Aldeyra Therapeutics, Inc.
Form 10-K
March 23, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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 x

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 x

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 x 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 x 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. x

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 x

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

As of June 30, 2014, 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 $11,936,438, 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 own 10% or more of the outstanding stock 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 15, 2015 there were 6,890,023 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 2015 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, 2014, are incorporated by reference into Part III of this Form 10-K.

Table of Contents

Aldeyra Therapeutics, Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2014

Table of Contents

		Page
	Part I	
	Special Note Regarding Forward-Looking Statements Industry and Market Data	3
Item 1.	Business	4
Item 1A.	Risk Factors	22
Item 1B.	Unresolved Staff Comments	52
Item 2.	Properties	52
Item 3.	Legal Proceedings	52
Item 4.	Mine Safety Disclosures	52
	Part II	
Item 5.	Market for Registrant s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities	53
Item 6.	Selected Financial Data	53
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	54
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	63
Item 8.	Financial Statements and Supplementary Data	63
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	63
Item 9A.	Controls and Procedures	63
Item 9B.	Other Information	64
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	65
Item 11.	Executive Compensation	74
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	79
Item 13.	Certain Relationships and Related Transactions, and Director Independence	81
Item 14.	Principal Accounting Fees and Services	83
	Part IV	
Item 15.	Exhibits, Financial Statements Schedules	83
Signatures		84
Index to Financial Statements		85
Exhibit Index		108

Table of Contents

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 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 for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency 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;

the anticipated trends and challenges in our business and the market in which we operate; and

the use of our cash or cash equivalents

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.

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

Table of Contents

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.

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

Aldeyra was formed as a Delaware corporation in 2004, and from inception until December 20, 2012, we operated as Neuron Systems, Inc. and from December 2012 until March 2014 we operated as Aldexa Therapeutics, Inc. 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.

We are a biotechnology company focused primarily on the development of new products for immune-mediated, inflammatory, orphan and other diseases that are thought to be caused in part by naturally occurring toxic chemical species known as free aldehydes. We have developed a series of product candidates that are designed specifically to trap and allow for the degradation of free aldehydes. In 2015, we plan to begin clinical testing of our most advanced product candidate, NS2, in diseases with significant unmet medical need where we believe aldehyde trapping may improve symptoms and slow or prevent disease progression. Since the diseases we plan to study are rare, we intend to request orphan drug designation from the United States Food and Drug Administration (FDA).

We intend to initiate a clinical trial of NS2, for the treatment of a disease called Sjögren-Larsson Syndrome (SLS), a rare condition that we believe afflicts approximately 1,000 patients in the United States. The disease is

Table of Contents

caused by mutations in an enzyme that metabolizes free fatty (generally 16-18 carbon) aldehydes, resulting in high levels of toxic aldehydes that are the suspected cause of severe skin disease, mental delay, spasticity, and, in some patients, retinal dysfunction. NS2 has demonstrated fatty aldehyde trapping in human skin cells in preclinical studies. In order to attempt to improve the dermatologic symptoms of SLS, we plan to initiate Phase II clinical testing of NS2 applied topically to the skin of SLS patients beginning in 2015. We are not aware of any therapy for SLS that has been approved by the FDA.

Preclinical testing with NS2 suggests that aldehyde trapping has the potential to improve symptoms related to and slow or prevent the progression of a variety of other diseases by reducing inflammation, promoting healing, diminishing the potential for scarring, and protecting a key lipid (fat) that is involved in lubricating the surface of the eye and preventing skin dryness.

We believe that inflammatory diseases of the eye may also be mediated in part by free aldehyde toxicity. We have developed an eye drop formulation of NS2 that has completed Phase I clinical testing for safety and tolerability in healthy volunteers. In 2015, we plan to initiate Phase II clinical trials of the NS2 eye drop formulation in a serious and, we believe, poorly treated ocular disease called noninfectious anterior uveitis. In noninfectious anterior uveitis, aldehydes may mediate, at least in part, inflammation, fibrotic changes, and lipid destruction leading to dryness and surface irritation. Patients with noninfectious anterior uveitis generally experience severe pain, sensitivity to light, and vision loss. We believe that novel medications are needed to improve symptoms and deter disease progression, especially in order to reduce dependence on topical corticosteroids, which can lead to cataracts (ocular lens opacities resulting in vision impairment) and glaucoma (increased intraocular pressure that can, in some cases, lead to blindness).

In 2015, we may initiate clinical trials with NS2 in other diseases thought to be mediated in part by free aldehydes, and we may initiate development of an oral formulation of NS2 for diseases for which we believe systemic aldehyde trapping may provide therapeutic benefit.

Business Strategy

We intend to develop NS2 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 across immune-mediated, inflammatory, orphan and other diseases. Accordingly, we have attempted 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.

