Aldeyra Therapeutics, Inc.
Form 10-K
March 30, 2017
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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, 2016

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)	**(IRS 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:

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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, 2016, the last business day of the registrant s last completed second quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $59,217,833, 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 30, 2017 there were 15,131,880 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 2017 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, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Aldeyra Therapeutics, Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2016

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in 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, int may, plan, contemplates, predict, project, target, likely, potential, continue, ongoing, design, 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:

- 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 ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets and pricing for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency or use of our cash resources and needs for additional financing;
- the rate and degree of market acceptance of any of our product candidates;
- our expectations regarding competition;
- our anticipated growth strategies;

our ability to attract or retain key personnel;

our ability to establish and maintain development partnerships;

our expectations regarding federal, state and foreign regulatory requirements;

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.

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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 they will have 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, we, us, and our mean Aldeyra Therapeutics, Inc. unless the context indicates otherwise.

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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, in addition to research, 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 is reliable and is based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed in Risk Factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

ITEM 1. *BUSINESS*

Overview

We are a biotechnology company focused primarily on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes. We are developing ADX-102 (formerly known as NS2), as well as other novel product candidates, including ADX-103 and ADX-104, that are designed specifically to sequester aldehydes for the treatment of:

- Noninfectious Anterior Uveitis, a rare but severe inflammatory eye disease that can lead to blindness;
- Allergic Conjunctivitis, a common disease that affects more than 20% of the population worldwide, and related rare allergic ocular diseases that are characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, swelling, and redness;
- Dry Eye Syndrome, a common inflammatory disease characterized by insufficient moisture and lubrication associated with the anterior surface of the eye, leading to ocular irritation, burning, stinging, and, in severe cases, loss of vision;
- Sjögren-Larsson Syndrome (SLS), a rare inborn error of metabolism caused by mutations in an enzyme that metabolizes fatty aldehydes, resulting in severe skin and neurological disorders; and
- Succinic Semi-Aldehyde Dehydrogenase Deficiency (SSADH), a rare inborn error of metabolism caused by genetic mutations in an aldehyde-metabolizing enzyme, leading to severe neurological disease.

In February 2016, we announced that the results of a randomized, parallel-group, double-masked, vehicle-controlled Phase 2a clinical trial of ADX-102 ophthalmic solution in patients with allergic conjunctivitis demonstrated

statistically and clinically significant activity of ADX-102 over vehicle in reducing ocular itching and tearing. In May 2016, we announced that the results of our randomized, parallel-group, investigator-masked, active-controlled Phase 2 clinical trial of ADX-102 ophthalmic solution in patients with noninfectious anterior uveitis demonstrated that ADX-102 reduced inflammatory cell count in the anterior chamber of the eye to a degree similar to that of standard-of-care corticosteroid therapy (which may lead to cataracts and glaucoma in some patients), but without the intraocular pressure elevations that were observed in subjects treated with corticosteroids. In August 2016, we announced that the results of a randomized, parallel-group, double-blind, vehicle-controlled clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of SLS demonstrated clinically relevant activity of ADX-102 in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. In all clinical trials to date, ADX-102 was well tolerated, and no serious adverse events have been reported.

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In February 2017, we announced the enrollment of the first patient in a Phase 2b clinical trial of topical ocular ADX-102 for the treatment of allergic conjunctivitis. We expect to begin a planned Phase 3 clinical trial of topical ocular ADX-102 for the treatment of noninfectious anterior uveitis in the second quarter of 2017. We expect to begin a planned Phase 3 clinical trial of topical dermatologic ADX-102 for the treatment of the skin manifestations of SLS in the second half of 2017. We expect to begin a planned Phase 2a clinical trial of topical ocular ADX-102 for the treatment of Dry Eye Syndrome in the second quarter of 2017. Contingent on preclinical results, regulatory feedback, and other factors, we may also initiate a planned Phase 2a clinical trial of ADX-103 in Dry Eye Syndrome. We expect to begin a planned Phase 1 clinical trial of systemically administered ADX-102 or ADX-104 in the first half of 2018. We expect to begin systemically administered Phase 2a clinical trials in SLS and SSADH in the second half of 2018. All of our development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials. Our clinical development pipeline is summarized in the figure below.

Clinical Development Pipeline

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 the development of our product candidates to obtain the regulatory approvals for and to manufacture, market and sell our products and 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.

Business Strategy

We intend to develop ADX-102 and other novel aldehyde traps for the diseases described above as well as potentially other diseases where aldehydes may mediate pathology. We believe that aldehyde trapping is a novel approach with broad therapeutic potential in inflammatory diseases and inborn errors of aldehyde metabolism. Accordingly, we have patented and will continue to attempt to patent novel drug compositions, formulations, and methods that relate to aldehyde trapping. While we may continue to develop and eventually attempt to market aldehyde traps for certain diseases following regulatory approval, if any, we may also partner with larger companies to develop and commercialize products for other diseases where aldehyde toxicity is implicated, particularly diseases that afflict large populations worldwide.

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Specifically, our business strategy is to:

Continue the development of and pursue regulatory approval for ADX-102 and other aldehyde traps. We have initiated clinical trials of ADX-102 in several diseases, and we may initiate clinical trials of ADX-103, ADX-104, and other aldehyde traps. If sufficient safety and efficacy is demonstrated over multiple clinical trials as part of the standard drug development process, we intend to apply to the United States Food and Drug Administration (FDA) and comparable foreign agencies for marketing approval of our product candidates.

Aggressively develop new intellectual property and consider partnerships to accelerate development and maximize commercial potential. We have discovered and synthesized a variety of aldehyde traps that we intend to develop and patent for new indications. For some indications, especially those that afflict large populations worldwide, we will consider development and commercialization licensing opportunities with strategic partners that have significant financial resources, commercialization experience, and global infrastructure.

Explore building in-house capabilities to commercialize ADX-102, ADX-103, and ADX-104 in the United States and other geographies. As, and if, ADX-102 and our other product candidates progress through clinical programs, in addition to partnering opportunities that we may consider, we also intend to evaluate the development of our own specialty sales force and marketing capabilities to allow us to directly market our product candidates in the United States or in other geographies, if approved by FDA or analogous regulatory agencies outside the United States.

Consider in-licensing complementary drug programs. We may consider in-licensing additional product candidates or technology rights that are unrelated to aldehyde trapping but complementary to our current development programs.

The Markets for Our Product Candidates

Occurring generally as a result of a large number of metabolic processes, aldehydes are an endogenously generated chemical species that, among other things, promote inflammation. At high levels, aldehydes are toxic and are implicated as mediators of many inflammatory diseases. Other diseases thought to be related to aldehydes include inborn errors of metabolism, where genetic mutations lead to the incapacity to metabolize certain toxic aldehydes. We believe that the medical needs of the patients suffering from aldehyde-mediated diseases are not currently well addressed and that there is a large market potential for therapies that can lower aldehyde levels. In particular, current therapies for inflammatory diseases are often inadequate and may lead to toxicity, and there are no FDA-approved therapies specifically indicated for inborn errors of aldehyde metabolism.

Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva, resulting in excessive ocular itching and tear production in addition to ocular swelling and redness. Allergic conjunctivitis has been estimated to affect more than 20% of the population worldwide. The mainstay of therapy for allergic conjunctivitis is anti-histamines, which may

lead to mydriasis (large pupils) and, in some patients, blurry vision. Further, approximately one million patients in the United States do not respond to anti-histamines, especially after the acute effects of the medication subside. Many anti-histamine refractory patients are treated with corticosteroids, which often lead to a variety of ocular toxicities that include glaucoma (a potentially blinding disease characterized by elevated intraocular pressure), cataracts (lens opacities that can lead to loss of vision), ocular infection, and ulceration. Other ocular diseases related to allergic conjunctivitis include atopic keratoconjunctivitis (AKC), a rare condition characterized by persistent allergic inflammation of the front of the eye. Treatment of AKC generally requires chronic corticosteroid administration, and physicians treating AKC patients must continuously balance the severity of the disease with the toxicity of corticosteroids.

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By trapping pro-inflammatory aldehydes, we believe ADX-102 may reduce inflammation in allergic conjunctivitis, AKC, and related diseases. ADX-102 may also reduce the burden of corticosteroid use in patients with persistent disease or in patients that do not respond adequately to anti-histamines. Given the toxicity of corticosteroids, we believe that there is a high demand for a novel topical anti-inflammatory agent to be used in conjunction with lower doses of, or in place of, corticosteroids.

Noninfectious Anterior Uveitis

Noninfectious anterior uveitis is an inflammatory ocular disease that is associated with elevated aldehyde levels and is characterized by severe pain, sensitivity to light, and loss of vision that can progress to blindness. The disease may occur with other autoimmune diseases. The annual incidence of noninfectious anterior uveitis in the United States is estimated to be 150,000 patients, and approximately one-third of these patients have one or more episodes per year. The disease is typically treated with topical corticosteroids, and many patients are at risk of developing glaucoma and cataracts as a result of corticosteroid treatment. Corticosteroids may also increase the incidence of infection and corneal ulceration.

By trapping pro-inflammatory aldehydes, we believe ADX-102 may diminish inflammation in noninfectious anterior uveitis and reduce the burden of corticosteroid use. Given the toxicity of corticosteroids, we believe that there is a high demand for a novel topical anti-inflammatory agent to be used in conjunction with lower doses of, or in place of, corticosteroids.

Dry Eye Syndrome

Dry Eye Syndrome is a common inflammatory disease that is estimated to affect five to ten percent of the population in the United States, and is characterized by insufficient moisture and lubrication of the anterior surface of the eye. Symptoms may include ocular irritation, burning, or stinging, and severe cases may lead to loss of vision. In patients with Dry Eye Syndrome, elevated ocular levels of pro-inflammatory aldehydes are correlated with disease severity and likely contribute to persistent inflammation. Since aldehydes covalently bind to lipids (fats) found in tears, the increased aldehyde load in Dry Eye Syndrome patients may also exacerbate insufficient ocular surface lubrication.

Until 2016, only one drug had been approved by the FDA for the treatment of Dry Eye Syndrome, and therapy for the disease is generally considered by patients and physicians to be inadequate. Patients with severe cases of Dry Eye Syndrome may require corticosteroids. Since lowering aldehyde levels may diminish ocular inflammation and preserve tear lubricating capacity in patients with Dry Eye Syndrome, ADX-102 and ADX-103 represent a potential novel, dual-acting therapeutic approach that could be used to augment the efficacy of currently available medications and, in severe cases, reduce or eliminate the need for corticosteroid therapy.

Sjögren-Larsson Syndrome

SLS is caused by genetic mutations of fatty aldehyde dehydrogenase (FALDH), an enzyme that converts long-chain aldehydes to fatty acids. FALDH dysfunction leads to fatty aldehyde accumulation, which is thought to result in a severe skin disorder called ichthyosis, which is characterized by thick, scaly, flaking, itchy and inflamed skin involving much of the body surface area, as well as mental delay, spasticity, and, in some patients, retinal disorders. SLS patients are generally diagnosed as neonates given the severe ichthyosis that presents at birth. The disease persists lifelong, and SLS patients have a shortened lifespan, often dying in the sixth decade of life. Some SLS patients are believed to inherit the disease, though most occurrences of SLS appear to be due to sporadic mutations. The disease occurs worldwide. To our knowledge, Sweden is currently the only country to have estimated the prevalence of the disease, at 1 per 250,000 people. Extrapolating from the Swedish estimate, it is generally assumed

that there are approximately 1,000 or fewer SLS patients in the United States and a larger number in Europe. The United States SLS prevalence estimate is supported by frequency analysis of FALDH missense mutations in the National Heart, Lung, and Blood Institute exome sequencing database. We believe that

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many older SLS patients may be undiagnosed, potentially due to the lack of available dermatologic and genetic medicine expertise available when those patients were younger. There is no FDA-approved treatment specifically indicated for SLS.

The primary day-to-day complaint of SLS patients and their caregivers is ichthyosis, a severe skin disease characterized in SLS patients by thick, scaly, dry, flaking, wrinkled, pigmented, pruritic (itchy), inflamed skin. SLS patients are consistently disturbed by pruritus and often excoriate skin by scratching. The scales that accumulate on the surface of the skin are subject to bacterial overgrowth, which results in an unpleasant odor that is associated with some SLS patients. The ichthyosis in SLS affects most of the body, generally sparing only the face, palms, and soles, and considerable social stigma and emotional burden is common, especially given scale odor, the flaking skin, and the misconception that patients suffer from diffuse cutaneous infectious disease. There is currently no specific therapy approved for the treatment of the dermatologic disease in SLS, though some patients and their caregivers apply non-specific topical creams, including keratinolytics (acids that soften skin), moisturizers, and retinoids. We believe that the effects of keratinolytic and moisturizing creams are minimal or non-existent in treating severe ichthyosis, and due to toxicity, retinoids are not suitable for chronic use.

The dermatologic disease in SLS is thought to be caused by aldehyde-mediated modification of lipids (fats) that are generated in the epidermis (the most superficial layer of skin) to form a moisture barrier that holds water in the skin. Moisture barrier compromise leads to water loss, which in turn leads to epidermal thickening characteristic of ichthyosis. We believe that by lowering levels of aldehydes and thereby preventing lipid modification and the ensuing moisture barrier dysfunction, ADX-102, when applied topically to the skin, has the potential to ameliorate the dermatologic symptoms of SLS. Further, by reducing aldehyde load throughout the body, we believe the systemic administration of ADX-102, ADX-104, or other aldehyde traps may be beneficial in the treatment of the neurological and ocular symptoms of SLS.

Succinic Semi-Aldehyde Dehydrogenase Deficiency

SSADH Deficiency is a neurological disease caused by mutations in succinic semi-aldehyde dehydrogenase that result in elevated levels of succinic semi-aldehyde, a toxic aldehyde that is converted into gamma-hydroxybutyrate (GHB) and other metabolites that lead to severe neurological dysfunction, including cognitive delay, seizures, and motor disease. Over 400 patients with SSADH Deficiency have been identified worldwide, though the precise prevalence of the disease is not known. GHB (also known as sodium oxybate, a drug marketed for psychiatric disorders) and possibly other succinic semi-aldehyde metabolites lead to depression of neurological function, and some patients with a diagnosis of autism have been found to have SSADH Deficiency.

