restrict the receiving Party from Processing the Personal Data as envisaged under this Agreement. If the transmitting Party becomes aware of any circumstances that it believes, acting [****], may give rise to such a prohibition or restriction, it shall [****] notify the receiving Party of the same and take all reasonable steps, including following receiving Party's [****] instructions, to ensure that it does not impact its performance of its obligations under Section 9.3.1.

9.3.3 Data Agreements; Data Export. At the [****] request of AbbVie, the Parties shall cooperate to enter into any necessary joint controller agreements or controller-processor agreements with respect to such Personal Data as necessary to comply with Applicable Law. In the event Licensor needs to transfer Personal Data from an originating country to an entity in a different country, Licensor shall enter into then-applicable standard contractual clauses or other required agreements under Applicable Law with the relevant data importer. The Parties agree that if the standard contractual clauses are invalidated or amended in any way, Licensor will agree a change to the requirements of this Agreement as required to ensure that data exports continue to be conducted in accordance with applicable Data Security and Privacy Laws.

9.3.4 Assistance. Without limiting either Party's obligations under this Agreement, each Party shall provide the other Party such assistance as the other Party may [****] request to comply with Data Security and Privacy Laws.

9.3.5 Security Breach Notification. Licensor shall notify AbbVie [****] upon learning of any actual or suspected misappropriation or unauthorized access to, or disclosure or use of, the Personal Data collected, Processed, hosted or transmitted with respect to one (1) or more Licensed Compounds or Licensed Products (a "**Data Breach**"). Licensor shall [****] investigate each Data Breach that it becomes aware of or has reason to suspect may have occurred and, in the case of an actual Data Breach, shall, at AbbVie's request, provide [****] levels of access and information to AbbVie in connection with any independent investigation that AbbVie may desire to conduct with respect to such Data Breach. Licensor shall cooperate with AbbVie in identifying any [****] steps that should be implemented to limit, stop or otherwise remedy any actual or suspected Data Breach.

9.4 Additional Mutual Representations and Warranties. Licensor and AbbVie each represents and warrants to the other Party, as of the Effective Date, that:

9.4.1 it has not ever been, is not currently, nor is it the subject of a proceeding that could lead to it becoming a Debarred Entity, Excluded Entity or Convicted Entity and it will not use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual. In the event the use by Licensor of any Debarred Individual, Debarred Entity, Excluded Individual, Excluded Entity, Convicted Individual or Convicted Entity in connection with the obligations performed under this Agreement prevents or delays approval of any Regulatory Approval or IND for a Licensed Product, then AbbVie shall have the right to terminate this Agreement pursuant to Section 11.2.1 without any further opportunity for Licensor to cure such material breach. Each Party further covenants that if, during the Term, it becomes a Debarred Entity, Excluded Entity or Convicted Entity or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual or a Convicted Individual, such Party shall immediately notify the other Party. This provision shall survive termination or expiration of this Agreement. For purposes of this provision, the following definitions shall apply:

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of such a corporation, partnership or association.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services or (ii) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise

ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A " **Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

9.4.2 it and its Affiliates (a) have complied and shall comply with all Applicable Law governing bribery, money laundering and other corrupt practices and behavior (including, as applicable, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), the Civil Monetary Penalties Law (42 U.S.C. § 1320-7a), the U.S. Foreign Corrupt Practices Act and UK Bribery Act), any regulations promulgated pursuant to such statutes and any analogous state or foreign statutes and (b) shall not, directly or indirectly, offer, give, pay, promise to pay or authorize the payment of any bribes, kickbacks, influence payments or other unlawful or improper inducements to any Person in whatever form (including gifts, travel, entertainment, contributions or anything else of value).

9.4.3 it and its Affiliates have and undertake that they shall continue to update and maintain during the Term an internal compliance program under which its (or its Affiliates') employees are required to comply with all Applicable Law, including applicable local and international anti-bribery and anti-corruption laws and regulations.

9.4.4 its and its Affiliates' respective employees and agents are regularly trained, and will continue to be regularly trained, on the requirements of its compliance program and compliance with applicable anti-bribery and anti-corruption laws and if the other Party so requests, each Party covenants and agrees that any Third Party's employees and agents providing services on behalf of such Party pursuant to this Agreement will attend training provided by the requesting Party on applicable anti-bribery and anti-corruption laws and the requirements of this Agreement.

9.5 Further Covenants. Neither Licensor nor any of its Affiliates shall (a) take any action that (i) would impose or result in a lien, charge or encumbrance on any of the Licensor Know-How or Licensor Patents that would prevent or limit AbbVie's exercise of its rights to such Licensor Know-How or Licensor Patents, or (ii) [****] could otherwise encumber, diminish or otherwise adversely affect the rights granted to AbbVie under this Agreement or (b) assign, transfer, convey or otherwise grant to any Person any rights to any Licensor Know-How or Licensor Patents (or any rights to any Information, Patents or other intellectual property that would otherwise be included in the Licensor Know-How or Licensor Patents if not assigned, transferred, conveyed or otherwise granted to a Third Party) or any Licensed Compounds or Licensed Products (and compounds, products and therapies that may become Licensed Compounds or Licensed Products) in any manner that is inconsistent with the exclusive licenses granted to AbbVie pursuant to Section 3.1.

9.6 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH

PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10
INDEMNITY

10.1 Indemnification of Licensor. AbbVie shall indemnify Licensor, its Affiliates and its and their respective directors, officers, employees and agents (individually and collectively, the "**Licensor Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (individually and collectively, "**Third Party Claims**") incurred or sustained by or rendered against the Licensor Indemnitees arising from or occurring as a result of:

[****];

[****];

[****];

[****].