Specifically, our business strategy is to:

Continue the development of and pursue regulatory approval for NS2. We are currently preparing to initiate clinical trials of NS2 in several diseases. 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 FDA and comparable foreign agencies for marketing approval of NS2.

Aggressively develop new intellectual property and consider partnerships to accelerate and maximize the potential for other product candidates that are aldehyde traps. 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 more financial resources, commercialization experience, and global infrastructures that could realize the commercial potential of NS2 to a greater extent than we could achieve operating without such partnerships.

Table of Contents

Explore building in-house capabilities to commercialize NS2 in the United States and other geographies. As, and if, NS2 progresses 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 NS2 for rare diseases 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. As NS2 and other aldehyde traps progress in development, we may consider in-licensing drug candidates that are unrelated to aldehyde trapping but complementary to the indications of our current development programs, particularly orphan and inflammatory disorders.

The Market for Aldehyde Traps

Occurring generally as a result of a large number of metabolic processes, free aldehydes are naturally occurring endogenous chemical species that, among other things, promote inflammation. At high levels, free aldehydes are toxic and are implicated as mediators of many immune-mediated and inflammatory diseases. A variety of diseases are thought to be related to free aldehydes, at least in part, including autoimmune diseases (e.g., systemic lupus erythematosis), inflammatory diseases (e.g., uveitis), neurological disease (e.g., multiple sclerosis), cardiovascular disease (e.g., atherosclerosis) and endocrinologic disease (e.g., diabetic nephropathy). 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 free aldehyde levels.

We may test our lead aldehyde trap product candidate, NS2, in diseases that we believe are likely to be mediated at least in part by free aldehydes and that we view as poorly treated, if treated at all, by currently available medications. SLS, for which we intend to initiate Phase II testing in 2015 with NS2, is a rare condition that we believe affects approximately 1,000 patients in the United States. In addition, we intend to initiate a Phase II clinical trial of NS2 in 2015 to test for efficacy in noninfectious anterior uveitis, also a rare disease. While the patient populations for rare diseases are limited, we believe that reimbursement and pricing have the potential to be sufficient to generate significant revenues for approved therapies that offer significant advantages over standard of care. In 2015, we may initiate clinical trials with NS2 in other diseases thought to be mediated in part by free aldehydes, and we may initiate development of an oral formulation of NS2 for diseases for which we believe systemic aldehyde trapping may provide therapeutic benefit.

We have discovered and synthesized other aldehyde traps that we may test in other diseases that afflict large populations worldwide, such as atherosclerosis, neurodegenerative diseases, and complications of diabetes. For some mass-market diseases, we may partner with larger companies for development and commercialization.

Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome (SLS) is caused by a variety of mutations of an enzyme called Fatty Aldehyde Dehydrogenase (FALDH), leading to the accumulation of fatty aldehydes or precursor molecules that are generally 16 to 18 carbons in length. The aldehyde accumulation is thought to result in the pathology of the disease, which includes a severe skin disorder called ichthyosis, as well as mental delay, spasticity, and, in some patients, retinal disorders. While FALDH dysfunction also leads to diminished levels of certain fatty acids, therapy with these fatty acids has been ineffective in SLS patients. 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 expiring 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. We believe that 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 treatment that is currently approved to treat SLS.

Table of Contents

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, wrinkled, pigmented, pruritic (itchy), inflamed skin. SLS patients are consistently disturbed by pruritus and often excoriate skin by scratching. The ichthyosis in SLS affects most of the body, and is worse in flexure areas and the nape of the neck. 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 dermal thickening characteristic of ichthyosis. We believe that by lowering levels of aldehydes and thereby preventing lipid modification and the ensuing moisture barrier dysfunction, NS2, when applied topically to the skin, has the potential to ameliorate the dermatologic symptoms of SLS, deter disease progression, and potentially cure the ichthyosis that occurs in SLS.

In order to estimate potential pricing for NS2 as a dermatologic topical treatment for SLS, we have assumed pricing of another topical product for a rare dermatologic disease, Targretin® Gel for cutaneous T cell lymphoma. Assuming twice per day treatment of 25% of the body surface area, and assuming a standard amount of cream per unit skin area, at the price per gram of Targretin® Gel, we believe that topically administered NS2 could command pricing in excess of $200,000 per SLS patient per year. To verify reimbursement for such pricing, we contracted a third party reimbursement expert to interview numerous clinical directors for large payors, representing in aggregate over 15 million covered lives. Assuming NS2 efficacy that exceeds standard of care (non-specific keratinolytic and moisturizing creams) in a clinically significant manner, the payor interviews lend strong support to reimbursement at annual per patient pricing in excess of $200,000. However, there can be no assurances regarding the actual reimbursement, pricing, or market penetration for our product candidates.