There is currently no FDA-approved therapy specifically indicated for SSADH Deficiency, and most patients are treated supportively with anti-epileptic medications. While several therapeutic approaches have been attempted in clinical trials, and one medication is currently undergoing testing in a clinical trial run by the National Institute of Neurological Disorders and Stroke, to our knowledge, none have shown promise in addressing the core toxicity of succinic semi-aldehyde, and patients are generally poorly responsive to these approaches. By trapping succinic semi-aldehyde, ADX-102, ADX-104, or other systemically administered aldehyde traps may have the potential to reduce the direct toxicity of succinic semi-aldehyde as well as the formation of neurotoxic metabolites, and represent a novel approach with considerable therapeutic potential in a disease where there remains significant unmet medical need.

A New Therapeutic Approach for Inflammation and Inborn Errors of Aldehyde Metabolism: ADX-102, ADX-103, ADX-104, and Other Novel Aldehyde Traps

Aldehyde Toxicity and Sequestration

Aldehydes are generated through a variety of metabolic processes. At high levels, aldehydes are toxic, binding proteins, lipids, carbohydrates, and DNA, and may mediate inflammation in, and the progression of, many

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serious diseases through signaling cascades that lead to the activation of intracellular inflammatory factors, including NF-kB, an important protein in the inflammatory response. In addition, aldehyde binding to cellular constituents leads to the formation of adducts and aggregates that may lead to cellular dysfunction. Because of the inherent toxicity of aldehydes, most, if not all, living organisms contain enzymes such as aldehyde dehydrogenases that detoxify aldehydes. The toxicity of aldehydes is evidenced by human studies showing an increased rate of cognitive decline, cancer, and cardiovascular disease in populations with diminished aldehyde dehydrogenase capacity. Additionally, most inflammatory diseases, including autoimmune disease, neurodegenerative disease, and cardiovascular diseases, manifest elevated aldehyde levels that apparently overwhelm endogenous aldehyde catabolic capacity. To our knowledge, there has never been a concerted pharmaceutical effort to lower all free aldehyde levels. Thus, we believe that aldehyde sequestration represents a novel platform for the treatment of inflammatory conditions and inborn errors of aldehyde metabolism where genetic mutations prevent the normal degradation of aldehydes.

Aside from increasing levels of inflammation, there is no generally accepted biological role of high levels of aldehydes. Some physiologic molecules have aldehyde forms, including retinaldehyde (a form of Vitamin A) and pyridoxal and pyridoxal phosphate (forms of Vitamin B6), but these molecules are not free aldehydes in that they are tightly chaperoned and protected by proteins that prevent the aldehydes from reacting with other molecules, including aldehyde traps. Thus, pharmacotherapeutic aldehyde sequestration is expected *a priori* not to adversely affect normal physiologic processes. Consistent with the toxicity of free aldehydes and the lack of accessibility to chaperoned physiologic aldehydes, our most advanced aldehyde trap, ADX-102, which has been administered to over 100 subjects across four clinical trials, has been generally well tolerated and has not resulted in any serious adverse events.

Aldehyde Traps

We are currently developing ADX-102, a new chemical entity, for the treatment of inflammatory diseases and inborn errors of aldehyde metabolism. ADX-102 is a small molecule designed specifically to trap, and thereby allow for the degradation of, aldehydes. In *in vitro* and animal studies, ADX-102 appears to have minimal pharmacology, meaning that ADX-102 does not appear to affect most cellular components, including most receptors, enzymes, ion channels, or other proteins. ADX-102 has been shown to bind and trap aldehydes more rapidly than aldehydes bind any cellular constituent. Evidence suggests that ADX-102 covalently binds to aldehydes to form ADX-102-aldehyde adducts, which appear to be rapidly degraded in cellular environments, after which neither ADX-102 or free aldehydes are detectable. Outside of biological systems, ADX-102-aldehyde adducts are remarkably non-reactive and stable, suggesting that ADX-102-aldehyde binding is effectively irreversible; hence the notion of ADX-102 as an aldehyde trap. By essentially irreversibly binding aldehydes to form covalent adducts that are then degraded, ADX-102 and other aldehyde traps have the potential to substantially lower aldehyde levels.

We believe we have been the first to demonstrate the positive effects of lowering aldehyde levels with an aldehyde trap in a variety of animal models relating to inflammation, suggesting that aldehyde traps may have potent anti-inflammatory effects that persist hours after ADX-102 administration at a variety of different doses relevant to clinical testing. In addition, we believe we have also been the first to demonstrate the activity of ADX-102 in binding aldehydes in *in vitro* and preclinical models of inborn errors of aldehyde metabolism.

In mouse models of ocular inflammation and post-surgical healing, topically applied ADX-102 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 ADX-102 statistically reduced a variety of inflammatory cytokines (protein inflammatory mediators), including IL-5, Il-1ß, IL-17, and TNF-a, while up-regulating the primary anti-inflammatory cytokine, IL-10. Additionally, in models of mouse contact dermatitis (induced by phorbol myristate acetate) and

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allergic contact dermatitis (induced by sensitivity to oxazolone), ADX-102 statistically reduced inflammation as measured by edema (swelling). (Data presented at the American Academy of Asthma Allergy and Immunology 2015 Annual Meeting)

In a model of radiation mucositis (oral inflammation) in hamsters, chronic subcutaneous administration of ADX-102 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 cells lacking FALDH (a model of SLS), ADX-102 prevented aldehydes from binding a lipid (fat) thought to be critical to the dermal moisture barrier. (Data presented at the Society for Inherited Metabolic Disorders 2015 Annual Meeting)

In a knock-out mouse model of SSADH Deficiency, ADX-102 trapped succinic semi-aldehyde in key tissues following intraperitoneal injection. (Data presented at the 2016 SSADH Symposium and at the 2015 American Society of Human Genetics Annual Meeting)

In two different mouse models of inflammatory pain, intraperitoneally administered ADX-102 dose-dependently reduced nociceptive behavior, suggesting that ADX-102 down-regulates pain signaling in inflammation. (Data presented at the 2016 International Conference on Pain Research and Management)

In rat cardiomyocyte culture, ADX-102 prevented fibrotic transformation, and inhibited NF-kB activation and IL-1ß release. (Data presented at the 2016 American Society for Cell Biology Annual Meeting)

Thus, we believe that aldehyde trapping with ADX-102 potentially has a variety of mechanisms of action lowering inflammation, reducing healing time, diminishing scarring, protecting a lipid important in tissue moisture barriers, and mitigating pain that may ameliorate aldehyde-mediated disease and deter aldehyde-mediated disease progression in different ways at the same time.

In addition to the development of ADX-102, we intend to continue the discovery and development of other novel aldehyde traps and we intend to continue to develop intellectual property around such molecules. We have identified, synthesized, and tested numerous molecules that may be more potent than ADX-102 in trapping aldehydes. We are currently screening novel traps for product candidates to address diseases where topical and systemic administration are applicable to reduce aldehyde-mediated pathology. We have nominated two new aldehyde traps, ADX-103 and ADX-104, for clinical development, which may begin 2018, depending on additional preclinical data, regulatory discussions, funding, and other factors.

Clinical Development

In order to assess the efficacy of aldehyde trapping in human disease, in 2015 we initiated a series of clinical trials in patients with ocular inflammatory disease and in patients with SLS, an inborn error of aldehyde metabolism. Our initial clinical trials in inflammation involved ocular testing, in part, due to the ability to non-invasively assess inflammation on the surface of and within the eye and the ability to treat the eye with topical administration of drug. Our initial clinical trial in inborn errors of aldehyde metabolism focused on SLS, in part, because the dermatologic aspects of the disease may respond to topical administration of drug, and assessment of dermatological response can

be performed with relatively non-invasive techniques and clinical examination. Most inflammatory diseases and inborn errors of aldehyde metabolism, involve at least some tissues that cannot be effectively treated topically, and thus we are developing systemic formulations of aldehyde traps, including ADX-102 and ADX-104. We plan to initiate Phase 1 clinical testing of a systemic formulation in the first half of 2018.

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Allergic Conjunctivitis

In September 2015, we initiated a randomized, parallel-group, double-masked, vehicle-controlled Phase 2a clinical trial of 0.5% ADX-102 ophthalmic solution in patients with allergic conjunctivitis. Using the conjunctival allergen provocation test (CAPT), one hundred healthy men and women with at least a two-year history of allergic conjunctivitis to grass, tree, or ragweed pollen were randomized in equal groups for treatment with topical ocular ADX-102 or vehicle, and ocular inflammation was induced by exposure to allergen. The clinical endpoints in the trial included patient assessment (on a 0 to 3 point scale) of ocular itching and tearing, two prominent inflammation-related symptoms of allergic conjunctivitis. In February 2016, we announced that the results demonstrated statistically significant activity of ADX-102 over vehicle in reducing ocular itching and tearing after a single dose (see figure below). Relative to baseline scores, ADX-102 demonstrated durable efficacy that persisted across substantially all time points over three hours following CAPT challenges. Despite a stronger than expected vehicle effect, peak changes in ocular itching and tearing scores were statistically superior to vehicle. The reductions from baseline scores were of the same magnitude previously observed in the CAPT model with existing therapies utilized in the treatment of allergic conjunctivitis. ADX-102 was generally well tolerated and there were no safety concerns during the trial. Transient and generally mild stinging was noted in the treatment arm. Two patients dropped out of the trial during treatment.

Allergic Conjunctivitis Phase 2a Clinical Trial Results for Ocular Itching and Tearing Following a Single Dose of ADX-102 vs. Vehicle

To our knowledge, the data from the allergic conjunctivitis Phase 2a clinical trial represent the first demonstration of the efficacy of aldehyde trapping in any human disease, and we believe that the results validate the potential of aldehyde traps as a novel anti-inflammatory therapy.

In February 2017, we announced the enrollment of the first patient in a Phase 2b allergic conjunctivitis clinical trial of topical ocular ADX-102. Given the unexpectedly large vehicle response observed in the Phase 2a clinical trial, we have reached agreement with the FDA that saline, instead of vehicle, will be the control in the Phase 2b clinical trial and subsequent clinical trials. The primary endpoint in Phase 2b will be difference from saline in patient-reported ocular itching following a single dose of ADX-102 in the Conjunctival Allergen Challenge (CAC) model, which has been used for the registration of other drugs for the treatment of allergic conjunctivitis. In addition to saline, two concentrations of ADX-102 topical ocular solution will be tested: 0.1% and 0.5%. Planned enrollment is 50 subjects in each of the three arms of the trial. Results from the trial are expected in the third quarter of 2017.

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Noninfectious Anterior Uveitis

In April 2015, we initiated a randomized, parallel-group, double-masked, comparator-controlled Phase 2 clinical trial of 0.5% ADX-102 ophthalmic solution in patients with noninfectious anterior uveitis, a rare but painful and potentially blinding ocular inflammatory disease. Forty-five subjects were randomized equally to receive six weeks of treatment with one of the following: ADX-102 0.5% four times daily; Pred Forte® 1% (a corticosteroid) four times daily (tapered); or ADX-102 0.5% four times daily and Pred Forte® 1% two times daily (tapered). In May 2016, we announced that the results of the trial demonstrated that the activity of ADX-102 was comparable to Pred Forte® in reducing anterior chamber inflammatory cell count (see figure below), which is the primary endpoint required for product registration. At the week 4 visit, grade 0 cell count (zero or one cells) was observed in 53% of ADX-102-treated patients versus 38% of corticosteroid-treated patients. Elevations of intraocular pressure observed in corticosteroid-treated patients were not observed in ADX-102-treated patients (see figure below). ADX-102 was generally well tolerated and there were no serious adverse events, consistent with previous Phase 1 and Phase 2 clinical trials.

Noninfectious Anterior Uveitis Phase 2 Clinical Trial Results for Anterior Chamber Cell Count Grade

Noninfectious Anterior Uveitis Phase 2 Clinical Trial Results for Intraocular Pressure (mmHg)

We expect to initiate, in the second quarter of 2017, a Phase 3 clinical trial of topical ocular 0.5% ADX-102 for the treatment of noninfectious anterior uveitis. We have reached agreement with the FDA that vehicle will be used as a control in the trial. The primary endpoint will be difference from control in time to cure (zero anterior chamber inflammatory cells). Up to 100 patients will be enrolled and randomized equally to receive either ADX-102 or vehicle for 4 weeks.

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Dry Eye Syndrome

In the second quarter of 2017, we expect to initiate enrollment of a Phase 2a clinical trial in Dry Eye Syndrome, a common ocular inflammatory disease characterized by pain, burning, and stinging. Approximately 45 patients will be equally randomized to 28 days of treatment with topical drops containing 0.1% ADX-102; 0.5% ADX-102 or 0.5% ADX-102 in a novel, lipid-based formulation. Endpoints will include assessment of tear quality (osmolarity and tear film breakup time), corneal integrity, and symptoms. Results from the trial are expected in the fourth quarter of 2017. Contingent on preclinical results, regulatory feedback, and other factors, we may also initiate a Phase 2a clinical trial of ADX-103 for the treatment of Dry Eye Syndrome.

Sjögren-Larsson Syndrome

In March 2015, we initiated a randomized, parallel-group, double-blinded, vehicle-controlled Phase 2 clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of SLS. Twelve subjects with SLS and moderate to severe ichthyosis were randomized equally to receive ADX-102 1% dermatologic formulation or vehicle formulation administered once daily on a 4 x 10 inch area of skin for two months. Investigators and subjects were blinded to treatment group. Ichthyosis was graded by a blinded central review of digital photographs, as well as by clinical exam, using the Ichthyosis Severity Score, which is comprised of assessments of global impression, scaling, erythema (redness), lichenification (thickness) and excoriation (abrasion).

In August 2016, we reported that ADX-102 consistently produced clinically meaningful effects in reducing the severity of ichthyosis. As assessed by central review, five of six subjects (83%) treated with ADX-102 achieved a rating of almost clear or mild on global assessment. Six of six (100%) subjects treated with ADX-102 improved over the course of therapy as assessed by central review ($p < 0.05$, see figure below), and the improvement was greater than that observed with vehicle-treated patients ($p < 0.05$). For ADX-102-treated subjects, mean reductions in ichthyosis severity were greater after 8 weeks of therapy than after 4 weeks of therapy, suggesting a disease modifying effect of ADX-102. ADX-102 was observed to be generally well tolerated, and there were no significant adverse events, serious adverse events or discontinuations in the trial.

Sjögren-Larsson Syndrome Phase 2 Clinical Trial Results for Each ADX-102-Treated Patient as Assessed by Central Review

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In the second half of 2017, we expect to initiate a Phase 3 clinical trial of topical dermatologic ADX-102 for the treatment of the skin manifestations of SLS. Up to 30 patients will be treated with a 1% dermatologic formulation of ADX-102 for at least four months. The endpoint of the clinical trial is the severity of ichthyosis following treatment.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for ADX-102 and other aldehyde traps in the United States and abroad. 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 ADX-102, ADX-103, ADX-104, and other novel aldehyde trapping compounds. As of December 31, 2016, we owned five United States patents and five pending United States non-provisional patent applications, as well as numerous foreign counterparts to these patents and patent applications. We expect the issued ADX-102 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 ADX-102 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 2034. ADX-102 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. ADX-102 composition of matter patent claims are pending in Brazil.