10.2 Indemnification of AbbVie. Without limiting Section [****], Licensor shall indemnify AbbVie, its Affiliates and its and their respective directors, officers, employees and agents (individually and collectively, the "**AbbVie Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred or sustained by or rendered against the AbbVie Indemnitees arising from or occurring as a result of:

[****];

[****];

[****];

[****].

10.3 Certain Losses. Notwithstanding the foregoing, any Losses in connection with any Third Party Claim brought against either Party or the Licensor Indemnitees or AbbVie Indemnitees resulting directly or indirectly from (a) the performance of Development activities by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) in accordance with a Development Plan, (b) the Commercialization of any Licensed Product for the United States or (c) the Manufacture of any Licensed Product for use in such Development or Commercialization activities, in each case ((a), (b) and (c)), shall be included as an Other Shared Expense, excluding:

10.3.1 any Loss covered in Article 7;

10.3.2 any Loss to the extent Licensor provides indemnification pursuant to, or to the extent arising from or occurring as a result of any of the matters set forth in, Section 10.2;

10.3.3 any Loss to the extent AbbVie provides indemnification pursuant to, or to the extent arising from or occurring as a result of any of the matters set forth in, Section 10.1; and

10.3.4 any Loss covered in Section [****].

If either Party learns of any Third Party Claim with respect to Losses covered by this Section 10.3, such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, AbbVie shall control such action with [****] consultation with, and cooperation from, Licensor.

10.4 Indemnification Procedures.

10.4.1 Notice of Claim. All indemnification claims in respect of a Licensor Indemnitee or AbbVie Indemnitee, as applicable (each, an "**Indemnitee**"), under Section 10.1 or Section 10.2, as applicable, shall be made solely by Licensor or AbbVie, as applicable (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 10.1 or Section 10.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

10.4.2 Control of Defense. Subject to the provisions of Section 7.5, Section 7.6 and Section 7.7, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [****] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party, which shall be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, (a) the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party or any of its Indemnitees in connection with the Third Party Claim and (b) the indemnifying Party shall have the right to defend such Third Party Claim by all appropriate proceedings. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section

10.4.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party or any of its Indemnitees in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested or authorized in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

10.4.3 Right to Participate in Defense. Without limiting Section 10.4.2, any Indemnified Party shall be entitled to participate in, but not control (except as provided in Section 7.5, Section 7.6 and Section 7.7), the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided that such employment shall be at the Indemnified Party's sole cost and expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 10.4.2 (in which case the Indemnified Party shall control the defense) or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles. For clarity, if the Indemnified Party has the right to control the defense of a Third Party Claim pursuant to Section 7.5, Section 7.6 or Section 7.7, the Indemnified Party shall be entitled to control such Third Party Claim, without limiting the indemnifying Party's responsibility for Losses under Section 10.1 or Section 10.2, as applicable.

10.4.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's or any of its Indemnitees' becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party or any of its Indemnitees in any manner and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.4.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Without limiting the rights and obligations of the Parties under Article 7 of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed). Except as provided in Article 7, the indemnifying Party shall not be liable for any settlement, compromise or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed). For clarity, if a Third Party

Claim, or the events giving rise to or resulting in such Third Party Claim, are subject to Article 7 and Section 10.1 or Section 10.2, then Article 7 shall apply with respect to the defense of such Third Party Claim and Section 10.1 or Section 10.2, as applicable, shall apply with respect to the allocation of financial responsibility for the related Losses.

10.4.5 Cooperation. The Indemnified Party shall, and shall cause each of its Indemnitees to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be [****] requested by or on behalf of the indemnifying Party in connection therewith. Such cooperation shall include access during normal business hours, upon [****] prior notice, afforded to the indemnifying Party to, and [****] retention by the Indemnified Party and its Indemnitees of, records and information that are [****] relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its [****] Costs in connection therewith.

10.4.6 Expenses. Except as provided above, the [****] Costs, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a [****] basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

10.5 Special, Indirect and Other Losses. EXCEPT (A) FOR THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER [****], (C) AS PROVIDED UNDER SECTION [****], (D) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 10 OR (E) LOSSES UNDER SECTION [****], NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF THE LICENSED COMPOUNDS OR LICENSED PRODUCTS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

10.6 Special Claims. Licensor shall indemnify the AbbVie Indemnitees, and defend and save each of them harmless, from and against, and compensate and reimburse each of them for, any and all Losses incurred or sustained by or rendered against the AbbVie Indemnitees arising from or occurring as a result of any challenge, claim or assertion by any Third Party of any right, title or interest in, or with respect to the ownership or inventorship of, [****].

10.7 Insurance. During the Term and for a minimum period of [****] thereafter (or for an otherwise longer period as may be required by Applicable Law), each Party shall at all

times maintain in force insurance coverage that is required by any federal, state, national or other Applicable Law that may govern or have jurisdiction over any provision of this Agreement and at all times remain fully compliant with any such Applicable Law, including a product liability insurance policy, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated. Upon request by a Party, the other Party shall provide certificates of insurance evidencing compliance with the above requirements in this Section 10.7. Notwithstanding the foregoing, AbbVie may self-insure, in whole or in part, the insurance requirements described above. It is understood that such insurance shall not be construed to create a limit of either Party's liability.

ARTICLE 11
TERM AND TERMINATION

11.1 Term and Expiration. This Agreement shall commence on the Effective Date and, unless earlier terminated, shall continue in force and effect until the later of (a) the expiration of the last Royalty Term for the last Licensed Product in the OUS Territory and (b) such time as neither Party nor any of its Affiliates or its or their (sub)licensees/Sublicensees is Developing or Commercializing any Licensed Product in the Field for the United States under this Agreement (and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent) (such period, the "**Term**"). Following the expiration of the Term, the rights granted in Section 3.1 shall become unrestricted, fully-paid, royalty-free, perpetual and irrevocable in their entirety.