Noninfectious anterior uveitis

Noninfectious anterior uveitis is an inflammatory ocular disease that is characterized by rapid-onset pain, sensitivity to light, and loss of vision. The disease may occur with other autoimmune diseases. The annual incidence of noninfectious anterior uveitis in the United States is about 25,000 patients, and approximately one-third of these patients have one or more episodes per year. Patients with recurrent episodes often develop cataracts, and severe cases may lead to glaucoma and retinal dysfunction. The disease is typically treated with topical corticosteroids, though prolonged used of corticosteroids increases the incidence of cataracts and glaucoma in uveitis. Corticosteroids may also increase the incidence of infection and corneal ulceration. It has been estimated that uveitis is responsible for 10% of the blindness in the United States.

Free aldehyde levels are elevated in anterior uveitis patients. By trapping aldehydes, we believe NS2 may reduce inflammation in anterior uveitis and reduce the burden of corticosteroid use. Because corticosteroids exacerbate the formation of cataracts and glaucoma in uveitis and may increase ocular infection and corneal ulceration, we believe that there is a high demand for a novel topical anti-inflammatory agent to be used in conjunction with, or in place of, corticosteroids. We have not performed reimbursement or pricing surveys for noninfectious anterior uveitis.

A New Immune-Mediating Approach: NS2 and Other Novel Aldehyde Traps

Free Aldehyde Toxicity

Free aldehydes are generated through a variety of metabolic processes and are pro-inflammatory. At high levels, free aldehydes are toxic, binding proteins, lipids, carbohydrates, and DNA, and may mediate inflammation in, and the progression of, many serious diseases through the activation of intracellular

Table of Contents

inflammatory factors, including NF-kB, an important protein in the inflammatory response. In many cases, aldehyde binding to cellular constituents leads to the formation of indigestible adducts and aggregates that are pro-inflammatory and 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 free 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 trapping aldehydes represents a novel platform for the treatment of inflammatory conditions and other diseases where aldehydes are implicated in pathogenesis.

NS2 Efficacy

We are currently developing NS2, a new chemical entity, for the treatment of SLS and inflammatory diseases where we believe that free aldehyde-mediated toxicity is implicated. NS2 is a small molecule designed specifically to trap and allow for the degradation of free aldehydes. In *in vitro* and animal studies, NS2 appears to have minimal pharmacology, meaning that it does not appear to affect most cellular components, including most receptors, enzymes and other proteins. NS2 has been shown to bind and trap free aldehydes more rapidly than free aldehydes bind any cellular constituent. Evidence suggests that NS2 chemically binds to aldehydes, so-called NS2-aldehyde adducts, are rapidly transported to cellular lysosomes, where the adduct is degraded within hours. Outside the lysosome, the adduct is remarkably stable, meaning that NS2-aldehyde binding is essentially irreversible *in vivo*, hence the notion of NS2 as an aldehyde trap. By essentially irreversibly binding free aldehydes to form covalent adducts that are transported to lysosomes for degradation, NS2 has the potential to substantially lower aldehyde levels.

To our knowledge, 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 NS2 administration at a variety of different doses relevant to clinical testing.

In mice injected with a pro-inflammatory agent known as endotoxin, a single intra-peritoneal (gut) injection of NS2, administered 30 minutes prior to endotoxin, 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, measured two hours after endotoxin exposure. Additionally, in models of murine contact (induced by phorbol myristate acetate) and allergic (induced by sensitivity to oxazolone) dermatitis, a single intra-peritoneal injection of NS2 statistically reduced swelling when measured 6.5 and 24.5 hours, respectively, after NS2 administration.

Table of Contents

In a model of radiation mucositis (oral inflammation) in hamsters, chronic subcutaneous administration of NS2 reduced healing time and decreased fibrosis (scarring).

In human skin cells and in cells lacking FALDH, NS2 was at low doses able to fully protect a lipid (fat) critical to the moisture barrier in skin and ocular tear lubrication and moisturizing effectiveness.

In dry eye and dry skin models where human ocular and skin tissues were exposed to abnormally dry conditions for 72 hours, NS2 was able to quench elevated levels of a known toxic aldehyde (malondialdehyde).

Thus, we believe that aldehyde trapping with NS2 potentially has a variety of mechanisms of action lowering inflammation, reducing healing time, diminishing scarring, and protecting a lipid important in tissue moisture barriers that may ameliorate aldehyde-mediated disease and deter aldehyde-mediated disease progression in different ways at the same time.

NS2 Safety and Therapeutic Index

Aside from increasing levels of inflammation, there is no generally accepted role of high levels of free 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 designed to prevent the aldehydes from reacting with other molecules. As such, retinaldehyde and pyridoxal are likely not exposed to the cellular milieu, thereby precluding the non-specific binding that is characteristic of free aldehydes. Thus, aldehyde trapping is expected *a priori* only to dampen inflammatory response and we believe would be predicted not to lead to overt toxicity.