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

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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 are currently seeking and will continue to seek to develop and commercialize ADX-102 or our other product candidates for certain diseases in the United States alone or with corporate partners. If approved by regulatory agencies for marketing, our current expectation is that ADX-102 or our other product candidates would initially be sold by us to small groups of physicians that specialize in rare disorders or severe disease. We may also plan to utilize strategic partners or contract sales forces to assist in the commercialization of ADX-102 or our other product candidates for common diseases, and with such partners, would seek to build awareness in the approved patient populations of the clinical utility of ADX-102 and our other product candidates.

Manufacturing

We do not own or operate manufacturing facilities for the production of ADX-102 or our other 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. We do not have any current contractual relationships for the manufacture of commercial supplies of ADX-102 or our other product candidates. If ADX-102 or our other product candidates are approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the 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 ADX-102, ADX-103, and ADX-104 are relatively easy to manufacture, and that multiple suppliers and formulators could be employed for this purpose. Further, the raw materials needed for manufacture of ADX-102, ADX-103 and ADX-104, as well as other components of our formulations, are generally readily available from multiple sources.

Employees

As of December 31, 2016, we had eleven full time employees and had engaged a number of consultants. We intend to increase our employee base in connection with the continuing clinical development of ADX-102, ADX-103, ADX-104, and other product candidates. 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 very good.

Competition

Aldehyde Modulation

Various academic groups have published on the idea of reducing aldehyde levels, primarily by using compounds with primary amines (certain nitrogen-containing compounds) that react with aldehydes through a well-known chemical

process known as the Schiff base reaction. 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 aldehyde substrate may be bound or unbound. In this way, Schiff base reactions alone represent reversible and

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temporary aldehyde binding. Various aldehyde-binding amines have been described, particularly carnosine (a naturally occurring dipeptide), which has a variety of additional potential mechanisms of action unrelated to aldehydes. At least one group has published on the use of certain nitrogen-containing marketed products to temporarily, in a reversible manner, bind retinaldehyde as a potential therapy for retinal disease. We believe that ADX-102 and other novel aldehyde traps that we have discovered are differentiated from the above approaches in that the chemical structures are novel and the reaction with aldehydes is essentially irreversible *in vivo*, which we believe may result in a more effective means of diminishing aldehyde levels.

Other Pharmacotherapies

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 lead to the commercial success of our product candidates are efficacy, safety, tolerability, and the ability to reduce the dependence on, or the dose of, more toxic 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 FDA 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. 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.

We expect that, if approved, ADX-102 and or our other product candidates, will compete with a variety of generic and proprietary pharmaceuticals, depending on the approved indication. Table 1 below summarizes competitive products by indication.

Table 1. Competitive Pharmaceuticals by Indication

Indication	Competitive Products
Allergic Conjunctivitis	Topical antihistamines and corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), mast cell stabilizers
Noninfectious Anterior Uveitis	Topical corticosteroids
Dry Eye Syndrome	Topical immunomodulators (cyclosporine, lifitegrast), topical corticosteroids, artificial tear solutions
Sjögren-Larsson Syndrome	Retinoids, keratinolytics, and moisturizers
Succinic Semi-Aldehyde Dehydrogenase Deficiency	Anti-epileptics

We believe that there is significant unmet medical need for the diseases that we intend to study. If ADX-102 or our other product candidates are proven to be safe and effective, we believe that ADX-102 and or our other product

candidates could be used in place of or in addition to current therapies, especially in instances where current therapies are toxic and reducing exposure to such therapies would be desirable. Topical corticosteroids for ocular inflammatory diseases are often associated with toxicity, including glaucoma, cataracts, ocular

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infection, and ulceration. There is no approved therapy for SLS. We believe that the current non-specific creams and medications for SLS are poorly effective, if effective at all. There is no approved therapy for SSADH Deficiency. We believe that anti-epileptics and other medications used in SSADH Deficiency are inadequate in controlling the symptoms of the disease. While ADX-102 and other novel aldehyde traps may manifest efficacy and safety advantages over currently available therapies, many such therapies are generic or may be priced considerably lower than the pricing we anticipate for our product candidates. Pricing factors may discourage the initial or prolonged use of ADX-102 or our other product candidates.

Many drugs are in development for allergic conjunctivitis and Dry Eye Syndrome. Novartis/Alcon (ESBA105, LME636) and EyeGate Pharmaceuticals, Inc. (EGP-437) have conducted or are conducting clinical trials in anterior uveitis. For the diseases we intend to study, there may be other developmental therapies of which we are not aware. We believe that there are no drugs in development specifically for SLS. The National Institute of Neurological Disorders and Stroke is conducting a clinical trial of a GABA receptor antagonist (SGS-742) for SSADH Deficiency.

A myriad of new treatments have been or are being developed to treat inflammatory diseases, and in theory could be used for the treatment of the diseases our products are intended to target. Immune-modulating products include cytokine inhibitors, immune cell receptor 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., and Pfizer, Inc. As these products become used more commonly, they may begin to be used in the diseases that we intend to target, and such products may manifest efficacy and safety advantages over ADX-102 or our other product candidates.

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, such as a new chemical entity, or a new dosage form, new 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 good clinical practices (GCP) to establish the safety and efficacy of the proposed product candidate for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA s cGMP regulations;

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submission to the FDA of a new drug application (NDA) which must be accepted for filing by the FDA;

satisfactory completion of an FDA advisory committee review, if applicable;

payment of user fees, if applicable; 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. Some preclinical testing may continue even after the IND is submitted. The IND automatically 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 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 it has concerns, such as if unacceptable safety risks arise.

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 IRB s requirements, or may impose other conditions.

If a Phase 2 clinical trial is the subject of discussion at an end-of-Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment (SPA) the purpose of which is to reach agreement with the FDA on the design of the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA and may not be changed unless the sponsor fails to follow the agreed-upon protocol, 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.

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 their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters 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 product is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The 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

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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: These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the product and to provide adequate information for the labeling of the product.

Phase 4: In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor s agreement to conduct additional clinical trials to further assess the product s safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting 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 and approval process.

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it was designed, the product will be entitled to seven years of product 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 circumstances, for seven years. If a competitor obtains approval of the same drug, as defined by the FDA, 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.

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 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 annual product and establishment user fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete 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.

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. 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.

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It is likely that our product candidates will be granted a Standard Review. 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 and the FDA s Center for Devices and Radiological Health, which may complicate or prolong the review.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP.

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 will typically 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 safety problems 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 marketed only for the approved 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 (typically life-threatening), or a REMS program. 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 such 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/device 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 these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly,

manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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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 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. While 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 Risk Evaluation and Mitigation Strategy, or 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.

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 their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

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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 or ion 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 an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This 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 NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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 facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant 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.

Research and Development Expenses

Substantially all of our research and development expenses incurred to date have been related to the development of ADX-102 and our other product candidates. Our research and development expenses totaled $13.2 million for the year

ended December 31, 2016 and $7.6 million for the year ended December 31, 2015.

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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.

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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 our submission is reviewed by a health authority, 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.

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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.

Risks Related to our Business

We have incurred significant operating losses since inception and we expect to incur significant losses for the foreseeable future. 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 and development programs for ADX-102 and our other product candidates. Net loss for the years ended December 31, 2016 and 2015 was approximately $18.7 million and $12.1 million, respectively. As of December 31, 2016, we had total stockholders equity of $21.6 million and an accumulated deficit of $77.3 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if ADX-102 or any of our other product candidates is approved, 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.

We currently generate no revenue from sales, and we may never be able to commercialize ADX-102 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 may not be profitable even if we or any of our future development partners succeed in commercializing any of our product candidates. 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.

Our business is dependent in large part on the success of a single product candidate, ADX-102. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, ADX-102.

Our product candidates are in the early stage of development and will require additional preclinical studies, substantial clinical development and testing, and regulatory approval prior to commercialization. We have not yet completed development of any product. We have only one product candidate that has been the focus of significant development: ADX-102, a novel small molecule chemical entity that is believed to trap and allow for the degradation of aldehydes, toxic chemical species suspected to cause and exacerbate numerous diseases in humans and animals. We are largely dependent on successful continued development and ultimate regulatory approval of this product candidate for our future business success. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of ADX-102. We will need to raise sufficient funds for, and successfully enroll and complete, our current and planned clinical trials of ADX-102. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for ADX-102 and our other product candidates;

we may not be able to provide evidence of safety and efficacy for ADX-102 and our other product candidates;

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;

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the safety and efficacy results of our later phase or larger clinical trials may not confirm the results of our earlier trials;

there may be variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;

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;

patients in our clinical trials may suffer other adverse effects or die for reasons that may or may not be related to ADX-102 and our other product candidates;

if approved for certain diseases, ADX-102 and our other product candidates will compete with well-established products already approved for marketing by the FDA, including corticosteroids and other agents that have demonstrated varying levels of efficacy in some of the diseases for which we may attempt to develop ADX-102 and our other product candidates;

the effects of legislative or regulatory reform of the health care system in the U.S. 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.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a NDA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market ADX-102 and 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 continue to fund our development programs, we cannot assure you that ADX-102 and our other product candidates will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval for or, if approved, successfully commercialize, ADX-102 and or our other product candidates, we may not be able to generate sufficient revenue to continue our business.

Because we have limited experience developing clinical-stage compounds, there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects.

We commenced our first clinical trial in 2010, and we have limited experience developing clinical-stage compounds upon which you can evaluate our business and prospects. In addition, as an early-stage clinical development company, we have limited experience in conducting clinical trials, and we have never conducted clinical trials of a size required for regulatory approvals. Further, we have not yet demonstrated an ability to successfully overcome many of the 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;

obtain required regulatory approvals for our product candidates;

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, sales, distribution, and marketing capabilities on our own or through third parties; and

gain broad market acceptance for our product candidates.

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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.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials, including ADX-102, 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. In addition, as product candidates proceed through development, the trial designs may often be different from phase to phase, 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. For instance, we plan to modify the control utilized in our expected Phase 2b allergic conjunctivitis trial from the control used in our prior Phase 2a trial. Success in early clinical trials 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 initial clinical testing. Furthermore, our clinical trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, 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.

In addition, the presumed mechanisms of aldehyde-mediated inflammation are distinct from the presumed aldehyde-mediated pathology in inborn errors of metabolism, and the efficacy and safety of ADX-102 or our other product candidates in one indication does not predict the safety and efficacy of ADX-102 and our other product candidates in other indications.

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 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.

Our clinical focus is on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to naturally occurring toxic and pro-inflammatory chemical species known as aldehydes. Our planned Phase 3 vehicle-controlled clinical program in noninfectious anterior uveitis and our planned Phase 3 clinical program in SLS represent the first such clinical trials performed, and thus the comparative effects of vehicle and drug are unpredictable.

We could also face challenges in designing clinical trials and obtaining regulatory approval of aldehyde sequestering agents due to the small number of historical clinical trial experience for this novel class of therapeutics. Because no aldehyde sequestering agents have received regulatory approval anywhere in the world, it is difficult to determine whether regulatory agencies will be receptive to the approval of our product candidates and to predict the time and cost associated with obtaining regulatory approval. The clinical trial requirements of the FDA and other regulatory agencies and the criteria these 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 take longer than for

other, better known or more extensively studied classes of product candidates. Any inability to design clinical trials with protocols 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.

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Because ADX-102 and our other 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.

Our product candidates are, to our knowledge, new chemical entities, and unexpected problems related to such new technology may arise that can cause us to delay, suspend or terminate our development efforts. Although we have seen signs of efficacy and observed ADX-102 to be well tolerated in our clinical trials to date, because ADX-102 is a novel chemical entity with limited use in humans, short and long-term safety, as well as prospects for efficacy, are poorly understood and difficult to predict due to our and regulatory agencies lack of experience with them. Regulatory approval of new product candidates such as ADX-102 can be more expensive and take longer than approval for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates.

Our dermatologic topical formulation of ADX-102 is unlikely to affect other clinical manifestations of Sjögren-Larsson Syndrome, which may decrease the likelihood of regulatory and commercial acceptance.

While the primary day-to-day complaint of SLS patients and their caregivers are symptoms associated with severe skin disease, SLS patients also manifest varying degrees of delay in mental development, spasticity, seizures and retinal disease. In August 2016, we announced that the results of our randomized, parallel-group, double-masked, vehicle-controlled clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of SLS demonstrated clinically relevant activity of ADX-102 in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. There were no serious adverse events reported in any of these trials. However, due to expected low systemic exposure of ADX-102 when administered topically to the skin, it is unlikely that ADX-102 will significantly affect the non-dermatologic conditions of SLS. Lack of effect in neurologic and ocular manifestations of SLS may negatively impact regulatory discussions with the FDA and may also negatively impact reimbursement, pricing and commercial acceptance of ADX-102, if it is approved.

ADX-102 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, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications, 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 is never guaranteed.

ADX-102 and our other product candidates and the activities associated with development and potential 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 for our product candidates may be delayed, modified or ceased for a variety of reasons, including:

determining that a product candidate is ineffective or causes harmful side effects during preclinical studies or clinical trials;

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;

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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;

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 to develop or commercialize, or may fail to achieve market acceptance or adequate reimbursement;

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 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:

such authorities may disagree with the design or implementation of our or any of our future development partners clinical trials, including the endpoints of our clinical trials;

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 which are 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 designs of such trials;

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 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, 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.

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 planned clinical trials for ADX-102 or other product candidates could significantly affect our product development costs. We do not know whether future trials will

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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:

- the FDA failing to grant permission to proceed or placing the 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 ADX-102 or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing ADX-102, any of our other product candidates or any of their components being ordered by the FDA or other government or regulatory authorities, to temporarily or permanently shut down due to violations of current Good Manufacturing Practices, or 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 the clinical trial or expiration of materials intended for use in the 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, Good Clinical Practice 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 an institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- 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 ADX-102 and our other product candidates or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we 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 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 ADX-102 or other product candidates could be significantly reduced.