11.2 Termination.

11.2.1 Termination for Material Breach. If either Party (the "**Breaching Party**") materially breaches any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement in its entirety by providing [****] (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; provided that:

(a) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period (or, if such breach cannot be cured within the Notice Period, if the Breaching Party commences actions to cure such breach within the Notice Period and [****] continues such actions, such termination shall not become effective for so long as the Breaching Party [****] continues such actions);

(b) with respect to any alleged breach by a Party of its diligence obligations set forth in Section 5.1.2(a), Section 5.2.2(b) or Section 5.3.1(b), the other Party shall first provide written notice to such first Party and the Parties shall meet within [****] after delivery of such notice to such first Party to discuss [****] such alleged breach and such first Party's plan to fulfill its applicable diligence obligations, which discussions must be concluded before the other Party may issue any Termination Notice with respect to such alleged breach (for clarity, the Notice Period shall not commence prior to the conclusion of such [****] discussions and the subsequent issuance of a Termination Notice by the other Party); and

(c) if either Party initiates a dispute resolution procedure under Section 12.6 as permitted under this Agreement during the Notice Period to resolve the dispute for which termination is being sought and is pursuing such procedure [****], the Notice Period set forth in this Section 11.2.1 shall be suspended and the termination shall become effective only if such breach remains uncured for [****] after the final resolution of the dispute through such dispute resolution procedure (or, if the breach cannot be cured within such [****], if the Breaching Party commences actions to cure such breach within such period and thereafter [****] continues such actions, such termination shall not become effective for so long as the Breaching Party [****] continues such actions).

11.2.2 Termination by AbbVie. AbbVie may terminate this Agreement in its entirety (a) [****] upon written notice to Licensor if AbbVie [****] determines that it is not advisable for AbbVie to continue to Develop or Commercialize one (1) or more Licensed Products due to safety concerns or (b) from and after [****], (i) prior to the [****], upon [****] prior written notice to Licensor, for any or no reason and (ii) [****], upon [****] prior written notice to Licensor, for any or no reason.

11.2.3 Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [****] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [****] of the filing or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

11.2.4 Termination for Cessation. Licensor may, at its election, terminate this Agreement upon [****] prior written notice to AbbVie in the event that during any [****], none of AbbVie or any of its Affiliates or Sublicensees conducted more than a *de minimis* level of Development or Commercialization activities in connection with the Licensed Compounds or Licensed Products in the United States or any Designated Country (a "**Cessation Event**"); provided that selling (even without promotion) a Licensed Product is deemed to be more than a *de minimis* level of Commercialization; provided further that if such Cessation Event is the direct result of (i) an action by a Regulatory Authority that prevents the Development or Commercialization of the Licensed Compounds or Licensed Products; (ii) a force majeure event; (iii) customary pauses or gaps between or following clinical trials or other studies for the analysis of data, preparation of reports and design of future clinical trials or preparation of regulatory filings and other customary regulatory or Development functions or (iv) an injunction, equitable remedy or other remedy available under Applicable Law or in equity, in each case ((i), (ii), (iii) and (iv)), such [****] period will be extended on a [****] basis for such time period; provided that, during such extension AbbVie uses [****] to resolve the cause for such delay and to resume performance of its Development or Commercialization obligations [****] after the resolution of such cause for delay. AbbVie will [****] respond [****] to Licensor's [****] questions or requests for additional information relating to such cause for delay and resumption of Development or Commercialization obligations.

11.3 Rights in Bankruptcy. The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted to AbbVie under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code, shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction. AbbVie shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, including the right to obtain the intellectual property from another entity.

11.3.1 Licensor will, during the Term, create and maintain current and updated copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed to AbbVie under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include [****]. In the event of the commencement of a bankruptcy proceeding by or against Licensor under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, AbbVie shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in AbbVie's possession, shall be [****] delivered to it upon AbbVie's written request (x) upon commencement of a bankruptcy proceeding, unless Licensor continues to perform all of its obligations under this Agreement, or (y) if not delivered pursuant to clause (x) above because Licensor continues to perform, upon the rejection of this Agreement by or on behalf of Licensor. Unless and until Licensor rejects this Agreement, Licensor shall perform this Agreement or provide the intellectual property (including all embodiments of such intellectual property) to AbbVie, and shall not interfere with the rights of AbbVie to such intellectual property, including the right to obtain the intellectual property from another entity.

11.3.2 The Parties intend and agree that any sale of Licensor's assets under Section 363 of the Bankruptcy Code shall be subject to AbbVie's rights under Section 365(n), that AbbVie cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of AbbVie's rights under this Agreement and Section 365(n) without the express, contemporaneous written consent of AbbVie.

11.3.3 All rights, powers and remedies AbbVie provided in this Section 11.3 are not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code). The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property rights (including all embodiments thereof) of Licensor, or any Third Party with whom Licensor contracts to perform an obligation of Licensor under this Agreement, and, in the case of any such Third Party, that is necessary or reasonably useful for the Exploitation of any Licensed Compounds or Licensed Products or the exercise of any other rights granted to AbbVie under this Agreement;

(b) the right to contract directly with any Third Party to complete the contracted work; and

(c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to Licensor under this Agreement.

11.3.4 The Parties acknowledge and agree that payments made under Section 6.2 and Section 6.3 shall not (a) constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction or (b) relate to licenses of or the use of intellectual property hereunder.