We have completed a number of non-clinical and preclinical toxicity studies of NS2, which appears to be generally well tolerated and safe. Based on the evidence collected by us to date, NS2 is an aldehyde trap that has minimal pharmacological activity per se, in that there are no known direct interactions with cellular components that appear to have significant effects in animals. After systemic exposure to high levels of NS2, no signs of retinaldehyde deficiency on retinal function have been observed, nor have we observed any effects in animals that would suggest pyridoxal deficiencies. No significant toxicity has been observed by us in an animal model when NS2 was administered as a 0.5% eye drop four times per day for up to nine months. No consistent toxicity was observed in animals topically treated once-daily with a 1% NS2 dermatologic formulation for 21 days. No NS2-related toxicity has been observed in animals when NS2 was systemically administered in special cardiovascular, neurobehavioral and pulmonary safety studies, or in other studies with NS2, either acutely or

Table of Contents

chronically, including a study where animals were administered NS2 intravenously for 60 days. We currently have three Investigational New Drug (IND) filings with the FDA that are active and in good standing relating to the clinical testing of NS2: as an eye drop for the treatment of aldehyde-mediated retinal disease, as an eye drop for the treatment of noninfectious anterior uveitis, and as a dermal topical formulation for the treatment of the dermatologic manifestations of SLS.

To our knowledge, levels of free aldehydes in tissue generally do not exceed 10μM for sustained durations, since, based on cell toxicity studies after exposure to free aldehydes, 10μM concentrations can lead to significant cell death. In skin cell culture from patients with SLS, over 80% cell death has been observed at 60μM concentrations of aldehydes; however, biopsies of SLS patients do not indicate cell death, suggesting that the actual aldehyde concentrations in the skin of SLS patients is far lower than 60μM. In the tears of patients with dry eye, aldehyde concentrations are estimated at 1μM. Based on the totality of these results, we believe that the levels of aldehydes in SLS or other human diseases are likely significantly lower than 10μM on a sustained basis. Relative to aldehyde levels, concentrations of NS2 are generally higher in our pharmaceutical preparations and in the tissue of animals after NS2 administration. Eye drops containing 0.5% NS2 are greater than 20mM (20,000-fold greater than reported aldehyde load in tears of dry eye patients), and a single drop results in anterior ocular tissue concentrations of greater than 15μM in non-human primates. Likewise, NS2 concentrations in 1% dermatologic topical preparations are greater than 40mM, and following 21 days of once-daily exposure to topical 1% NS2 in animals, dermal tissue levels of NS2 ranged from 10 to 30 μM, with systemic levels of NS2 estimated to be less than 1 μM. Given the potential to be able to administer NS2 topically in concentrations that far exceed predicted free aldehyde concentrations, we believe that NS2 will significantly lower free aldehyde loads in diseases where topical administration of NS2 is applicable.

NS2 Phase I Clinical Trial

We completed a double-masked, placebo-controlled, United States-based Phase I clinical trial of 0.25% and 0.5% NS2 administered as an eye drop in 48 healthy volunteers. Results of this Phase I clinical trial were reported in 2011. Up to four doses per day were administered per volunteer for seven days for both concentrations. No NS2 was detectable in plasma, and NS2 was well tolerated in all subjects throughout the duration of the study. NS2 did not affect visual acuity or dark adaptation, and therefore did not disrupt the function of retinaldehyde in the retina or other physiologic processes that relate to visual function.

NS2 Clinical Trials

In 2015, pending successful IND submissions, we intend to initiate clinical trials in SLS and noninfectious anterior uveitis. Table 1 summarizes the proposed key characteristics of these clinical trials, which are subject to change depending on input from regulatory agencies, advisors and other entities. We can provide no assurances that the clinical designs below will be utilized.

Table 1. Clinical Trial Designs

Indication	**SLS Dermatologic Topical**	Noninfectious **Anterior Uveitis**
Drug Product	NS2 1%	NS2 0.5%

		eye drop
Patients	12	45
Control	1:1 Placebo	1:1:1 (NS2, topical corticosteroid, and sub-therapeutic corticosteroid + NS2)
Treatment Time	8 weeks	6 weeks
Endpoints	Visual Ichthyosis Scale	Ocular inflammation, pain and visual acuity

Table of Contents

Our currently anticipated timing of the initiation and completion of our clinical trials is 2015 and the second half of 2015, respectively, although trial timing may change depending on input from regulatory agencies, advisors and other entities.