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 plan to evaluate the development and commercialization of product candidates for the treatment of orphan and other rare diseases. Given that we are in the early stages of clinical

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trials for ADX-102, 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 product candidates for the treatment of similar diseases, we would potentially compete with them for the enrollment in these rare patient populations, which may adversely impact the rate of patient enrollment in and the timely completion of our current and planned clinical trials. Additionally, insufficient patient enrollment, may be a function of many 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 altogether. 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. 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 advance into clinical trials could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result 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 have not yet completed testing of any of our product candidates in humans for the treatment of the indications for which we intend to seek approval, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. ADX-102, for example, has been observed to be toxic at high concentrations in *in vitro* human dermal tissue. In addition, there was transient and generally mild stinging noted in the ADX-102 treatment arm of our Phase 2a clinical trial in allergic conjunctivitis, with two patients out of the 50 patients in the treatment arm dropping out of the trial during treatment. There was an increased frequency of ocular stinging and burning in the ADX-102 treated arms of our Phase 2 clinical trial in noninfectious anterior uveitis, with one subject in the ADX-102 treatment arm and one subject in combination ADX-102 and Pred Forte® arm dropping out of the trial during treatment for an adverse event of stinging. However, there were no serious adverse events in this trial. In preparation for clinical testing of systemically administered ADX-102, we believe that we have identified a preliminary No Adverse Effect Level in pre-clinical toxicology studies where ADX-102 is administrated intravenously. 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.

Final marketing approval for ADX-102 or our other product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

After the completion of our clinical trials and, assuming the results of the trials are successful, the submission of an NDA, we cannot predict whether or when we will obtain regulatory approval to commercialize ADX-102 or our other product candidates and we cannot, therefore, predict the timing of any future revenue. We cannot commercialize

ADX-102 or our other product candidates until the appropriate regulatory authorities have reviewed and approved the applicable applications. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for ADX-102 or

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our other product candidates. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. If marketing approval for ADX-102 or 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.

Even if we obtain marketing approval for ADX-102 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 candidate, when and if any of them 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, post-market surveillance or clinical trials. Following approval, if any, of ADX-102 or any other product candidates, 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 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 ADX-102 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 plan as part of a 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 ADX-102 or any of our other product candidates is approved, our 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

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labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their 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 FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we receive regulatory approval for ADX-102 or any other product candidate, we still may not be able to successfully commercialize it 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, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, is also generally necessary for commercial success. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulation by health care providers and their patients;
- the prevalence and severity of any adverse effects;
- new procedures or methods of treatment that may be more effective in treating or may reduce the incidences of SLS or other conditions for which our products are intended to treat;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- unfavorable publicity relating to the product candidate; and

the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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 ongoing initiatives in the U.S. to increase pressure on drug pricing. Such reforms could have an adverse effect on 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 efforts to educate the medical community and third-party payors on the benefits of ADX-102 or any of our other product candidates may require significant resources and may never be successful. In addition, our 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.

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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. As a result of negative trends in the general economy in the U.S. 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; 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 various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. The new presidential administration and Congress have indicated they may further reform the Medicare program and the U.S. healthcare system, but have not made any definitive proposals which allow us to gauge the impact of such potential reforms, if any, on our business and operations. 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. They 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 their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. 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, and additional legislative proposals as well as country, regional or local healthcare budget limitations.

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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, inflammatory, orphan and other diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from immune-mediated or orphan or other 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. 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. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Orphan drug designation or Breakthrough Therapy Designation from the FDA may be difficult or not possible to obtain, and if we are unable to obtain one or both such designations for ADX-102 or our other product candidates, regulatory and commercial prospects may be negatively impacted.

The FDA designates orphan status to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan status drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and can be marketed without generic competition for seven years. We believe that ADX-102 will qualify as an orphan drug for SLS and noninfectious anterior uveitis, and possibly other diseases that we may test. However, we cannot guarantee that we will be able to receive orphan drug status from the FDA for ADX-102. If we are unable to secure orphan drug status or Breakthrough Therapy Designation for ADX-102 or our other product candidates, our regulatory and commercial prospects may be negatively impacted.

In addition, during challenging and uncertain economic times and in tight credit markets, 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 and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of ADX-102 and our other product candidates.

As of December 31, 2016, we had only eleven 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, financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or 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 ADX-102 and clinical trials for our other future 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

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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 any 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. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

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 these 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 of the product candidate. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications and within regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We will 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 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 us with 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 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.

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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 FDA s 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 studies or the termination or hold on a clinical study, 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. 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.

Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take 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.

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

We may choose to enter into development or other strategic partnerships in the future, including collaborations with major biotechnology or pharmaceutical companies. 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 a development partnership or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and 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 and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to maintain development or other strategic partnerships related to our product candidates that we may choose to enter into:

the development of certain of our current or future product candidates may be terminated or delayed;

our cash expenditures related to development 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 of any such product candidates.

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We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may 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 for the continued development or commercialization of ADX-102 or our other product candidates. These relationships or those like them 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 ADX-102 or our other product candidates because third parties may view the risk of success in our planned clinical trial 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.

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 and biopharmaceutical markets. 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 as well as with new treatments that may be introduced by our competitors. With the exception of SLS and SSADH, there are a variety of drug candidates in development for the indications that we intend to test. 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 may be active in aldehyde research, and some could be in direct competition with us. We also may compete with these organizations to recruit management, scientists, 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. There are methods that can potentially be employed to trap aldehydes that we have not conceived of or attempted to patent, and other parties may discover and patent aldehyde trapping 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 ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of ADX-102 or our other product candidates. Noninfectious anterior uveitis and other inflammatory diseases may be treated with general immune suppressing therapies, including corticosteroids, some of which are generic. Our potential competitors in these diseases may be developing novel immune modulating therapies that may be safer or more effective than ADX-102 or our other product candidates.

We have no sales, marketing or distribution capabilities and we will have to invest significant resources to develop these capabilities.

We have no internal sales, marketing or distribution capabilities. If ADX-102 or any of our other product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute the

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product candidate. We will have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that ADX-102 or any of our other product candidates will be approved. We may not be able to hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by ADX-102 or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

We are highly dependent on the services of our employees 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 composed of three individuals and certain other employees: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; Stephen J. Tulipano, our Chief Financial Officer; and David J. Clark, M.D., our Chief Medical Officer. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, dermatologic drug development and ocular drug development consultants. The loss of such individuals or the services of future members of our management team could delay or prevent the further development and potential 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. 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, harming future regulatory approvals, sales of our product candidates and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Because, as of December 31, 2016, we only had eleven full-time employees, we will need to grow our organization to continue development and pursue the potential commercialization of ADX-102 and our other product candidates, as well as function as a public company. As we seek to advance ADX-102 and other product candidates, 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

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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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates 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 our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not 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 marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States 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.

In the United States, the Medical Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formulas where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In early 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, PPACA), a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and imposed additional health policy reforms. Effective October 1, 2010, the PPACA s definition of average manufacturer price was revised for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, beginning in 2011, the PPACA imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. Although it is too early to determine the effect of the PPACA on our business, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under Medicare, and may also increase our regulatory burdens and operating costs.

More recently, the new presidential administration and the U.S. Congress have indicated they may seek to replace PPACA and related legislation with new healthcare legislation. There is uncertainty with respect to the impact these potential changes may have, if any, and any changes will likely take time to unfold, and could have an impact on

coverage and reimbursement for healthcare items and services covered by plans that were

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authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

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;
- the level of taxes that we are required to pay; and
- the availability of capital.

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.

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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 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 European Union, 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. 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.

Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent new products and services from being developed or commercialized by our life science tenants, 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 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. Currently, the FDA Commissioner position is vacant, pending the appointment of a new Commissioner by the new presidential administration. The confirmation process for a new commissioner may not occur efficiently. 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 biologics industry.

In December 2016, the 21st Century Cures Act was signed into law. This new legislation is 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 is 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.

In the first week of the new presidential administration, it issued executive orders to freeze government hiring of new employees with the exception of military, national security and public safety personnel. This hiring freeze could impede current or future operations at the FDA and other agencies. It is unknown at this time what the impact of the hiring freeze will have on the FDA and on programs such as the 21st Century Cures Act. Furthermore, future government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, biologics and devices to be reviewed and/or approved by necessary government agencies and the healthcare and drug industries ability to deliver new products to the market in a timely manner, which would adversely affect our tenants operating results and business. Interruptions to the function of the FDA and other government agencies could adversely affect the demand

for office/laboratory space and significantly impact our operating results and our business.

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If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of ADX-102 or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of ADX-102 and our other product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if ADX-102 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 ADX-102 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 commercialize ADX-102 or our other product candidates; and

a decline in our stock price.

We maintain product liability insurance with $3.0 million in coverage. 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 ADX-102 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

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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 action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

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.

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 considered, 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. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders percentage ownership;
- incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, technologies and products; and

assume substantial actual or contingent liabilities.

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

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computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While 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.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or 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 ADX-102 and our other product candidates. Our ability to obtain clinical supplies of ADX-102 or our other product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our employees may engage in misconduct or other improper activities including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

In addition, during the course of our operations our directors, executives, and employees 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 a director, executive, or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive, or employee was to be investigated or an action were to be brought against a director, executive, or employee 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.

Risks Relating to Our Intellectual Property

Our success depends on our 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 their uses as well as our ability to

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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 biological or chemical 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 ADX-102, we cannot be certain that the claims in our patent applications covering composition-of-matter of our other product 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 methods that can be employed to trap aldehydes that we have not conceived of or attempted to patent, and other parties may discover and patent aldehyde trapping 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.

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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 this information 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 ADX-102 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 delays;

prevent us from commercializing ADX-102 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 ADX-102 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 ADX-102 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 ADX-102 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 our loan and security agreement with Pacific Western. In the case of a continuing event of default under the loan, Pacific Western, the lender, could, among other remedies, elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. Although as of December 31, 2016, we had sufficient cash and cash equivalents to repay all obligations owed to Pacific Western if the debt was accelerated, in the event we do not or are not able to repay the obligations at the time a default occurred, Pacific Western may elect to commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Pacific Western under the loan, which includes our intellectual property.

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

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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 the validity question, 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 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 licensors who would be suitable replacements and it may take a significant amount of time to transition to a replacement licensor.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees 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 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 a consultant 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 ADX-102 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.

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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. As of March 2014, we adopted a new brand, Aldeyra Therapeutics. Our marks ALDEYRA THERAPEUTICS and our logo are registered with the USPTO. 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 biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical 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 in certain circumstances or weakening the rights of patent owners in certain situations. 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 ADX-102 in the United States and other countries, filing, prosecuting and defending patents on ADX-102 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 can be less extensive 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 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 biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of

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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 and 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.

Risks Related to Our Financial Position and Need for Capital

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize ADX-102 and our other product candidates.

We will require substantial future capital in order to complete the remaining clinical development for ADX-102 and our other product candidates and to potentially commercialize these product candidates. We expect our spending levels to increase in connection with our clinical trials of ADX-102 and our other product candidates, as well as other corporate activities. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our planned clinical trials of ADX-102 or any our other product candidates which we are pursuing or may choose to pursue in the future;
- the need for, and the progress, costs and results of, any additional clinical trials of ADX-102 and our other product candidates we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of ADX-102 and our other product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for ADX-102 and our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us;
- costs associated with any other product candidates that we may develop, in-license or acquire;

the effect of competing technological and market developments;

our ability to establish and maintain partnering arrangements for development; and

the costs associated with being a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of our clinical trials and remaining development program through commercial introduction. We expect that we will need to raise 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. Uncertain economic conditions as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. 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

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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 will be unable to complete the planned clinical trials for ADX-102 and our other product candidates and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or some of our technologies or otherwise agree to terms unfavorable to us.

The terms of our secured debt facility require us to meet certain operating and financial 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.

We have a $5.0 million Credit Facility with Pacific Western that is secured by a lien covering all of our assets as of December 31, 2016. As of December 31, 2016 and December 31, 2015, the outstanding principal balance under the Credit Facility was approximately $1.4 million. 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 property, changing our business, including changing the composition of our executive team or board of directors, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets and other financial covenants, in each case subject to customary exceptions. If we default under the terms of the loan agreement, including failure to satisfy our operating covenants, 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 of the Internal Revenue Code of 1986, as amended (Code), 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, even those outside our control, such as purchases or sales by investors, within the testing period 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. Prior to 2016, we underwent two ownership changes and it is possible that additional ownership changes have occurred since. However, our management believes that we have sufficient Built-In-Gain to offset the Section 382 of the Code limitation generated by such ownership changes. Any future ownership changes, including those resulting from our recent or future financing activities, may cause our existing tax attributes to have additional limitations.

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Risks Related to Our Common Stock

An active trading market for our common stock may not develop or be sustained and investors may not be able to resell their shares at or above the price at which they purchased them.

We have a limited history as a public company. An active trading market for our shares may never develop or be sustained. 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:

- our ability to enroll patients in our planned clinical trials;
- results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory developments in the United States and foreign countries;
- 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 and market conditions other events or factors, many of which are beyond our control;

additions or departures of key personnel; and

intellectual property, product liability or other litigation against us.

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.

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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:

- variations in the level of expenses related to our clinical trial and development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting ADX-102 and our other product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- 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.

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, 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.

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.

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

Our management has broad discretion in the application of our cash and cash equivalents. Because of the number and variability of factors that will determine our use of our cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our cash and cash equivalents in ways that ultimately increase the value of your investment. We expect to use of our cash and cash equivalents to fund our planned clinical trials of ADX-102 and our other product candidates, development of other molecules that may relate to our aldehyde trapping platform, and the remainder for working capital and other general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash and cash equivalents 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 and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Because a small number of our existing stockholders own a majority of our voting stock, your ability to influence corporate matters will be limited.

As of December 31, 2016, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 67.0% of our outstanding common stock. As a result, such persons, acting together, will 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.

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 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, they would apply even if an offer rejected by our board were considered beneficial by some

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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.

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, our loan and security agreement with Pacific Western currently prohibits us from paying dividends on our equity securities, and any future debt financing arrangement 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 their value. 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 their 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 are eligible for sale as are common stock issuable under vested and exercisable stock options. 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. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2019, although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer, if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and 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 these 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.

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

As a public company, we are incurring 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 The NASDAQ Capital Market to implement provisions of the Sarbanes-Oxley Act, impose 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. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years from our Initial Public Offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to 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 these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and 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 these requirements 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. When and if we are a large accelerated filer or an accelerated filer and are no longer an emerging growth company, each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls 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 comply with the requirements of being a reporting company

under the Exchange Act, we need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff.

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Historically, we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate formally documented accounting policies and procedures to support, effective internal controls. As we grow, we will 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.

If securities or industry analysts do not 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. We currently have limited research coverage by securities and industry analysts. If other securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock, 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.

We could 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. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, 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 biopharmaceutical industry, over the last few years. We may be particularly vulnerable to these actions due to the highly concentrated ownership of our common stock. If faced with a proxy contest or other type of shareholder 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 shareholder 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***

Not applicable.