11.4 Consequences of Termination.

11.4.1 Transition Activities. In the event of any termination of this Agreement by a Party pursuant to Section [****] (but, for clarity, not if this Agreement expires pursuant to Section 11.1), the Parties shall use [****] efforts to negotiate and enter into a termination transition plan to wind-down, cease and, transition to Licensor any on-going Development, Manufacturing and Commercialization activities with respect to the Licensed Compounds or Licensed Products in accordance with appropriate professional and ethical standards and Applicable Law. Except if Licensor terminates this Agreement under Section [****] or Section [****], or AbbVie terminates this Agreement under Section [****], the [****] costs and expenses incurred by the Parties in connection with the foregoing transition (but not, for clarity, any wind-down) shall be borne by Licensor.

11.4.2 Licenses and Other Rights. In the event of a termination of this Agreement by a Party pursuant to Section [****] the following shall apply:

(a) except to the extent necessary for AbbVie to perform activities in accordance with Section 11.4.1, all rights and licenses granted by one Party to the other Party shall immediately terminate;

(b) if requested by Licensor, AbbVie (i) shall transfer to Licensor all Regulatory Documentation for each Reversion Product Controlled by AbbVie or any of its Affiliates, (ii) with respect to each Reversion Product, hereby grants to Licensor, effective as of the effective date of termination, a royalty-bearing ([****]) license and right of reference to any Information Controlled by AbbVie or any of its Affiliates that is incorporated into the Regulatory Documentation transferred to Licensor pursuant to clause (i), and (iii) shall assign (or cause its Affiliates to assign) to Licensor all agreements between AbbVie or any of its Affiliates, on the one hand, and any Third Party, on the other hand, that relate to the supply of each Reversion Product and are necessary for Licensor to Exploit each Reversion Product as it exists as of the effective date of termination, unless, with respect to any such agreement, such agreement expressly prohibits such assignment or relates to products other than the applicable Reversion Products, in which case AbbVie shall cooperate with Licensor in [****] respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with respect to each Reversion Product with Licensor on terms substantially similar to

those granted to AbbVie; provided that neither AbbVie nor any of its Affiliates shall be required to make any payments or agree to any material undertakings in connection therewith;

(c) if Licensor notifies AbbVie in writing within [****] after the effective date of termination that Licensor desires to receive a license under any Patent or Information that is (i) owned or otherwise controlled by AbbVie or any of its Affiliates as of the effective date of termination ([****]), (ii) specific to ([****]) any Reversion Product and (iii) necessary to Exploit any Reversion Product, then the Parties shall negotiate [****] an agreement under which AbbVie would grant Licensor a license to such Patents and Information for the Exploitation of any Reversion Product, which agreement shall contain financial terms reflecting the net present value of such a license and other reasonable and customary terms. For clarity, nothing in this Agreement shall obligate AbbVie to grant such a license; and

(d) unless otherwise agreed in the termination transition plan pursuant to Section 11.4.1, Licensor shall be responsible for all ongoing costs and expenses with respect to the Licensed Products, including [****] reporting and [****] monitoring (for [****]) of patients who were or are administered a Licensed Product before, on or after the effective date of termination.

11.4.3 Sell-Off. Notwithstanding the termination of AbbVie's licenses and other rights under this Agreement, AbbVie shall have the right for [****] after the effective date of termination to sell or otherwise dispose of all Licensed Product then in its inventory and any in-progress inventory, as though this Agreement had not terminated, and such sale or disposition shall not constitute infringement of Licensor's or its Affiliates' Patent or other intellectual property or proprietary rights. For the avoidance of doubt, AbbVie shall continue to make payments on such Licensed Product as provided in Section 6.3 and Section 6.5 (as if this Agreement had not terminated with respect to such Licensed Product).

11.5 Modification In Lieu of Termination. If, at any time during the Term, AbbVie has the right to terminate this Agreement pursuant to Section [****], subject to the notice, cure and dispute procedures set forth in Section [****], AbbVie may, by written notice to Licensor, exercise a right to continue this Agreement as modified by this Section 11.5, in which case, effective as of the date AbbVie delivers such notice of such election to Licensor:

11.5.1 with respect to any Net Profits or Net Losses incurred thereafter, (a) Licensor shall receive [****] of all Net Profits and bear [****] of all Net Losses, as applicable, with respect to the Licensed Products in the United States, and (b) AbbVie shall receive [****] of all Net Profits and bear [****] of all Net Losses, as applicable, with respect to the Licensed Products in the United States;

11.5.2 with respect to royalties payable by AbbVie to Licensor pursuant to Section 6.5 with respect to any Net Sales in the OUS Territory thereafter, the royalty rates set forth in Section 6.5.1 shall be reduced by [****] of the applicable rate set forth in such Section (and, for clarity, the foregoing shall not affect any further adjustment that may be made in accordance with Section 6.5.3 or Section 6.5.5, which shall be applied to such reduced royalty rate);

11.5.3 the amount of any milestone payments payable by AbbVie to Licensor pursuant to Section 6.2 for any milestone event achieved thereafter shall be reduced by [****] of the applicable amount set forth in such Section;

11.5.4 AbbVie's diligence obligations under this Agreement, including Section [****] [****], Section 5.2.2(b) and Section 5.3.1(b), shall all terminate; and

11.5.5 all other provisions of this Agreement shall remain in full force and effect without change.

Once AbbVie has exercised its right under this Section 11.5, AbbVie shall have no right to exercise such right again with respect to any future breaches by Licensor for which AbbVie has the right to terminate this Agreement pursuant to Section 11.2.1.

11.6 Remedies. Except as otherwise expressly provided herein, termination of this Agreement shall not limit remedies that may otherwise be available in law or equity.