Novel Aldehyde Trap Development

In addition to the development of NS2, 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 *in vitro* numerous molecules that may be more potent than NS2 in trapping free aldehydes. We are currently screening for product candidates to address diseases where oral and topical administration are applicable to reduce free aldehyde-mediated toxicity. We expect to nominate a new oral product candidate in 2015; however, given the unpredictable nature of medicinal chemistry and early stage molecular screening, the timing of product candidate selection is difficult to ascertain.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for NS2 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 NS2, and the compositions and uses of other novel aldehyde trapping compounds. As of December 31, 2014, we owned three United States patents, three pending United States non-provisional patent applications, three PCT applications at the international-stage as well as numerous foreign counterparts to these patents and patent applications. We expect the issued NS2 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 NS2 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. NS2 composition of matter patents have been issued in Australia, Canada, China, Europe (validated in about 14 member countries), Hong Kong, Indonesia, Japan, Mexico, Russia and South Korea. NS2

composition of matter patent claims are pending in Brazil and India.

Table of Contents

Other Intellectual Property Rights

The United States Patent and Trademark Office has determined that our applications to register ALDEYRA THERAPEUTICS and our logo are allowable, and we expect the registration certificates to issue in due course.

In February 2010, we entered into a License and Supply Agreement with CyDex Pharmaceuticals, Inc., which was subsequently acquired by Ligand Pharmaceuticals Incorporated. The agreement grants us an exclusive license in the field of retinal degeneration (with certain exclusions) to certain excipient-related composition of matter and method of use patents to produce, use or sell our products that contain a certain solubilizing excipient, and allows for us to purchase at a defined cost an excipient used in our eye drop formulation of NS2. We will also be obligated to make milestone payments of up to an aggregate of $2.15 million upon reaching certain development and regulatory milestones in the development of our product. In the event of commercialization of a product containing the excipient, the agreement stipulates royalties at a low single digit percentage of applicable net sales, with an annual cap. The agreement continues in effect until the 7th anniversary of the expiration of all patents licensed under the agreement, which we currently estimate to be April 2036 unless earlier terminated by the parties. CyDex has the right to terminate the agreement if we are in default under the agreement and should fail to cure such default within thirty (30) days (or ten (10) days with respect to any payment obligation). Default includes, among other things, the failure to fulfill certain obligations and meet certain deadlines in connection with the commercialization of our product. We have the right to terminate the agreement at any time by 90 days written notice, or 45 days written notice in the event of a material breach by CyDex.

Confidential Information and Inventions Assignment Agreements

We currently require and will continue to require each of our employees and consultants to execute confidentiality agreements upon the commencement of such individual s employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances.

In the case of employees, the agreements provide that all inventions resulting from such individual s work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. Our consulting agreements also provide for assignment to us of any intellectual property resulting from services performed by a consultant for us.

Sales and Marketing

We are currently seeking and will continue to seek to develop and commercialize NS2 for certain diseases in the United States alone, or with partners. Our intended strategy for NS2, if approved, will be to establish NS2 as the prescription product of choice for SLS and noninfectious anterior uveitis. If the product candidate is approved for SLS or noninfectious anterior uveitis, our current expectation is that NS2 would initially be sold to small groups of physicians that specialize in these relatively rare disorders. We may also plan to utilize strategic partners or contract sales forces to assist in the commercialization of NS2, and with such partners, would seek to build awareness in the approved patient populations of the clinical utility of NS2.

Manufacturing

We do not own or operate manufacturing facilities for the production of NS2 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

Table of Contents

contractual relationships for the manufacture of commercial supplies of NS2 or our other product candidates. If NS2 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 NS2 and other materials needed for the formulation of NS2 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 NS2 and other ingredients in NS2 formulations are generally readily available from multiple sources.

Employees

As of December 31, 2014, we had six full time employees and had engaged a number of key consultants. We intend to increase our employee base in connection with the commencement of our clinical trials for NS2. We expect that a number of consultants previously engaged in development of NS2 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 temporary aldehyde binding. Various amines have been described, particularly carnosine (a naturally occurring dipeptide), which has a variety of additional potential mechanisms of action unrelated to aldehyde binding. 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 NS2 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 free aldehydes is essentially irreversible *in vivo*, which we believe may result in a more effective means of diminishing aldehyde levels.

At least one company (Aldea Pharmaceuticals) has developed catalysts of aldehyde dehydrogenases in order to facilitate the catabolism of certain aldehydes. Initial applications of this approach appear to include reducing levels of acetaldehyde, a product of ethanol consumption. While we believe that NS2 and other aldehyde traps may also diminish acetaldehyde levels, we do not, in the near future, intend to pursue acetaldehyde reduction following ethanol consumption as a commercial opportunity. We do not believe that catalysis of specific aldehyde dehydrogenases would be likely to benefit disorders where aldehyde dehydrogenase activity is missing due to genetic mutations. Further, we are not aware that any aldehyde dehydrogenase catalyst manifests anti-inflammatory activity.

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 dependence on or 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

Table of Contents

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, NS2 will compete with a variety of generic and proprietary pharmaceuticals, depending on the approved indication. Table 2 below summarizes competitive products by indication.