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ITEM 2. ***PROPERTIES***

Our offices are located in Lexington, Massachusetts. As of December 31, 2016, we had leased approximately 6,888 square feet of office space pursuant to leases that expire in 2017. 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 leases, additional or alternative space will be available at commercially reasonable terms.

ITEM 3. ***LEGAL PROCEEDINGS***

From time to time, we may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. We currently are not a party to any threatened or pending material litigation and do not have contingency reserves established for any litigation liabilities. However, third parties might allege that we are infringing their patent rights or that we are otherwise violating their intellectual property rights, including trade names and trademarks. Such third parties may resort to litigation. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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PART II

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

Market Price of Our Common Stock

Our common stock has been trading on The NASDAQ Capital Market (NASDAQ) under the symbol ALDX since our IPO on May 1, 2014. Prior to that time, there was no established public trading market for our common stock. The following table sets forth, for the periods indicated, the range of high and low per share sale prices of our common stock as reported by NASDAQ.

Year Ended December 31, 2016	High	Low
First quarter	$ 6.76	$ 3.52
Second quarter	$ 6.50	$ 4.24
Third quarter	$ 7.82	$ 5.37
Fourth quarter	$ 7.51	$ 4.65
Year Ended December 31, 2015	**High**	**Low**
First quarter	$ 12.30	$ 6.90
Second quarter	$ 11.79	$ 6.64
Third quarter	$ 10.90	$ 5.35
Fourth quarter	$ 7.70	$ 4.84

Holders of Record

As of December 31, 2016, there were 16 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 our current or future financing instruments. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

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Securities Authorized for Issuance under Equity Incentive Plans

The following table provides information as of December 31, 2016, 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 2013 Equity Incentive Plan (2013 Plan), 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan), 2004 Employee, Director and Consultant Stock Plan (2004 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	1,525,682(1)	$ 6.75(2)	966,568(3)
Equity compensation plans not approved by security holders			
Total	1,525,682	$ 6.75(2)	966,568(3)

(1) Of these shares, 27,096 were underlying then outstanding restricted stock unit awards and 984,786 were subject to options then outstanding under the 2013 Plan, 489,846 were subject to options then outstanding under the 2010 Plan and 23,954 were subject to options then outstanding under the 2004 Plan.

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

(3) Represents 869,068 shares of common stock available for issuance under our 2013 Plan and 97,500 shares of common stock available for issuance under our 2016 ESPP. No shares are available for future issuance under the 2010 Plan or 2004 Plan. Our 2013 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) 1,000,000 shares of our common stock; (2) 7% of the shares of common stock outstanding at that time; and (3) such other amount as our board of directors may determine. Our 2016 ESPP provides for annual increases in the number of shares available for issuance thereunder on the first 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 1, 2017, an additional 880,343 shares became available for future issuance under the 2013 Plan and an additional 125,763 shares became available for future issuance under the 2016 ESPP. The additional shares from the annual

increase on January 1, 2017 are not included in the table above.

ITEM 6. ***SELECTED FINANCIAL DATA***

As a smaller reporting company, we are not required to provide this information.

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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 focused primarily on the development of new products for inflammation, inborn errors of metabolism and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes. We are developing ADX-102 (formerly known as NS2), as well as other novel product candidates, including ADX-103 and ADX-104, that are designed specifically to sequester aldehydes for the treatment of:

- Noninfectious Anterior Uveitis, a rare but severe inflammatory eye disease that can lead to blindness;
- Allergic Conjunctivitis, a common disease that affects more than 20% of the population worldwide, and related rare allergic ocular diseases that are characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, swelling and redness;
- Dry Eye Syndrome, a common inflammatory disease characterized by insufficient moisture and lubrication associated with the anterior surface of the eye, leading to ocular irritation, burning, stinging, and, in severe cases, loss of vision;
- Sjögren-Larsson Syndrome (SLS), a rare inborn error of metabolism caused by mutations in an enzyme that metabolizes fatty aldehydes, resulting in severe skin and neurological disorders; and
- Succinic Semi-Aldehyde Dehydrogenase Deficiency (SSADH), a rare inborn error of metabolism caused by genetic mutations in an aldehyde-metabolizing enzyme, leading to severe neurological disease.

In 2015, we began clinical testing of ADX-102 in diseases where we believe aldehyde trapping may improve symptoms and slow or prevent disease progression. In February 2016, we announced that the results of a randomized, parallel-group, double-masked, vehicle-controlled Phase 2a clinical trial of ADX-102 ophthalmic solution in patients with allergic conjunctivitis demonstrated statistically and clinically significant activity of ADX-102 over vehicle in reducing ocular itching and tearing. In May 2016, we announced that the results of our randomized, parallel-group, investigator-masked, active-controlled Phase 2 clinical trial of ADX-102 ophthalmic solution in patients with noninfectious anterior uveitis demonstrated that ADX-102 reduced inflammatory cell count in the anterior chamber of

the eye to a degree similar to that of standard-of-care corticosteroid therapy (which may lead to cataracts and glaucoma in some patients), but without the intraocular pressure elevations that were observed in subjects treated with corticosteroids. In August 2016, we announced that the results of a randomized, parallel-group, double-blind, vehicle-controlled clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of SLS demonstrated clinically relevant activity of ADX-102 in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. In all clinical trials to date, ADX-102 was well tolerated, and no serious adverse events have been reported.

In February 2017, we announced the enrollment of the first patient in a Phase 2b clinical trial of the topical ocular ADX-102 for the treatment of allergic conjunctivitis We expect to begin a planned Phase 3 clinical trial of

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topical ocular ADX-102 for the treatment of noninfectious anterior uveitis in the second quarter of 2017. We expect to begin a planned Phase 3 clinical trial of topical dermatologic ADX-102 for the treatment of the skin manifestations of SLS in the second half of 2017. We expect to begin a planned Phase 2a clinical trial of topical ocular ADX-102 for the treatment of Dry Eye Syndrome in the second quarter of 2017, and we may also subsequently initiate a planned Phase 2a clinical trial of ADX-103 in Dry Eye Syndrome. We expect to begin a planned Phase 1 clinical trial of systemically administered ADX-102 or ADX-104 in the first half of 2018. We expect to begin systemically administered Phase 2a clinical trials in SLS and SSADH in the second half of 2018. All of our development timelines could be subject to adjustment depending on recruitment rate, regulatory agency review, and other factors that could delay the initiation and completion of clinical trials.

We have no products approved for sale. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties. We have primarily funded our operations through the sale of our convertible preferred stock, common stock, convertible promissory notes, warrants and borrowings under our loan and security agreements.

In January 2015, we received net proceeds of approximately $9.0 million, after placement agent fees and expenses from two private placements of common stock and warrants to purchase common stock. In addition, in May 2015, we raised approximately $19.5 million, after deducting underwriting discounts and commissions and other offering expenses through the issuance and sale of 2,822,500 shares of common stock in a follow-on public offering, including shares sold pursuant to the underwriters exercise of their option to purchase additional shares of common stock. In June 2016, we closed an underwritten public offering in which we sold, an aggregate of 2,760,000 shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by us. In February 2017, we closed an underwritten public offering in which we sold, 2,555,555 shares of its common stock, including 333,333 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $10.5 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

We will need to raise additional capital in the form of debt or equity or through partnerships to fund additional development of ADX-102 and other aldehyde traps, 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 plan described herein.

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;

expenses related to generating, filing, and maintaining intellectual property; and

employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

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Substantially all of our research and development expenses to date have been incurred in connection with ADX-102. We expect our research and development expenses to increase for the foreseeable future as we advance ADX-102 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 ADX-102 and our future 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;
- 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 cost of 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; and
- the efficacy and safety profile of the product candidate.

We do not expect ADX-102 and our other product candidates to be commercially available, if at all, for the next several years.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Our general and administrative expenses consisted primarily of payroll expenses for our full-time employees during the years ended December 31, 2016 and 2015. Other general and administrative expenses include professional fees for auditing, tax, and legal services. We expect that general and administrative expenses will increase in the future as we expand our operating activities and 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, legal fees, accounting fees, directors and officers liability insurance premiums and fees associated with investor relations.

Total 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 December 31, 2016, comprehensive loss is equal to our net loss of $18.7 million and an unrealized gain on marketable securities of $8,000. For December 31, 2015, comprehensive loss is equal to net loss of $12.1 million and an unrealized loss on marketable securities of $8,000.

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Critical Accounting Policies and Significant Judgments and 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 policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue 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 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 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 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 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 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 studies and other research activities.

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Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of restricted stock awards and stock option grants, which are being recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures. For stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. We generally estimate the fair value of stock option grants using the Black-Scholes option pricing model. If vesting is based on market-based milestones, we perform Monte Carlo simulations to estimate the timing and number of shares that are most likely to vest and record the expense on a straight-line basis over the estimated period the milestone will be achieved. We account for stock options to non-employees using the fair value approach. Stock options to non-employees are subject to periodic revaluation over their vesting terms.

We generally estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. Due to the lack of sufficient historical public market trading activity, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily closing prices for the selected companies shares over approximately the expected life of the options. The resulting volatility estimate was approximately 89%, and we have employed this value throughout our calculations. We have also computed the historical volatility of ALDX historical information regarding the volatility of our own stock price and have determined that a volatility estimate of 89% is reasonable. We have estimated the expected life of our 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. 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.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of employee stock option grants in 2016 and 2015 were as follows:

	December 31, 2016	December 31, 2015
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	$ 3.94 - $7.48	$ 7.19 - $8.37
Exercise price	$ 3.94 - $7.48	$ 7.19 - $8.37
Expected life (years)	5.50 - 6.25	5.50 - 6.25
Risk free interest rate	0.59% - 2.20%	0.27% - 1.91%

Other Information

Net Operating Loss Carryforwards

As of December 31, 2016, we have Federal and State income tax net operating loss (NOL) carryovers of approximately $42.8 million and $39.9 million, respectively, which will expire at various dates through 2036. As of December 31, 2016, we have Federal and State tax carryovers of credits for increasing research activities (R&D tax

credits) of approximately $1.2 million and $178,000, respectively, which will expire at various dates through 2036.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change NOLs and

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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, even those outside our control, such as purchases or sales by investors, within the testing period 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. Prior to 2016, we underwent two ownership changes and it is possible that additional ownership changes have occurred since. However, our management believes that we have sufficient Built-In-Gain to offset the Section 382 of the Code limitation generated by such ownership changes. 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

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-15 (ASU 2016-15), Statement of Cash Flows. The standard is intended to reduce the diversity in practice around how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. ASU 2016-15 may be adopted retrospectively or prospectively if it is impractical to apply the amendments retrospectively. The Company does not expect this standard to have a material impact on its financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instrument-Credit Losses (ASU 2016-13). ASU 2016-13 requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. The Company does not expect this standard to have a material impact on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting (ASU 2016-09), to simplify the accounting for stock compensation. This update focuses on income tax accounting, award classification, estimating forfeitures, and cash flow presentation. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02 (ASU 2016-02), Leases. ASU 2016-02 requires lessees to recognize on the balance sheet a right-of-use asset, representing its right to use the underlying asset for the lease term, and a lease liability for all leases with terms greater than 12 months. The guidance also requires qualitative and quantitative disclosures designed to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard requires the use of a modified retrospective transition approach, which includes a number of optional practical expedients that entities may elect to apply. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The Company does not expect this standard to have a material impact on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01). ASU 2016-01 amends the guidance on the classification and measurement of financial instruments. Although ASU 2016-01 retains many current requirements, it significantly revises accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. ASU 2016-01 also amends certain disclosure requirements associated with the fair value of financial instruments and is effective for fiscal years beginning after December 15, 2017. The Company does not expect this standard to have a material impact on its financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (ASU 2015-17). ASU 2015-17 simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as

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noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in ASU 2015-17. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03). The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for fiscal years beginning after December 15, 2017. The Company does not expect this standard to have a material impact on its financial statements.

JOBS Act

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy or information statements, exemptions from the requirements of holding a non-binding advisory vote on executive compensation and seeking stockholder approval of any golden parachute payments not previously approved and not being required to adopt certain accounting standards until those standards would otherwise apply to private companies.

As an emerging growth company, we have irrevocably elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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 and regulatory requirements. 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, 2016 and 2015

Net loss. Net loss for the years ended December 31, 2016 and 2015 was approximately $18.7 million and $12.1 million, respectively. As of December 31, 2016, we had total stockholders equity of $21.6 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses.

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Research and development expenses. Research and development expenses were $13.2 million for the year ended December 31, 2016 compared to $7.6 million for the same period in 2015. The increase of $5.6 million is primarily related to the increase in our external research and development expenditures, including manufacturing, preclinical and clinical costs and an increase in personnel costs.

General and administrative expenses. General and administrative expenses were $5.5 million for the year ended December 31, 2016, compared to $4.4 million for the year ended 2015. The increase of approximately $1.1 million is primarily related to an increase in legal costs, rent, consulting costs, and personnel costs.

Other income (expense). Total other income (expense) was approximately $(3,472) for the year ended December 31, 2016 and consisted of interest expense related to our credit facility partially offset by interest income. Total other income (expense) was $(101,180) for the same period in 2015 and primarily consisted of interest expense related to our credit facility partially offset by interest income. In 2016, there was twelve months of investment income as opposed to only one month in 2015.

Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and convertible equity securities and borrowings under our Credit Facility discussed below. We have incurred operating losses since inception and negative cash flows from operating activities in devoting substantially all of our efforts towards research and development. At December 31, 2016, we had total stockholders equity of approximately $21.6 million and cash, cash equivalents and marketable securities of $24.9 million. During the year ended December 31, 2016, we had net loss of approximately $18.7 million. We expect to generate operating losses for the foreseeable future.

We are a party to a loan and security agreement (the Credit Facility) with Pacific Western Bank (Pacific Western, formerly Square 1 Bank) which was originally entered into in April 2012 and has been subsequently amended. Pursuant to the Credit Facility, Pacific Western agreed to make term loans in a principal amount of up to $5.0 million available to us to fund expenses related to our clinical trials and general working capital purposes. The term loans are to be made available to us upon the following terms: (i) $2.0 million was made available in November 2014 (which was used in part to refinance then outstanding loans from Pacific Western); and (ii) $3.0 million (the Tranche B Loan) became available to the Company in 2016 following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Any term loan made is payable as interest-only prior to November 2017 and thereafter is scheduled to be payable in monthly installments of principal plus accrued interest through the maturity date in October 2020. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. The annualized interest rate as of December 31, 2016 was 5.60%. The Credit Facility is collateralized by our assets, including our intellectual property. As of December 31, 2016, $1.4 million was outstanding under the Credit Facility. At December 31, 2016, the Credit Facility is shown net of a remaining debt discount of $79,663 which is being amortized using the effective interest method through the current maturity date of the Credit Facility, October 2020.