11.7 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration; *provided* that (a) in no event shall Licensor accrue any rights to, and AbbVie shall have no obligation to make, any milestone payment under Section 6.2 based on any milestone event that occurs on or after the [****] pursuant to Section 11.2 and (b) unless Licensor terminates pursuant to Section 11.2.1 or AbbVie terminates pursuant to Section 11.2.2(b), each Party's diligence obligations under this Agreement, including pursuant to Section 5.1.2(a), Section 5.2.2(b) and Section 5.3.1(b) shall terminate on [****] pursuant to Section 11.2. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing:

11.7.1 Sections 5.2.5 (solely the second sentence, for the applicable period set forth therein), 6.10, 6.11 and 6.12 (in each case, for the periods set forth therein), 6.13, 7.2, 7.4.2 through 7.4.4 (in each case, solely with respect to any Joint Patents), 7.4.6, 7.4.8 (solely with respect to any Joint Patents), 7.5.1 through 7.5.4 (in each case, solely with respect to any Joint Patents; provided that references to "the IP Group" therein shall be deemed to refer to "AbbVie"), 7.6.1 through 7.6.4 (in each case, solely with respect to any Joint Patents; provided that references to "the IP Group" therein shall be deemed to refer to "AbbVie"), 7.7 (solely with respect to any Third Party Infringement Claim with respect to the Exploitation of Licensed Compounds or Licensed Products by AbbVie or its Affiliates or its or their Sublicensees; provided that the reference to "the IP Group" therein shall be deemed to refer to "AbbVie"), 7.8.4 (solely to the extent (a) any payment obligations thereunder have accrued but are unpaid as of the effective date of termination or (b) applicable to any post-Term payment obligations under Section 6.3, 11.4.1, 11.4.2(d) or 11.4.3), 7.9.3, 7.10, 8.1 and 8.2 (in each case, for the period set forth in Section 8.1), 8.3 (for the period set forth in Section 8.1; provided that Section 8.3.3 shall apply only with respect to any Joint Patents), 8.6, 8.8, 9.1, 9.2, 9.6, 10.1, 10.2, 10.3 (solely with respect to activities during the Term), 10.4 through 10.6, 10.7 (for the period set forth therein), 11.3, 11.4, 11.6 and this Section 11.7 (but not 11.7.2) and Articles 1 (to the extent necessary to construe the other surviving provisions), 6 (other than Sections 6.10 through Section 6.13 (which are addressed above), and

solely to the extent (a) any payment obligations thereunder have accrued but are unpaid as of the effective date of termination or (b) applicable to any post-Term payment obligations under Section 6.3, 11.4.1, 11.4.2(d) or 11.4.3) and 12 (other than Section 12.2) of this Agreement shall survive the termination of this Agreement for any reason; and

11.7.2 Sections 2.6 (last sentence), 3.1 (subject to the last sentence of Section 11.1), 3.3, 3.4 (subject to the last sentence of Section 11.1), 3.5, 3.6, 5.2.5 (solely the last three sentences, for the applicable period set forth therein), 5.5, 6.10, 6.11 and 6.12 (in each case, for the periods set forth therein), 6.13, 8.1 through 8.3 (in each case, for the period set forth in Section 8.1), 8.4.1, 8.4.3, 8.6, 8.7, 8.8, 9.1 through 9.3, 9.5, 9.6, 10.1 through 10.6, 10.7 (for the period set forth therein), 11.1 (last sentence only), 11.3 and this Section 11.7 (but not Section 11.7.1) and Articles 1 (to the extent necessary to construe the other surviving provisions), 5 (but not Sections 5.1.2, 5.2.2, 5.3.1, 5.3.5(a)), 6 (other than Sections 6.10 through Section 6.13 (which are addressed above), and solely to the extent (a) any payment obligations thereunder have accrued but are unpaid as of the effective date of termination or (b) applicable to any post-Term payment obligations under Section 6.3, 11.4.1, 11.4.2(d) or 11.4.3), 7 (other than Section 7.1) and 12 (other than Section 12.2) of this Agreement shall survive the expiration of this Agreement.

ARTICLE 12
MISCELLANEOUS

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term (except payment obligations) of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, pandemics, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (including any Regulatory Authority) (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [****] after such occurrence by providing a written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

12.2 Change of Control of Licensor.

12.2.1 Licensor (or its successor) shall provide AbbVie with [****] written notice of any Change of Control of Licensor following [****].

12.2.2 [****] following [****] of a Change of Control of Licensor or Licensor's or any of its Affiliates' acquisition of an Acquired Program, Licensor shall establish, maintain and implement the Firewall Procedures.

12.2.3 In the event [****].

12.3 Export Control. This Agreement, and the rights and obligations of the Parties under this Agreement, shall be subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export or transfer, directly or indirectly, any technical data, information or materials acquired from the other Party under this Agreement or any products using such technical data, information or materials 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 agency or other governmental entity in accordance with Applicable Law.