Table 2. Competitive Pharmaceuticals by Indication

Indication	Competitive Products
Sjögren-Larsson Syndrome	Retinoids, keratinolytics, and moisturizers
Noninfectious Anterior Uveitis	Topical corticosteroids

We believe that there is significant unmet medical need for the diseases that we intend to study. If NS2 is proven to be safe and effective, we believe that NS2 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. 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. Topical corticosteroids for ocular inflammatory diseases are often associated with toxicity, including corneal ulceration, cataracts, and glaucoma. While NS2 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 NS2 pricing that we anticipate. Pricing factors may discourage the initial or prolonged use of NS2.

We believe that there are no drugs in development specifically for SLS. Novartis (ESBA105) 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.

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 NS2 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, or 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.

Table of Contents

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, or 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, or 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, or 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;
- submission to the FDA of a new drug application, or 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. Pre-clinical 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 II clinical trial is the subject of discussion at an end-of-Phase II meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the design of the Phase III 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

Table of Contents

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 I: 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 II: 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 and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.

Phase III: These are commonly referred to as pivotal studies. When Phase II 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 IV: 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 IV 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.

Table of Contents

For some products, the FDA may require a risk evaluation and mitigation strategy, or 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, or 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.

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, or 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 IV 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 the company to develop additional data or conduct additional preclinical studies and clinical trials.

Table of Contents

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.

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.

Table of Contents

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.

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, or 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.

19

Table of Contents

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 NS2. Our research and development expenses totaled $3.7 million for the year ended December 31, 2014 and $1.5 million for the year ended December 31, 2013.

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 and milestone payments under in-licensing agreements;
- 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;

Table of Contents

the length of time required to enroll eligible patients;

the number of patients that participate in the trials;

the number of doses that patients receive;

the drop-out or discontinuation rates of patients;

the duration of patient follow-up;

the phase of development the product candidate is in; and

the efficacy and safety profile of the product candidate.

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

None of our product candidates have received FDA or foreign regulatory marketing approval. In order to grant marketing approval, a health authority such as the FDA or foreign regulatory agencies must conclude that clinical and preclinical data establish the safety and efficacy of our product candidates with an appropriate benefit to risk profile relevant to a particular indication, and that the product can be manufactured under cGMP in a reproducible manner to deliver the product s intended performance in terms of its stability, quality, purity and potency. Until 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.

Table of Contents

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, financial condition and operating results.

Risks Related to our Business

We have incurred significant operating losses since inception, as of December 31, 2014, we had an accumulated deficit $46.5 million, 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 NS2 and our other product candidates. Net (loss) income attributable to common stockholders for the years ended December 31, 2014 and 2013 was approximately $(9.6) million and $1.1 million, respectively. As of December 31, 2014, we had total stockholders equity of $6.3 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 NS2 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 NS2 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, NS2, which has not entered a clinical trial to demonstrate efficacy in humans. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, NS2.

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: NS2, a novel small molecule chemical entity that is believed to trap and allow for the degradation of free 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 NS2. We will need to raise sufficient funds for, and successfully enroll and complete, our planned clinical trials of NS2, which we intend to commence in 2015. 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 NS2;

we may not be able to timely 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;

Table of Contents

we may not be able to provide evidence of safety and efficacy for NS2;

the results of our clinical trials may not confirm the results of our Phase I trial of NS2 as an eye drop in healthy volunteers, particularly because the safety of NS2 has not been confirmed in a diseased population nor has NS2 been tested in humans in any other dosage form other than an eye drop;

we have not demonstrated efficacy of NS2 in any clinical trial;

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 level of statistical or clinical significance required by the United States Food and Drug Administration, or FDA, or comparable foreign regulatory bodies for marketing approval;

patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to NS2;

if approved for certain diseases, NS2 will compete with well-established products already approved for marketing by the FDA, including corticosteroids and other agents that have demonstrated efficacy in some of the diseases for which we may attempt to develop NS2; 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 New Drug Application (NDA) to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market NS2, 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 NS2 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, NS2, 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 completing our product design and formulation and our clinical trial programs;

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.

Table of Contents

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 scientific rationale for our Sjögren-Larsson Syndrome clinical program does not necessarily predict the clinical success of NS2.

Sjögren-Larsson Syndrome (SLS) is a rare disease afflicting an estimated 1 in 250,000 people worldwide, equivalent to approximately 1,000 patients in the United States and a larger number in Europe. SLS is caused by genetic mutations in an enzyme, Fatty Aldehyde Dehydrogenase (FALDH) that converts long-chain aldehydes into fatty acids. In addition to manifesting what is believed to be severe aldehyde toxicity, SLS patients also have elevated levels of fatty alcohols and may manifest diminished levels of fatty acids.