On May 7, 2014, we closed our Initial Public Offering, in which 1,500,000 shares of common stock were sold at a price to the public of $8.00 per share for an aggregate offering price of $12.0 million. The offer and sale of all of the shares in the Initial Public Offering were registered under the Securities Act of the 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-193204), which was declared effective by the SEC on May 1, 2014. We raised approximately $10.0 million in net proceeds after deducting underwriting discounts and commissions of $0.8 million, $1.0 million in prepaid offering and printing costs and other offering costs of $0.2 million.

On January 15, 2015, we sold, in a private placement, an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. The warrants will expire 3 years from the date

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of issuance. The warrants do not include a net-exercise feature. The warrants may be redeemed by us at a price of $0.001 per share upon notice to the holders in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is 50,000 shares per day. Following Aldeyra s notification to the warrant holders of its exercise of the redemption right under the warrants, each warrant holder will have the option to exercise their warrants prior to the redemption date rather than having them redeemed. We raised approximately $7.1 million in net proceeds in the private placement of common stock and warrants.

On January 22, 2015, in a subsequent private placement, we sold an aggregate of 211,528 shares of common stock at a price of $9.33 per share and a warrant to purchase up to 211,528 shares of common stock at a price of $0.125 per share subject to the warrant. The exercise price of the warrant is $9.50 per share. The warrant will expire 3 years from the date of issuance. The warrant does not include a net-exercise feature. The warrant may be redeemed by us at a price of $0.001 per share upon notice to the holder thereof in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is 50,000 shares per day. Following Aldeyra s notification to the warrant holder of its exercise of the redemption right under the warrant, the warrant holder will have the option to exercise the warrant prior to the redemption date rather than having it redeemed. We raised approximately $1.9 million in net proceeds in the private placement of common stock and a warrant to purchase common stock.

We raised approximately $19.5 million, after deducting underwriting discounts and commissions and other offering expenses, which closed on May 22, 2015, through the issuance and sale of 2,822,500 shares of common stock in a follow-on public offering, including shares sold pursuant to the underwriters exercise of their option to purchase additional shares of common stock.

In June 2016, we closed an underwritten public offering in which we sold, an aggregate of 2,760,000 shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by us.

In February 2017, we closed an underwritten public offering in which we sold, 2,555,555 shares of its common stock, including 333,333 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $10.5 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2016, together with the proceeds from the February 2017 public offering and the amounts available under the Credit Facility, will be adequate to fund operations into approximately the third quarter of 2018 based on our current business plan. However, these amounts will not be sufficient for us to commercialize 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 ADX-102 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 progress, costs, results of and timing of our clinical development program for ADX-102 and our other product candidates, including our current and planned clinical trials;

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- the need for, and the progress, costs and results of, any additional clinical trials of ADX-102, including systemic formulations, we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of ADX-102 and our other product candidates;

- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;

- the timing and costs associated with manufacturing ADX-102 and our other product candidates for clinical trials and other studies and, if approved, for commercial sale;

- our need and ability to hire additional management, development and scientific personnel;

- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;

- the timing and costs associated with establishing sales and marketing capabilities;

- market acceptance of ADX-102 and our other product candidates;

- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and

- our need to remediate any material weaknesses and implement additional internal systems and infrastructure, including financial and reporting systems.

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. 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 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. The following table summarizes our cash flows:

	Years ended December 31,	
	2016	2015
Net cash used in operating activities	$ (15,147,512)	$ (9,311,753)
Net cash used in investing activities	(225,234)	(13,036,256)
Net cash provided by financing activities	12,738,941	28,469,571
Net (decrease) increase in cash and cash equivalents	$ (2,633,805)	$ 6,121,562

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Operating Activities. Net cash used in operating activities was $15.1 million in 2016 compared to net cash used in operating activities of $9.3 million in 2015. The primary use of cash was to fund our operations. The increase in the amount of cash used in operating activities for 2016 as compared to 2015 was due to an increase in both research and development and general and administrative expenses.

Investing Activities. Net cash used in investing activities in 2016 were $(225,234) related primarily to the purchase of marketable securities partially offset by sales and maturities of marketable securities compared to net cash used in investing activities in 2015 of $13.0 million related primarily to the purchase of marketable securities.

Financing Activities. Net cash provided by financing activities was $12.7 million for the year ended December 31, 2016 related to our public placement offering, compared to net cash provided by financing activities of $28.5 million for year ended 2015 which was related to our private and public offerings.

Off-Balance Sheet Arrangements

Through December 31, 2016, 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.

Contractual Obligations and Commitments

During the year ended December 31, 2014, we entered into a lease agreement for a certain commercial office space. The thirty-seven month lease which began in September 2014 provides us with approximately 3,700 square feet of space in Lexington, Massachusetts. Base annual rent is initially set at $5,604 per month. Total base rent payable over the lease period is approximately $205,000. In March 2016, we entered into a sublease for approximately 3,188 additional square feet of office space to expand our headquarters in Lexington, Massachusetts. The sublease expires in September 2017. The sublease provides for the payment of annual base rent in the amount of $67,000 payable in monthly installments and the requirement to pay certain operating expenses, taxes and other fees in accordance with the terms of the master lease.

Our long-term debt obligation consists of amounts we are obligated to repay under our Credit Facility with Pacific Western, of which $1.4 million was outstanding as of December 31, 2016. We entered into the Credit Facility in April 2012 and it has been subsequently amended to make term loans in a principal amount of up to $5,000,000 available to us with proceeds to be used first to refinance outstanding loans from Pacific Western, second to fund expenses related to our clinical trials, and the remainder for general working capital purposes. The term loans are to be made available to us upon the following terms: (i) $2,000,000 was made available on November 10, 2014; and (ii) $3.0 million (the Tranche B Loan) which was made available to the Company in May 2016 following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. In November 2016, we amended our Credit Facility such that any term loan we draw is payable as interest-only prior to November 2017 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. The following table summarizes our contractual obligations at December 31, 2016.

The following table summarizes our contractual obligations at December 31, 2016:

	Total	Less than 1 Year	Years 1 - 3	Years 3 - 5	More than 5 Years
Credit Facility	$ 1,395,833	$ 77,546	$ 1,318,287	$	$
Operating lease obligations	$ 107,195	$ 107,195	$	$	$
Total	$ 1,503,028	$ 184,741	$ 1,318,287	$	$

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The table above detailing contractual commitments and obligations does not include severance pay obligations to certain of our executive officers in the event of a not-for-cause termination under existing employment contracts and any contingent obligations under licensing agreements. The cash amount for which we might be liable upon any such termination, based on current executive pay and bonus levels, could be up to approximately $1.0 million.

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

Interest rates

Our exposure to market risk is currently confined to our cash and cash equivalents and our Credit Facility. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. Our Credit Facility accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. The annualized interest rate as of December 31, 2016 was 5.60%.

Effects of inflation

Inflation has not had a material impact on our results of operations.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The information required by this Item 8 is contained on pages 73 through 93 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 President and our 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 U.S. 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 President and our 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 controls evaluation, 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 President and our 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.

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Based on our management s evaluation (with the participation of our Chief Executive Officer and President and our Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and President and our 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, 2016. Based on the assessment, our management has concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

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 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

On March 28, 2017, the Compensation Committee of our Board of Directors approved and established the Aldeyra Therapeutics, Inc. Change in Control Plan (the CIC Plan), which provides for the accelerated vesting for outstanding unvested equity awards held by our eligible employees are subject to a qualifying employment termination in connection with a change in control, including our named executive officers. The CIC Plan provides for acceleration of 100% of the unvested equity held by our executive officers in the event the officer s employment is terminated without cause, or the officer resigns for good reason, in each case within 3 months before or 12 months of a change of control.

For the purpose of the CIC Plan, the following terms have the definitions set forth below:

A termination for cause means termination by us of the executive officer s employment by reason of the occurrence of any one or more of the following: (i) an act or acts of personal dishonesty taken by the executive officer and intended to result in substantial personal enrichment of the executive officer at the expense of the Company; (ii) repeated violations by the executive officer of the executive officer s duties and obligations (other than as a result of incapacity due to physical or mental illness) which are demonstrably willful and deliberate on the executive officer s part, which are committed in bad faith or without reasonable belief that such violations are in the Company s best interests and which are not remedied in a reasonable period of time after receipt of written notice from the Company; (iii) indictment or plea of nolo contendere of the executive officer of a felony involving moral turpitude; or (iv) the material breach of the executive s proprietary information and inventions agreement.

Change in Control means the occurrence of any of the following: (i) any person (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the beneficial owner (as defined in Rule 13d-3 of the

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Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company s then-outstanding voting securities; (ii) the consummation of the sale or disposition by the Company of all or substantially all of the Company s assets; (iii) the consummation of a merger or consolidation of the Company with or into any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or individuals who are members of the Board (the Incumbent Board) cease for any reason to constitute at least a majority of the members of the Board over a period of 12 months; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board. A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company s incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company s securities immediately before such transaction.

Good reason means (i) a material diminution in the executive officer s base compensation or target bonus by more than 10%, except in connection with company-wide cost reduction; (ii) a material diminution in the executive officer s authority, duties or responsibilities with respect to the Company or any successor or acquiring entity, including, without limitation, any requirement that an officer who is the Chief Executive Officer report to anyone other than to the Board of Directors of the ultimate parent entity of the Company (the Ultimate Parent) or that the executive officer (other than the Chief Executive Officer) report to anyone other than the Chief Executive Officer of the Ultimate Parent; (iii) a breach of a material provision of the executive officer s employment or other written agreement governing employment with the Company (it being understand that a change in title without the executive officer s consent shall be a material breach); or (iv) a relocation of the executive officer s principal workplace by more than 50 miles from where the executive officer performed services prior to the relocation, without the executive officer s prior consent. However, good reason shall not exist unless (i) the executive officer has given written notice to us within 90 days of the initial existence of the good reason event or condition(s) giving specific details regarding the event or condition; (ii) we have failed to cure such event or condition within 30-days of receiving such notice, and (iii) the executive officer resigns within 30 days of the expiration of the 30-day cure period provided for in clause (ii) provided that we have not cured the event or condition.

This summary of the CIC Plan is qualified in its entirety by reference to the text of the CIC Plan, which is included as Exhibit 10.25 hereto and incorporated herein by reference.

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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 the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2016 (the Proxy Statement), and is incorporated in this annual report on Form 10-K by reference.

Code of 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 Investors portion of our website at http://ir.aldeyra.com. 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 Part II, Item 5 of this annual report, 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

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 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 and indexed at page 73. 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 listed in the Exhibit Index immediately preceding the Exhibits are filed as part of this annual report on Form 10-K.

ITEM 16. Form 10-K Summary

None.

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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 30, 2017.

ALDEYRA THERAPEUTICS, INC.

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

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.	Chief Executive Officer and Director	March 30, 2017
Todd C. Brady, M.D., Ph.D.	(principal executive officer)	
/s/ Stephen J. Tulipano	Chief Financial Officer	March 30, 2017
Stephen J. Tulipano	(principal financial and accounting officer)	
/s/ C. Boyd Clarke	Chairman of the Board of Directors	March 30, 2017
C. Boyd Clarke		
/s/ Ben Bronstein, M.D.	Director	March 30, 2017
Ben Bronstein, M.D.		
/s/ Richard H. Douglas, Ph.D.	Director	March 30, 2017
Richard H. Douglas, Ph.D.		
/s/ Martin J. Joyce	Director	March 30, 2017
Martin J. Joyce		
/s/ Gary Phillips, M.D.	Director	March 30, 2017
Gary Phillips, M.D.		

/s/ Jesse Treu, Ph.D. Jesse Treu, Ph.D.	Director	March 30, 2017
/s/ Neal Walker, D.O. Neal Walker, D.O.	Director	March 30, 2017

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ALDEYRA THERAPEUTICS, INC.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Aldeyra Therapeutics, Inc.

Lexington, Massachusetts

We have audited the accompanying balance sheets of Aldeyra Therapeutics, Inc. (the Company) as of December 31, 2016 and 2015 and the related statements of operations, comprehensive loss, and stockholders equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aldeyra Therapeutics, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

March 30, 2017

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ALDEYRA THERAPEUTICS, INC.

BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,015,061	$ 14,648,866
Marketable securities	12,897,584	12,941,776
Prepaid expenses and other current assets	218,682	497,552
Total current assets	25,131,327	28,088,194
Deferred offering costs		36,236
Fixed assets, net	56,352	80,334
Total assets	$ 25,187,679	$ 28,204,764
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 275,441	$ 851,160
Accrued expenses	1,946,251	1,186,429
Current portion of credit facility	77,546	77,546
Total current liabilities	2,299,238	2,115,135
Credit facility, net of current portion and debt discount	1,238,624	1,211,310
Total liabilities	3,537,862	3,326,445
Commitments and contingencies (Note 11)		
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 12,576,325 and 9,712,521 shares issued and outstanding, respectively	12,576	9,713
Additional paid-in capital	98,938,446	83,478,851
Accumulated other comprehensive income (loss)	129	(8,361)
Accumulated deficit	(77,301,334)	(58,601,884)
Total stockholders equity	21,649,817	24,878,319
Total liabilities and stockholders equity	$ 25,187,679	$ 28,204,764

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

	Years ended December 31, 2016	2015
Operating expenses:		
Research and development	$ 13,175,670	$ 7,574,398
General and administrative	5,520,308	4,414,709
Loss from operations	(18,695,978)	(11,989,107)
Other income (expense):		
Interest income	102,037	11,126
Interest expense	(105,509)	(112,306)
Total other expense, net	(3,472)	(101,180)
Net loss	$ (18,699,450)	$ (12,090,287)
Net loss per share basic and diluted	$ (1.65)	$ (1.40)
Weighted average common shares outstanding basic and diluted	11,352,230	8,633,897

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE LOSS

	Years ended December 31,	
	2016	**2015**
Net loss	$ (18,699,450)	$ (12,090,287)
Other comprehensive income/(loss):		
Unrealized gain/(loss) on marketable securities	8,490	(8,361)
Total other comprehensive income/(loss)	$ 8,490	$ (8,361)
Comprehensive loss	$ (18,690,960)	$ (12,098,648)

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

	Stockholders Equity					
	Common Voting Stock			Accumulated Other		
	Shares	Amount	Additional Paid-in Capital	Comprehensive Income/(Loss), net of tax	Accumulated Deficit	Total Stockholders Equity
Balance, December 31, 2014	5,565,415	$ 5,565	$ 52,790,090	$	$ (46,511,597)	$ 6,284,058
Stock-based compensation			2,187,102			2,187,102
Issuance of common stock, net of issuance costs	4,147,106	4,148	28,501,659			28,505,807
Other comprehensive loss				(8,361)		(8,361)
Net loss					(12,090,287)	(12,090,287)
Balance, December 31, 2015	9,712,521	9,713	83,478,851	(8,361)	(58,601,884)	24,878,319
Stock-based compensation			2,759,753			2,759,753
Issuance of common stock, net of issuance costs of $240,000	2,760,000	2,760	12,610,863			12,613,623
Issuance of common stock, upon exercise of stock options	103,804	103	88,979			89,082
Other comprehensive loss				8,490		8,490
Net loss					(18,699,450)	(18,699,450)
Balance, December 31, 2016	12,576,325	$ 12,576	$ 98,938,446	$ 129	$ (77,301,334)	$ 21,649,817

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

	Years ended December 31, 2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,699,450)	$ (12,090,287)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,759,753	2,187,102
Amortization of debt discount non-cash interest expense	27,314	35,829
Net amortization of premium on debt securities available for sale	266,106	
Depreciation	35,792	18,778
Change in assets and liabilities:		
Prepaid expenses and other current assets	278,870	(264,984)
Accounts payable	(575,719)	509,866
Accrued expenses	759,822	291,943
Net cash used in operating activities	(15,147,512)	(9,311,753)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(11,810)	(86,119)
Purchases of marketable securities	(16,048,424)	(12,950,137)
Sales of marketable securities	15,835,000	
Net cash used in investing activities	(225,234)	(13,036,256)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and exercise of options	12,738,941	28,505,807
Deferred offering costs paid in cash		(36,236)
Net cash provided by financing activities	12,738,941	28,469,571
NET (DECREASE)/INCREASE IN CASH	(2,633,805)	6,121,562
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	14,648,866	8,527,304
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 12,015,061	$ 14,648,866
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 78,128	$ 74,299

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

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ALDEYRA THERAPEUTICS, INC.