12.4 Assignment. Except as provided in Section 5.5, without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), neither Party shall sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided that (a) AbbVie shall have the right, without such consent, to (i) perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates (in accordance with Section 12.15) or its or their Sublicensees or distributors, and (ii) assign this Agreement without Licensor's consent (A) in whole or in part, to any Affiliate or (B) in its entirety, to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates and (b) Licensor shall have the right to assign this Agreement in its entirety, without AbbVie's consent but subject to Section 3.7.2 and Section 12.2, (i) in whole or in part, to any Affiliate that has the [****] or (ii) to any successor in interest in connection with a Change of Control; provided that Licensor and, solely with respect to an assignment pursuant to clause (B) above, AbbVie, shall provide written notice to the other Party within [****] after such assignment. With respect to an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. In addition, notwithstanding anything to the contrary in this Agreement, Licensor may sell, assign or otherwise transfer or pledge as a security all or any part of its rights to receive royalties in the OUS Territory pursuant to Section 6.5; provided that Licensor shall (x) consult with AbbVie prior to entering into any such sale, assignment, transfer or pledge, (y) consider [****] any comments from AbbVie regarding such sale, assignment, transfer or pledge and (z) provide written notice to AbbVie within [****] after such sale, assignment, transfer or pledge. Any attempted assignment or delegation in violation of this Section 12.4 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Licensor or AbbVie, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of Licensor, and the obligations of AbbVie, including the payment obligations, shall run in favor of any such successor or permitted assignee of Licensor's benefits under this Agreement.

12.5 Severability. If, under Applicable Law, any one (1) or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable at law or in equity in any court of competent jurisdiction and the rights of the Parties will not be materially and adversely

affected thereby, (a) such invalid, illegal or unenforceable provision(s) shall be considered severed from this Agreement with respect to such jurisdiction, (b) this Agreement shall be construed and enforced as if such invalid, illegal or unenforceable provision(s) had never comprised a part hereof and (c) the Parties shall make reasonable efforts to replace any invalid, illegal or unenforceable provision(s) with a valid, legal and enforceable provision(s) such that the objectives contemplated by the Parties when entering this Agreement may be realized (and, to the extent the Parties agree to a replacement provision, the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the invalid, illegal or unenforceable provision(s) or by its or their severance herefrom). To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof invalid, illegal or unenforceable in any respect.

12.6 Dispute Resolution.

12.6.1 Except for disputes resolved by the procedures set forth in Section 2.5.4, Section 6.12 or Section 12.11, if a dispute arises between the Parties in connection with, arising out of or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), it shall be resolved pursuant to this Section 12.6.

12.6.2 General. Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer [****] on the resolution of the issue. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. If the Executive Officers are not able to agree on the resolution of any such issue within [****] (or such other period of time as mutually agreed by the Executive Officers) after such issue was first referred to them, then, except as otherwise set forth in Section 12.6.3, either Party may, by written notice to the other Party, elect to initiate an alternative dispute resolution ("**ADR**") proceeding pursuant to the procedures set forth in **Schedule 12.6.4** for purposes of having the matter settled.

12.6.3 Intellectual Property Disputes. In the event that a Dispute arises with respect the validity, scope, enforceability, inventorship or ownership of any Patent, Trademark or other intellectual property rights, and such Dispute cannot be resolved by the IP Group or Executive Officers, unless otherwise agreed by the Parties in writing, such Dispute shall not be submitted to an ADR proceeding in accordance with Section 12.6.4 and instead, either Party may initiate litigation in a court of competent jurisdiction, notwithstanding Section 12.6.7, in any country or other jurisdiction in which such rights apply.

12.6.4 ADR. Any ADR proceeding under this Agreement shall take place pursuant to the procedures set forth in **Schedule 12.6.4**.

12.6.5 Adverse Ruling. Any determination pursuant to this Section 12.6 that a Party is in material breach of its obligations hereunder shall specify a (nonexclusive) set of actions to be taken to cure such material breach, if feasible.

12.6.6 Interim Relief. Notwithstanding anything herein to the contrary and without limiting Section 12.11, nothing in this Section 12.6 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute following the ADR procedures set forth in Section 12.6.4, except as set forth in Section 12.11, if necessary to protect the interests of such Party. This Section shall be specifically enforceable.

12.6.7 Continuance of Rights and Obligations during Pendency of Dispute Resolution. If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under Article 11, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this Section 12.6.7.

12.7 Governing Law, Jurisdiction and Service.

12.7.1 Governing Law. This Agreement and the performance, enforcement, breach or termination hereof shall be governed by and construed in accordance with the laws of [****], excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided that all questions concerning (a) inventorship of Patents under this Agreement shall be determined in accordance with Section 7.2.3 and (b) the construction or effect of Patents shall be determined in accordance with the laws of the country or other jurisdiction in which the particular Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

12.7.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 12.8.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

12.8 Notices.

12.8.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, (b) by internationally recognized overnight delivery service that maintains records of delivery addressed to the relevant Party at its address specified in Section 12.8.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 12.8.1 or (c) solely as specifically set forth in this Agreement, emailed to the email address of the relevant Party specified in Section 12.8.2 or to such other email address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 12.8.1. Such notice shall be deemed to have been given as of the date delivered by hand or on the [****] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 12.8.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

12.8.2 Address for Notice.

If to AbbVie, to:

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064
United States
Facsimile: [****]
Attention: [****]

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

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064
United States
Facsimile: [****]
Attention: [****]

If to Licensor, to:

Aldeyra Therapeutics, Inc.
131 Hartwell Ave., Suite 302
Lexington, MA 02421
Attention: Todd Brady, Chief Executive Officer
E-mail: tbrady@aldeyra.com

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

Goodwin Procter LLP
100 Northern Ave.
Boston, MA 02210
Attention: Kathleen Kean, Esq.
E-mail: KKean@goodwinlaw.com

12.9 Entire Agreement; Amendments. This Agreement, together with the attached Schedules and Exhibits, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter here and all prior agreements, understandings and representations, whether written or oral, with respect thereto, including the Confidentiality Agreement and Option Agreement, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

12.10 English Language. This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English

language. Any translation into any other language shall not be an official version and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

12.11 Equitable Relief. Each Party acknowledges and agrees that the provisions of Section 3.7, Section 4.1 and Articles 7 and 8 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such provisions and that any breach or threatened breach of any provision of such Sections or Articles, notwithstanding Section 12.8, will result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Sections or Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Each Party agrees to waive any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 12.11 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

12.12 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of an authorized representative of the Party waiving such term or condition. The waiver by either Party of any right or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided in this Agreement are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available, except as expressly provided herein.