The dermal pathology of SLS is thought to be due to aldehyde-mediated damage of lipids (fats) that contribute to the formation of the dermal moisture barrier. As a result, SLS patients are thought to lose water from skin, leading to compensatory mechanisms that include proliferation of the superficial layers of skin that may be only partially effective in preventing water loss. Increased levels of skin proliferation in SLS patients lead to ichthyosis, a severe skin disorder characterized by plaques and scales, thickening, dryness, redness, inflammation and pruritus (itching).

NS2 traps aldehydes and has been shown to prevent fatty aldehyde-mediated modification of lipids *in vitro*, in human skin cells and in cells that have been genetically modified to lack FALDH. Thus, NS2 may be partially or wholly effective in preventing and treating ichthyosis or other dermal symptoms, signs, or pathologies in SLS. However, the proposed mechanism of action of NS2 in SLS has not been demonstrated in humans. Further, our assumptions about the pathogenesis of skin disease in SLS patients may not be accurate. For instance, SLS skin disease may be caused by elevated fatty alcohol levels or decreased fatty acid levels, neither of which NS2 is predicted to affect directly.

In addition, the presumed mechanisms of aldehyde-mediated inflammation are distinct from the presumed aldehyde-mediated pathology in SLS, and the outcome of clinical trials of NS2 in SLS is unlikely to predict the outcome of clinical trials with NS2 in inflammatory diseases.

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 NS2, 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, 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 future 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.

Table of Contents

Because NS2 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. NS2 administered as an eye drop has completed a Phase I clinical trial in healthy volunteers. NS2 has not been administered to humans by any other route. Further, NS2 has not demonstrated efficacy in humans for any disease. Because NS2 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 NS2 can be more expensive and take longer than approval for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates.

Aldehyde trapping is an unproven approach, the safety and efficacy of which has not been demonstrated in humans.

Aldehydes are thought to be mediators of inflammation and other pathology. However, we are aware of only a limited number of attempts to lower aldehyde levels and modulate disease in animals or humans. Thus, there is only moderate justification for the approach of lowering aldehyde levels to treat disease. Despite evidence suggestive of benefit in animal models, clinical trials may indicate that aldehyde trapping has no effect or negative effects on the diseases we intend to test. Animal studies may not predict safety or efficacy in humans.

Our dermatologic topical formulation of NS2 is unlikely to affect other clinical manifestations of SLS, 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 mental delay, spasticity, seizures and retinal disease. Due to expected low systemic exposure of NS2 when administered topically to the skin, it is unlikely that NS2 will 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 NS2.

The FDA or other regulatory agencies may prohibit us from initiating clinical trials that are necessary for demonstrating drug safety and efficacy in patients.

NS2 and the activities associated with its development and potential commercialization, including its testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other jurisdictions.

We are not permitted to test a drug under a new IND in the United States until the FDA has no objection to the initial IND submission. To date, we have completed one Phase I clinical trial for NS2 administered as an eye drop in healthy volunteers. In 2014, we filed two IND applications to initiate a Phase II clinical trial in SLS and a Phase II trial in noninfectious anterior uveitis. We will have to submit separate INDs for each additional indication that we intend to study, which could mean additional delays in the commencement of each of the related trials and the performance of additional preclinical studies. We have not demonstrated efficacy of NS2 in any patient population.

There is no guarantee that future trials will be allowed by the FDA to proceed or generate successful results, or that regulators will agree with our assessment of the clinical trials for NS2. In addition, we expect to rely on consultants and third party contract research organizations to assist us with regulatory filings and the conduct of our clinical trials. The FDA and other regulators have substantial discretion and may refuse to accept any application or may decide that our current data is insufficient for clinical trial initiation and require additional clinical trials, or preclinical or other studies.

Table of Contents

NS2 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.

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;
- 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;
- 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.

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

Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing to the FDA as part of an IND application, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial

Table of Contents

protocol. We may rely in part on preclinical, clinical, and quality data generated by contract research organization (CROs) and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates, it will delay our clinical development. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND for future clinical trials, which may lead to additional delays and increase the costs of our preclinical and clinical development. Delays in the commencement or completion of our planned clinical trials for NS2 or other product candidates could significantly affect our product development costs. We do not know whether future trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed or placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing NS2 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 NS2, 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;
- 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 NS2 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

Table of Contents

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 NS2 or other product candidates could be significantly reduced.

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. NS2, for example, has been observed to be toxic at high concentrations in *in vitro* human dermal tissue. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product candidate.

Final marketing approval for NS2 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 NS2 or our other product candidates and we cannot, therefore, predict the timing of any future revenue. We cannot commercialize NS2 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 NS2 or 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 NS2 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 NS2 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 NS2 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 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

Table of Contents

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 NS2 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 NS2 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 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 NS2 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;

Table of Contents

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.

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 NS2 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.

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. 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.

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

Table of Contents

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.