NOTES TO THE FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

Aldeyra Therapeutics, Inc. (the Company or Aldeyra) 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. The Company is a biotechnology company focused primarily on the development of new products for inflammation, inborn errors of metabolism and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes. 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.

The Company s principal activities to date include raising capital and research and development activities.

2. BASIS OF PRESENTATION

Basis of Presentation and Management s Plans The accompanying financial statements were prepared in conformity with accounting principles generally accepted in the United States of America (US GAAP).

Liquidity and Management s Plans At December 31, 2016, the Company had an accumulated deficit of approximately $77.3 million and cash and cash equivalents and marketable securities of approximately $24.9 million.

On May 7, 2014, the Company closed its Initial Public Offering, in which 1,500,000 shares of common stock were sold at a price to the public of $8.00 per share for an aggregate offering price of $12.0 million. The offer and sale of all of the shares in the Initial Public Offering were registered under the Securities Act of the 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-193204), which was declared effective by the SEC on May 1, 2014. The Company raised approximately $10.0 million in net proceeds after deducting underwriting discounts and commissions of $0.8 million, $1.0 million in prepaid offering and printing costs and other offering costs of $0.2 million.

On January 15, 2015, the Company sold, in a private placement, an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. The warrants will expire 3 years from the date of issuance. The

warrants do not include a net-exercise feature. The warrants may be redeemed by the Company at a price of $0.001 per share upon notice to the holders in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is 50,000 shares per day. Following Aldeyra s notification to the warrant holders of its exercise of the redemption right under the warrants, each warrant holder will have the option to exercise their warrants prior to the redemption date rather than having them redeemed. The Company raised approximately $7.1 million in net proceeds in the private placement of common stock and warrants.

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On January 22, 2015, in a subsequent private placement, the Company sold an aggregate of 211,528 shares of common stock at a price of $9.33 per share and a warrant to purchase up to 211,528 shares of common stock at a price of $0.125 per share subject to the warrant. The exercise price of the warrant is $9.50 per share. The warrant will expire 3 years from the date of issuance. The warrant does not include a net-exercise feature. The warrant may be redeemed by the Company at a price of $0.001 per share upon notice to the holder thereof in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is 50,000 shares per day. Following Aldeyra s notification to the warrant holder of its exercise of the redemption right under the warrant, the warrant holder will have the option to exercise the warrant prior to the redemption date rather than having it redeemed. The Company raised approximately $1.9 million in net proceeds in the private placement of common stock and a warrant to purchase common stock.

On May 22, 2015, the Company raised approximately $19.5 million, after deducting underwriting discounts and commissions and other offering expenses, through the issuance and sale of 2,822,500 shares of common stock in a follow-on public offering, including shares sold pursuant to the underwriters exercise of their option to purchase additional shares of common stock.

In June 2016, the Company closed an underwritten public offering in which the Company sold, an aggregate of 2,760,000 shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by the Company.

In February 2017, the Company closed an underwritten public offering in which we sold, 2,555,555 shares of its common stock, including 333,333 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $10.5 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

In addition, as discussed in Note 7, the Company entered into its credit facility (the Credit Facility) in April 2012 and it has been subsequently amended to make term loans in a principal amount of up to $5,000,000 available to the Company with proceeds to be used first to refinance outstanding loans from Pacific Western, second to fund expenses related to the Company s clinical trials, and the remainder for general working capital purposes. The term loans are to be made available to the Company upon the following terms: (i) $2,000,000 was made available on November 10, 2014; and (ii) $3.0 million (the Tranche B Loan) which was made available to the Company in May 2016 following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. In November 2016, the Company amended its Credit Facility such that any term loan the Company may draw is payable as interest-only prior to November 2017 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. The Credit Facility is collateralized by the Company s assets, including its intellectual property.

The Company s management believes that its currently available resources, including the funds from the February 2017 public offering and amounts available under the Credit Facility, will provide sufficient funds to enable the Company to meet its obligations into at least the third quarter of 2018 based on its current business plan. The Company will need to raise additional capital to implement its near-term business plan. Additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to secure additional capital, or meet financial covenants that could be implemented under the Company s term loans in certain circumstances, it will be

required to significantly decrease the amount of planned expenditures, and may be required to cease operations.

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

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Use of Estimates The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the 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 financial statements relate to accruals, including research and development costs, accounting for income taxes and the related valuation allowance and accounting for stock based compensation and the related fair value. Although these estimates 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.

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 a treatment for diseases related to high levels of aldehydes.

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 and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with original maturities of greater than three months are classified as marketable securities.

Marketable Securities Marketable securities consist of government securities and obligations with original maturities of more than 90 days. 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. The carrying amount of the Company s term loans under its credit facility approximates market rates currently available to the Company. Marketable securities are carried at fair value and are more fully described in Note 5.

Concentration of Credit Risk Financial instruments that potentially subject us to significant concentrations of credit risk principally consist of cash, cash equivalents and marketable securities. We place our cash and cash equivalents and marketable securities with financial institutions with high credit ratings. As part of our cash and investment management processes, we perform periodic evaluations of the credit standing of the financial institutions with whom we maintain deposits, and have not recorded any credit losses to-date.

Intellectual Property The legal and professional costs incurred by the Company to acquire its patent rights are expensed as incurred and included in operating expenses. At December 31, 2016 and 2015, the Company has

determined that these expenses have not met the criteria to be capitalized. Intellectual property related expenses for the years ended December 31, 2016 and 2015 were $553,871 and $473,878, respectively.

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Income Taxes The Company follows the provisions of FASB ASC 740, *Income Taxes*, 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 of 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 costs are charged to expense as incurred. Research and development expenses include consulting expenses, preclinical studies, clinical trials, clinical trial materials, regulatory and clinical consultants, lab supplies, lab services, lab equipment maintenance, non-refundable license fees and small equipment purchased to support the research laboratory. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until 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, fair value is based on the fair value of the stock on the date of grant. The resulting fair value for restricted stock 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 or option.

Equity instruments issued to nonemployees are accounted for under the provisions of ASC 718 and ASC 505-50, *Equity Equity-Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services are completed and are marked to market through the date of vesting.

From time to time the Company may grant awards with performance conditions necessary to be achieved in order to vest in the award. The Company records compensation expense for those awards over the vesting period of the award to the extent the performance conditions are deemed probable of achievement.

From time to time the Company may grant awards with a market condition necessary to be achieved in order to vest in the award. The Company records compensation expense for those awards over the vesting period of the award on a straight-line basis utilizing Monte Carlo simulations to estimate the timing and number of shares that are most likely to vest.

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, 2016, comprehensive loss is equal to the Company s net loss of $18.7 million and an unrealized gain on marketable securities of $8,490. For December 31, 2015, comprehensive loss is equal to net loss of $12.1 million and an unrealized loss on marketable securities of $(8,361).

Net Loss Per Share

Basic net loss per share available to common stockholders is calculated by dividing the net loss available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share available to common

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stockholders is computed by dividing the net loss available to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, restricted stock units and common stock warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share available to common stockholders when their effect is dilutive.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-15 (ASU 2016-15), Statement of Cash Flows. The standard is intended to reduce the diversity in practice around how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. ASU 2016-15 may be adopted retrospectively or prospectively if it is impractical to apply the amendments retrospectively. The Company does not expect this standard to have a material impact on its financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instrument-Credit Losses (ASU 2016-13). ASU 2016-13 requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. The Company does not expect this standard to have a material impact on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting (ASU 2016-09), to simplify the accounting for stock compensation. This update focuses on income tax accounting, award classification, estimating forfeitures, and cash flow presentation. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02 (ASU 2016-02), Leases. ASU 2016-02 requires lessees to recognize on the balance sheet a right-of-use asset, representing its right to use the underlying asset for the lease term, and a lease liability for all leases with terms greater than 12 months. The guidance also requires qualitative and quantitative disclosures designed to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard requires the use of a modified retrospective transition approach, which includes a number of optional practical expedients that entities may elect to apply. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. The Company does not expect this standard to have a material impact on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01). ASU 2016-01 amends the guidance on the classification and measurement of financial instruments. Although ASU 2016-01 retains many current requirements, it significantly revises accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. ASU 2016-01 also amends certain disclosure requirements associated with the fair value of financial instruments and is effective for fiscal years beginning after December 15, 2017. The Company does not expect this standard to have a material impact on its financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (ASU 2015-17). ASU 2015-17 simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in

ASU 2015-17. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

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In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03). The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for fiscal years beginning after December 15, 2016. The Company does not expect this standard to have a material impact on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for fiscal years beginning after December 15, 2017. The Company does not expect this standard to have a material impact on its financial statements.

3. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share:

	Years ended December 31,	
	2016	2015
Net loss basic and diluted	$ (18,699,450)	$ (12,090,287)
Weighted-average number of common shares basic and diluted	11,352,230	8,633,897
Net loss per share basic and diluted	$ (1.65)	$ (1.40)

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

	Years ended December 31,	
	2016	2015
Options to purchase common stock	1,498,585	1,077,330
Warrants to purchase common stock	1,384,608	1,384,608
Restricted stock units	27,096	
Total of common stock equivalents	2,910,289	2,461,938

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4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

At December 31, 2016, cash, cash equivalents and marketable securities were comprised of:

	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 394,849	$	$	$ 394,849	$ 394,849	$
Money market funds	70,212			70,212	70,212	
U.S. reverse repurchase agreements	11,550,000			11,550,000	11,550,000	
U.S. government agency securities	12,897,455	1,396	(1,267)	12,897,584		12,897,584
Available for Sale(1)	24,447,455	1,396	(1,267)	24,447,584	11,550,000	12,897,584
Total Cash, cash equivalents and current marketable securities					$ 12,015,061	$ 12,897,584

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

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of all available for sale securities are less than one year at December 31, 2016.

5. 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.

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There were no liabilities measured at fair value at December 31, 2016 or 2015, respectively.

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 70,212	$	$	$ 70,212
U.S. reverse repurchase agreements		11,550,000		11,550,000
U.S. government agency securities		12,897,584		12,897,584
Total assets at fair value	$ 70,212	$ 24,447,584	$	$ 24,517,796

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 35,886	$	$	$ 35,886
U.S. reverse repurchase agreements		12,950,000		12,950,000
U.S. government agency securities		12,941,776		12,941,776
Total assets at fair value	$ 35,886	$ 25,891,776	$	$ 25,927,662

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. The carrying amount of the Company s term loans under its credit facility approximates market rates currently available to the Company. Marketable securities are carried at fair value.

6. ACCRUED EXPENSES

Accrued expenses at December 31, 2016 and 2015 were:

	2016	2015
Accrued compensation	$ 983,449	$ 413,172
Accrued research and development	913,838	574,742
Accrued general & administrative	48,964	198,515
Accrued expenses	$ 1,946,251	$ 1,186,429

7. CREDIT FACILITY

The Company s long-term debt obligation consists of amounts the Company is obligated to repay under its Credit Facility with Pacific Western, of which $1.4 million was outstanding as of December 31, 2016. The Company entered

into the Credit Facility in April 2012 and it has been subsequently amended to make term loans in a principal amount of up to $5,000,000 available to the Company with proceeds to be used first to refinance outstanding loans from Pacific Western, second to fund expenses related to its clinical trials, and the remainder for general working capital purposes. The term loans are to be made available upon the following terms: (i) $2,000,000 was made available on November 10, 2014; and (ii) $3.0 million (the Tranche B Loan) which was made available to the Company in May 2016 following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. In November 2016, we amended our Credit Facility such that any term loan the Company draws is payable as interest-only prior to November 2017 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months.

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The Credit Facility is collateralized by the Company s assets, including its intellectual property. As of December 31, 2016, $1.4 million was outstanding under the Credit Facility. Future maturities of the existing term loans under the Credit Facility as of December 31, 2016 are as follows:

2017	$ 77,546
2018	465,278
2019	465,278
2020	387,731
Total	$ 1,395,833

In conjunction with obtaining the November 2013 amended credit facility, the Company issued a warrant exercisable for 9,692 shares of Series B Preferred Stock with an exercise price of $5.16 per share and a term of seven years (Note 12). The warrant was valued at $178,000 and, together with the fair value of the warrant issued in connection with the April 12, 2012 Credit Facility ($88,000), was recorded as a discount on the Credit Facility. These discounts are being amortized using the effective interest method through the current maturity date of the Credit Facility in November 2018. All amendments to the credit facility were determined to be modifications in accordance with ASC 470, *Debt* and did not result in extinguishment.