12.13 No Benefit to Third Parties. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights to any Third Party (including any Third Party beneficiary rights).

12.14 Further Assurance. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

12.15 Performance by Affiliates. AbbVie may use one (1) or more of its Affiliates to perform its obligations and duties hereunder and such AbbVie Affiliates are expressly granted certain rights herein; provided that each such Affiliate shall be bound by the corresponding

obligations of AbbVie and AbbVie shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

12.16 Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and AbbVie, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, including for all tax purposes. Neither Licensor, on the one hand, nor AbbVie, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All individuals employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

12.17 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

12.18 Construction. Except where the context otherwise requires, wherever used, (a) the singular shall include the plural, the plural the singular, (b) the use of any gender shall be applicable to all genders, (c) the word "or" is used in the inclusive sense (and/or), (d) any reference herein to any person shall be construed to include the person's successors and assigns, (e) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (f) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (g) 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), and (h) references to any specific law, rule or regulation, or Section, 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. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include" or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. All references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Each Party 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 will apply against the Party that drafted such terms and provisions.

12.19 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.**]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

ABBVIE INC.	**ALDEYRA THERAPEUTICS, INC.**
By:	By:
Name:	Name:
Title:	Title:

[Signature Page to Co-Development, Co-Commercialization and License Agreement]

[****]

Exhibit 21.1

SUBSIDIARIES OF ALDEYRA THERAPEUTICS, INC.

Name of Subsidiary	**Jurisdiction of Organization**
Helio Vision, LLC	United States of America
Helio Vision Germany GmbH	Germany

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-254175) and Form S-8 (Nos. 333-196674, 333-203076, 333-210492, 333-213045, 333-217043, 333-224019, 333-230161, 333-237129, 333-254144, 333-263660, 333-270401 and 333-275315) of Aldeyra Therapeutics, Inc. of our report dated March 7, 2024, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, P.C.
Boston, Massachusetts

March 7, 2024

Exhibit 31.1

CERTIFICATION

I, Todd C. Brady, certify that:

1. I have reviewed this annual report on Form 10-K of Aldeyra Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2024

/s/ Todd C. Brady, M.D., Ph.D.

Todd C. Brady, M.D., Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Bruce Greenberg, certify that:

1. I have reviewed this annual report on Form 10-K of Aldeyra Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2024

/s/ Bruce Greenberg

Bruce Greenberg
Vice President of Finance, Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

In connection with the Annual Report of Aldeyra Therapeutics, Inc. (the "Registrant") on Form 10-K for the annual period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Todd C. Brady, M.D., Ph.D., Chief Executive Officer and Director of the Registrant, and Bruce Greenberg, Vice President of Finance and Interim Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their respective knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 7, 2024

/s/ Todd C. Brady, M.D., Ph.D.
Todd C. Brady, M.D., Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 7, 2024

/s/ Bruce Greenberg
Bruce Greenberg
Vice President of Finance, Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97

ALDEYRA THERAPEUTICS, INC. POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

1. **Purpose**. The purpose of this Policy is to describe the circumstances in which Executive Officers will be required to repay or return Erroneously Awarded Compensation to members of the Company Group. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended, Rule 10D-1 promulgated thereunder and the Listing Standards. Each Executive Officer shall be required to sign and return to the Company the Acknowledgment Form attached hereto as Exhibit A pursuant to which such Executive Officer will agree to be bound by the terms of and comply with this Policy.

2. **Administration**. This Policy shall be administered by the Committee. The Committee is authorized to interpret and construe this Policy and to make all determinations, and take all actions, necessary, appropriate or advisable for the administration of this Policy. Any determinations and interpretations made by the Committee shall be final and binding on all affected individuals, and need not be uniform with respect to each individual covered by this Policy.

3. **Definitions**. As used in this Policy, the following capitalized terms shall have the meanings set forth below.

(a) "***Accounting Restatement***" shall mean an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement (i) that corrects an error in previously issued financial statements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement). An Accounting Restatement does not include situations in which financial statement changes did not result from material noncompliance with financial reporting requirements, such as, but not limited to, retrospective: (i) application of a change in accounting principles; (ii) revision to reportable segment information due to a change in the structure of the Company's internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; (v) adjustment to provisional amounts in connection with a prior business combination; and (vi) revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(b) "***Board***" shall mean the Board of Directors of the Company.

(c) "***Clawback Eligible Incentive Compensation***" shall mean, in connection with an Accounting Restatement and with respect to each individual who served as an Executive Officer at any time during the applicable performance period for any Incentive-Based Compensation (whether or not such Executive Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company Group), all Incentive-Based Compensation Received by such Executive Officer (i) on or after the Effective Date (even if such Incentive-Based Compensation was approved, awarded, granted or paid prior to the effective date of the Listing Standards), (ii) after beginning service as an Executive Officer, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the applicable Clawback Period.

(d) "***Clawback Period***" shall mean, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(e) "***Committee***" shall mean the Compensation Committee of the Board.

(f) "***Company***" shall mean Aldeyra Therapeutics, Inc., a Delaware corporation.

(g) "***Company Group***" shall mean the Company, together with each of its direct and indirect subsidiaries.

(h) "***Effective Date***" shall mean the effective date of this Policy, which date is October 2, 2023.

(i) "***Erroneously Awarded Compensation***" shall mean, with respect to each Executive Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts as reflected in the Accounting Restatement, computed without regard to any taxes paid. For Incentive-Based Compensation based on (or derived from) stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq).