At December 31, 2016 and 2015, the Credit Facility is shown net of a remaining debt discount of $80,000 and $107,000, respectively.

8. INCOME TAXES

No provision for federal and state taxes has 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 ASC 740, *Income Taxes*, the Company considers whether it is more likely than not that some portion or all of 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 taxes.

As of December 31, 2016, the Company had Federal and State income tax net operating loss (NOL) carryforwards of approximately $42.8 million and $39.9 million, respectively, which will expire at various dates through 2036. As of December 31, 2016, the Company had Federal and State research and development tax credit carryforwards of approximately $1.2 million and $178,000, respectively, which will expire at various dates through 2036.

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Significant components of the Company s deferred tax assets and liabilities at December 31, 2016 and 2015 are as follows:

	12/31/2016	12/31/2015
Deferred Tax Assets		
Federal & State NOL carryforward	$ 16,669,295	$ 10,115,458
Federal & State R&D credit carryforward	1,271,891	667,688
Intangibles net	700,215	932,060
Accounts payable and accrued expenses	772,841	591,843
Stock options	2,399,666	2,152,854
Fixed assets net	3,861	213
Gross deferred tax assets	21,817,769	14,460,116
Valuation Allowance US	(21,786,477)	(14,418,095)
Net Deferred Tax Assets	31,292	42,021
Deferred Tax Liabilities		
Note Discounts	(31,292)	(42,021)
Gross deferred tax liabilities	(31,292)	(42,021)
TOTAL	$	$

The change in valuation allowance of $7.4 million from December 31, 2015 to December 31, 2016 is driven by no tax benefit being recorded on the current year loss from operations.

Under Section 382 of the Internal Revenue Code of 1986, as amended (Code), 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 the Company s common stock, even those outside the Company s control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on the Company s ability to utilize some or all of its NOLs or credits could have a material adverse effect on the Company s results of operations and cash flows. Prior to 2016, Aldeyra underwent two ownership changes and it is possible that additional ownership changes have occurred since. However, the Company s management believes that it has sufficient Built-In-Gain to offset the Section 382 of the Code limitation generated by such ownership changes. Any future ownership changes, including those resulting from the Company s recent or future financing activities, may cause the Company s existing tax attributes to have additional limitations.

All tax years are open for examination by the taxing authorities for both federal and state purposes.

A reconciliation of the federal statutory tax rate of 34% to the Company s effective income tax rates are as follows:

	Years ended December 31,	
	2016	2015
Statutory tax rate	34.00%	34.00%
State taxes, net of federal benefits	5.24%	5.22%
Federal research and development credits	2.84%	1.92%
Change in valuation allowance	(39.42)%	(40.10)%
Stock-based compensation	(2.63)%	0.00%
Other	(0.03)%	(1.04)%
Effective tax rate	0.00%	0.00%

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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.

9. STOCK INCENTIVE PLAN

The Company has three incentive plans. One was adopted in 2004 (2004 Plan) and provided for the granting of stock options and restricted stock awards and generally prescribed a contractual term of seven years. The 2004 Plan terminated in August 2010. However, grants made under the 2004 Plan are still governed by that plan. As of December 31, 2016, options to purchase 23,954 shares of common stock at a weighted average exercise price of $3.24 per share remained outstanding under the 2004 Plan.

The Company approved the 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan) in September 2010 to replace the 2004 Plan. The 2010 Plan provided for the granting of stock options and restricted stock awards. The 2010 Plan terminated upon the Initial Public Offering. However, grants made under the 2010 Plan are still governed by that plan. As of December 31, 2016, options to purchase 489,846 shares of common stock at a weighted average exercise price of $1.58 per share remained outstanding under the 2010 Plan.

The Company approved the 2013 Equity Incentive Plan (2013 Plan) in October 2013. The 2013 Plan became effective immediately on adoption although no awards were to be made under it until the effective date of the Registration Statement for the Initial Public Offering. The 2013 Plan provides for the granting of stock options, restricted stock, stock appreciation rights, stock units, and performance cash awards to certain employees, members of the board of directors and consultants of the Company. As of December 31, 2015, the number of shares of common stock authorized for issuance in connection with the 2013 Plan was 847,614. On January 1 of each year the aggregate number of common shares that may be issued under the Plan shall automatically increase. As of January 1, 2016, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 333,333 shares. In June 2016, the 2013 Plan was amended to provide an increase of 700,000 shares of common stock authorized for issuance increasing the number of shares of common stock available for issuance under the 2013 Plan to 1,880,950 shares and that the annual increase would equal a number of shares equal to the least of (a) 7% of the total number of common shares outstanding on the last calendar day of the prior fiscal year, (b) subject to adjustment for certain corporate transactions, 1,000,000 common shares, or (c) a number of common shares determined by the Company s board of directors. As of December 31, 2016, options to purchase 984,786 shares of common stock at a weighted average exercise price of $6.18 per share and restricted stock units of 27,096 remained outstanding under the 2013 Plan. As of December 31, 2016, there were 869,068 shares of common stock available for grant under the 2013 Plan. As of January 1, 2017, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 880,343 shares, increasing the number of shares of common stock available for issuance under the 2013 Plan to 2,761,293.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the respective plan they were granted. Options granted by the Company typically vest over a four year period. Certain of 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 2013 Plan must be at a price no less than 100% of the fair market value of a common share on the date of grant.

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The Company recognizes stock-based compensation expense over the requisite service period. The Company s share-based awards are accounted for as equity instruments. The amounts included in the consolidated statements of operations relating to stock-based compensation are as follows:

	Year ended December 31,	
	2016	2015
Research and development expenses	$ 1,167,142	$ 841,289
General and administrative expenses	1,592,611	1,345,813
Total stock-based compensation expense	$ 2,759,753	$ 2,187,102

The following table summarizes option activity under the incentive plans for the years ended December 31, 2016 and 2015:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value(a)
Outstanding at December 31, 2015	1,077,330	$ 3.98		
Granted	759,314	5.43		
Cancelled	(63,096)	4.85		
Forfeited	(171,159)	6.30		
Exercised	(103,804)	0.88		463,604
Outstanding at December 31, 2016	1,498,585	$ 4.63	7.86	$ 2,185,696
Exercisable at December 31, 2016	802,532	$ 2.34	7.10	$ 1,874,659

(a) The aggregate intrinsic value in this table was calculated on the positive difference, if any, between the closing market value of our common stock on December 31, 2016 of $5.35 and the price of the underlying options.

The Company records stock-based compensation related to stock options granted at fair value. During the years ended December 31, 2016 and 2015, 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 fair value of options granted was $ 5.43 and $7.78 for the years ended December 31, 2016 and 2015, respectively. The assumptions used in determining fair value of the employee stock options for the years ended December 2016 and 2015, are as follows:

	December 31, 2016	December 31, 2015

Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	$ 3.94 - $7.48	$ 7.19 - $8.37
Exercise price	$ 3.94 - $7.48	$ 7.19 - $8.37
Expected life (years)	5.50 - 6.25	5.50 - 6.25
Risk free interest rate	0.59% - 2.20%	0.27% - 1.91%

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 based on the historical volatility of a group of similar companies. The Company has also computed the historical volatility of the Company s historical information regarding the volatility of its stock price and has determined that a volatility estimate of 89% is reasonable. The Company has estimated the expected life of our 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

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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, 2016, there is approximately $3.2 million of unrecognized compensation cost relating to stock options outstanding, which the Company expects to recognize over a weighted average period 2.11 years. Total unrecognized compensation cost will be adjusted for future forfeitures, if necessary.

Restricted Stock Units

Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. During the year ended December 31, 2016, the Company granted a restricted stock unit award for 27,096 underlying shares of common stock with a weighted-average grant date fair value of $6.33 per share. As of December 31, 2016, the outstanding restricted stock units had unamortized stock-based compensation of $134,281 with a weighted-average remaining recognition period of 3.33 years and no aggregate intrinsic value.

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 authorizes the initial issuance of up to a total of 97,500 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 lesser 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. As of December 31, 2016, there was no activity under the 2016 ESPP. On January 1, 2017, the number of shares available for issuance under the 2016 ESPP was automatically increased by 125,763 shares, increasing the number of shares of common stock available for issuance under the 2016 ESPP to 223,263.

10. STOCK PURCHASE WARRANTS

On January 14, 2015, the Company sold, in a private placement, an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. The Company raised approximately $7.1 million in net proceeds in the private placement of common stock and warrants. Additionally, on January 21, 2015, in a subsequent private placement, the Company sold an aggregate of 211,528 shares of common stock at a price of $9.33 per share and a warrant to purchase up to 211,528 shares of common stock at a price of $0.125 per share subject to the warrant. The Company raised approximately $1.9 million in net proceeds in the private placement of common stock and a warrant to purchase common stock. In both transactions, the exercise price of the warrants is $9.50 per share. The warrants will expire 3 years from their respective date of issuance. The warrants do not include a net-exercise feature. The warrants may be redeemed by the Company at a price of $0.001 per share upon notice to the holders thereof in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is at least 50,000 shares per day. Following Aldeyra s notification to the warrant holders of its exercise of the redemption right under the warrants, the warrant holders will have the option to exercise the warrants prior to the redemption date rather than having them redeemed.

In connection with the Initial Public Offering, the Company issued the underwriters of the offering warrants to purchase up to 60,000 shares of common stock. The warrants are exercisable beginning on May 1, 2015 for cash or on a cashless basis at a per share price of $10.00. The warrants will expire on May 1, 2019.

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All of the warrants above were outstanding at December 31, 2016.

11. 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, 2016, the Company had not experienced any losses related to these indemnification obligations and no material claims were outstanding. The Company 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.

Other Contractual Arrangements During the year ended December 31, 2014, the Company entered into a lease agreement for a certain commercial office space. The thirty-seven month lease which began in September 2014 provides the Company with approximately 3,700 square feet of space in Lexington, Massachusetts. Base annual rent is initially set at $5,604 per month. Total base rent payable over the lease period is approximately $205,000. In March 2016, the Company entered into a sublease for approximately 3,188 additional square feet of office space to expand its headquarters in Lexington, Massachusetts. The sublease expires in September 2017. The sublease provides for the payment of annual base rent in the amount of $67,000 payable in monthly installments and the requirement to pay certain operating expenses, taxes and other fees in accordance with the terms of the master lease.

The Company s gross future minimum payments under all non-cancelable operating leases as of December 31, 2016, are $107,195 for the year ending December 31, 2017.

12. SUBSEQUENT EVENT

In February 2017, the Company closed an underwritten public offering in which it sold, 2,555,555 shares of its common stock, including 333,333 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $10.5 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

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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 7, 2014, 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	Investor Rights Agreement dated as of December 20, 2012 (filed as Exhibit 4.2 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)
4.3	Form of Representative s Warrant Agreement (filed as Exhibit 4.3 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)
4.4	Form of Warrant to Purchase Common Stock of Aldeyra Therapeutics, Inc. (filed as Exhibit 4.4 to the Registrant s Current Report on Form 8-K as filed on January 15, 2015, and incorporated herein by reference)
4.5	Form of Warrant to Purchase Common Stock of Aldeyra Therapeutics, Inc. (filed as Exhibit 4.5 to the Registrant s Current Report on Form 8-K as filed on January 22, 2015, 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 7, 2014, and incorporated herein by reference)
10.4	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 7, 2014, and incorporated herein by reference)
10.4(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)
10.6	2004 Employee, Director and Consultant Stock Plan, as amended, and form of option agreement thereunder (filed as Exhibit 10.6 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 7, 2014, and incorporated herein by reference)
10.7	

	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 7, 2014, and incorporated herein by reference)
10.8	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)

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Exhibit Number	Exhibit Title
10.8.(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)
10.8(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)
10.9	Loan and Security Agreement, dated as of April 12, 2012, between Square 1 Bank and the Registrant (filed as Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 7, 2014, and incorporated herein by reference)
10.10	Amendment No. 1 to Loan and Security Agreement, date as of November 20, 2013 between Square 1 Bank and the Registrant (filed as Exhibit 10.12 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 7, 2014, and incorporated herein by reference)
10.11	Amendment No. 1 to Loan and Security Agreement, date as of November 20, 2013 between Square 1 Bank and the Registrant (filed as Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 7, 2014, and incorporated herein by reference)
10.12	Offer Letter dated June 13, 2014 between the Registrant and Stephen Tulipano (filed as Exhibit 10.14 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 (as filed on August 7, 2014, and incorporated herein by reference))
10.13	Sublease dated August 18, 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))
10.14	Second Amendment to Loan and Security Agreement, dated as of November 7, 2014, between Square 1 Bank and the Registrant (filed as Exhibit 10.2 to the Registrant s Current Report on Form 8-K as filed on November 7, 2014, and incorporated herein by reference)
10.15	Form of Purchase Agreement dated January 12, 2015 (filed as Exhibit 10.42 to the Registrant s Current Report on Form 8-K as filed on January 13, 2015, and incorporated herein by reference)
10.16	Form of Registration Rights Agreement, dated as of January 14, 2015 (filed as Exhibit 10.43 to the Registrant s Current Report on Form 8-K as filed on January 15, 2015, and incorporated herein by reference)
10.17	Form of Purchase Agreement dated January 20, 2015 (filed as Exhibit 10.44 to the Registrant s Current Report on Form 8-K as filed on January 20, 2015, and incorporated herein by reference)
10.18	Form of Registration Rights Agreement, dated as of January 21, 2015 (filed as Exhibit 10.45 to the Registrant s Current Report on Form 8-K as filed on January 22, 2015, and incorporated herein by reference)
10.19	Third Amendment to Loan and Security Agreement, dated as of March 18, 2015, between Pacific Western Bank and the Registrant. (filed as Exhibit 10.21 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 (as filed on May 14, 2015, and incorporated herein by reference))
10.20	Fourth Amendment to Loan and Security Agreement, dated as of November 9, 2015, between Pacific Western Bank and the Registrant. (filed as Exhibit 10.21 to the Registrant s Quarterly Report on Form

10-Q for the quarter ended September 30, 2015 (as filed on November 13, 2015, and incorporated herein by reference))

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Exhibit Number	Exhibit Title
10.21*	Fifth Amendment to Loan and Security Agreement, dated as of December 1, 2016, between Pacific Western Bank and the Registrant
10.22	Offer Letter between the Registrant and David J. Clark, M.D. dated December 15, 2015 (filed as Exhibit 10.23 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))
10.23	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 10.23 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))
10.24	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)
10.25 *	Aldeyra Therapeutics, Inc. Change in Control Plan
23.1*	Consent of BDO USA, LLP, 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
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

Compensation Arrangement.
Confidential treatment has been granted with respect to certain portions of this document.
* Filed herewith.