(j) "***Executive Officer***" shall mean each individual who is or was designated as an "officer" of the Company in accordance with 17 C.F.R. 240.16a-1(f). Identification of an executive officer for purposes of this Policy would include, at a minimum, executive officers identified pursuant to 17 C.F.R. 229.401(b). As of the Effective Date (and subject to later amendments to the above-referenced rules), Executive Officer covers the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a significant policy-making function, or any other person (including any executive officer of the Company's affiliates including a parent or subsidiary of the Company) who performs similar policy-making functions for the Company.

(k) "***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements (including "non-GAAP financial measures," such as those appearing in earnings releases), and any measures that are derived wholly or in part from such measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC. Stock price and total shareholder return shall for purposes of this Policy also be considered Financial Reporting Measures.

(l) "***Incentive-Based Compensation***" shall mean any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the sake of clarity, examples of compensation that is not Incentive-Based Compensation include, but are not limited to: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either of cash or equity) that are based solely upon subjective, strategic or operational metrics or measures; and (iv) equity awards that vest solely upon continued service or the passage of time.

(m) "***Listing Standards***" shall mean Nasdaq Listing Rule 5608.

(n) "***Nasdaq***" shall mean The Nasdaq Stock Market.

(o) "***Policy***" shall mean this Policy for the Recovery of Erroneously Awarded Compensation, as the same may be amended, restated, supplemented or otherwise modified from time to time.

(p) "***Received***" shall, with respect to any Incentive-Based Compensation, mean actual or deemed receipt, and Incentive-Based Compensation shall be deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if grant or payment of the Incentive-Based Compensation occurs after the end of that period.

(q) "***Restatement Date***" shall mean the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement, in each case regardless of if or when the restated financial statements are filed.

(r) "***SEC***" shall mean the U.S. Securities and Exchange Commission.

4. **Required Recovery of Erroneously Awarded Compensation**.

(a) In the event the Company is required to prepare an Accounting Restatement, the Committee shall determine the amount of any Erroneously Awarded Compensation for each Executive Officer in connection with such Accounting Restatement, shall thereafter provide each Executive Officer with a written notice containing the amount of Erroneously Awarded Compensation and a demand for repayment or return, as applicable, and shall take all other actions necessary and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officers reasonably promptly.

(b) The Committee shall determine, in its sole discretion, the timing and method for recovering Erroneously Awarded Compensation reasonably promptly based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. Such methods may include, without limitation, (i) seeking reimbursement of all or part of any cash or equity-based award, (ii) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (iii) cancelling or offsetting against any planned future cash or equity-based awards, (iv) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations promulgated thereunder, and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Committee may effect recovery under this Policy (i) from any amount otherwise payable to the Executive Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions, and compensation previously deferred by the Executive Officer, and (ii) from any amount of compensation approved, awarded, granted, payable or paid to the Executive Officer prior to, on or after the effective date of the Listing Standards. For the avoidance of doubt, except as set forth in Section 4(d) below, in no event may the Company Group accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive Officer's obligations hereunder.

(c) To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company Group when due, the Company shall, or shall cause one or more other members of the Company Group to, take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company Group for any and all expenses reasonably incurred (including legal fees) by the Company Group in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d) Notwithstanding anything herein to the contrary, the Company shall not be required to recover Erroneously Awarded Compensation from any Executive Officer if the following conditions are met and the Committee determines that recovery would be impracticable:

(i) The direct expenses paid to a third party to assist in enforcing this Policy against an Executive Officer would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously Awarded Compensation, documented such attempt(s) and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law of the Company where that law was adopted prior to November 28, 2022, after the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. **Reporting and Disclosure**. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable SEC filings. The Company shall also file a copy of this Policy and any amendments thereto as an exhibit to its annual report on Form 10-K.

6. **No Indemnification of Executive Officers**. Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Executive Officer that may be interpreted to the contrary, no member of the Company Group shall be permitted to indemnify any Executive Officer against, or pay or reimburse the premiums for an insurance policy to cover, (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company Group's enforcement of its rights under this Policy. Further, no member of the Company Group shall enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company Group's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

7. **Committee Indemnification**. Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

8. **Effective Date**. This Policy shall be effective as of the Effective Date.

9. **Amendment**; **Termination**. The Committee may amend, modify, supplement, rescind or replace all or any portion of this Policy at any time and from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed. The Committee may terminate this Policy at any time. Notwithstanding anything in this Section 9 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

10. **Other Recoupment Rights; Company Claims**.

(a) The Committee intends that this Policy will be applied to the fullest extent of the law and with respect to all Incentive-Based Compensation granted to an Executive Officer, whether pursuant to a pre-existing contract or arrangement, or one that is entered into after the Effective Date. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company Group under applicable law, regulation or rule or pursuant to the terms of any similar policy in any employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company Group.

(b) Nothing contained in this Policy, and no recoupment or recovery as contemplated by this Policy, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against an Executive Officer arising out of or resulting from any actions or omissions by the Executive Officer.

11. **Successors**. This Policy shall be binding and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

* * *

Exhibit A

ALDEYRA THERAPEUTICS, INC. POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

ACKNOWLEDGMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Aldeyra Therapeutics, Inc. Policy for the Recovery of Erroneously Awarded Compensation (as may be amended, restated, supplemented or otherwise modified from time to time, the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgment Form (this "***Acknowledgment Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgment Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company Group. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by promptly returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company Group to the extent required by, and in a manner permitted by, the Policy. In the event of any inconsistency between the Policy and the terms of any employment agreement to which the undersigned is a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern.

_____
Signature

_____
Print Name

_____
Title

_____
Date