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 from the FDA may be difficult or not possible to obtain, and if we are unable to obtain orphan drug designation for NS2 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 NS2 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 NS2. If we are unable to secure orphan drug status for NS2 or our other product candidates, our regulatory and commercial prospects may be negatively impacted.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of NS2 and our other product candidates.

As of December 31, 2014, we had only six 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 NS2 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

Table of Contents

parties and may occur on substantially different timing from our estimates. Specifically, we use CROs to conduct our clinical trials and rely on medical institutions, clinical investigators, CROs, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that 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

Table of Contents

in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We and our contract manufacturers must comply with the 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;

Table of Contents

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.

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 NS2 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 NS2 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, 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 NS2 or our other product candidates. Noninfectious anterior uveitis and other inflammatory diseases may be treated with general immune suppressing therapies, including corticosteriods,

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 NS2 or our other product candidates.

Table of Contents

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 NS2 or any of our other product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We will have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that NS2 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 NS2 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; Scott L. Young, our Chief Operating Officer; Stephen J. Tulipano, our Chief Financial Officer; as well as our Directors of Clinical Affairs and our Director of Chemistry, Manufacturing and Controls. In addition we rely on the services of a number of key consultants, including IP consultants, pharmacokinetic consultants, chemistry consultants, toxicology consultants, dermatologic drug development consultants 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 we currently have only six full-time employees, we will need to grow our organization to continue development and pursue the potential commercialization of NS2 and our other product candidates, as well as

Table of Contents

function as a public company. As we seek to advance NS2 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 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, or 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 Health Care Reform Law, 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 Health Care Reform Law revised the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, beginning in 2011, the Health Care Reform Law 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 Health Care Reform Law 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.

36

Table of Contents

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.

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.

Table of Contents

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of NS2 or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of NS2 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 NS2 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 NS2 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 NS2 or our other product candidates; and

a decline in our stock price.

We maintain product liability insurance with $2.0 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 NS2 or our other product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in

whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

We and our development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our development partner, third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or

Table of Contents

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 would 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. 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, 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

Table of Contents

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 NS2 and our other product candidates. Our ability to obtain clinical supplies of NS2 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 operate without infringing upon the proprietary rights of others. There can be no assurance that our patent

Table of Contents

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 NS2, 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.

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

Table of Contents

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 NS2 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 NS2 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 NS2 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 NS2 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 NS2 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 Square 1 Bank. In the case of a continuing event of default under the loan, Square 1 Bank could,

among other remedies, elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Square 1 Bank under the loan.

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

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading

Table of Contents

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 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 a technology license that is important to our business and we may enter into additional licenses in the future. We currently hold a license from Ligand Pharmaceuticals Incorporated that covers use of an excipient in our eye drops. This license imposes various 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 would lose valuable rights under our collaboration agreements and our ability to develop product candidates.

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 NS2 or other product candidates, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be

Table of Contents

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. The USPTO has determined that our applications to register ALDEYRA THERAPEUTICS and our logo are allowable, and we expect the registration certificates to issue in due course. 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 NS2 in the United States and other countries, filing, prosecuting and defending patents on NS2 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 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

Table of Contents

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 NS2 and our other product candidates.

We will require substantial future capital in order to complete the remaining clinical development for NS2 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 NS2, 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 NS2 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 NS2 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 NS2 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 NS2 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. 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. 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 NS2 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.

Table of Contents

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 had a $5.0 million Credit Facility with Square 1 Bank (Square 1) that is secured by a lien covering all of our assets as of December 31, 2014. As of December 31, 2014 and December 31, 2013, the outstanding principal balance under the Credit Facility was approximately $1.4 million. The term loans under the Credit Facility are to be made available to us upon the following terms: (i) $2,000,000 was made available on November 10, 2014; and (ii) $3,000,000 (the Tranche B Loan) is to be made available to us following the satisfaction of certain conditions, including receipt of positive phase 2 data in either SLS or noninfectious anterior uveitis However, we can provide no assurances that we will satisfy the conditions for the Tranche B Loan. 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 and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of our Initial Public Offering.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We believe that, as a result of our Initial Public Offering, our preferred stock financings and other transactions, we have experienced an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2014, we had federal and state net operating loss carryforwards of approximately $16.2 million and $13.4 million, respectively, and federal and state research and development credits of approximately $392,000 and $45,000, respectively, which could be limited if we experience an ownership change. Any such limitations would generally be equal to our equity value at the time of the ownership change multiplied by a risk-free rate of return published monthly by the IRS.

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.

Table of Contents

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. 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.

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 NS2 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.

Table of Contents

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.

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.

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

Our management will have 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 NS2, 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, 2014, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 84.0% of our outstanding common stock. As a result, such persons, acting

Table of Contents

together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. 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 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 Square 1 Bank 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.

Table of Contents

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 for up to five years, 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.

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

Table of Contents

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.

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. We have previously identified a material weakness (as defined under the Exchange Act definition of internal controls over financial reporting) in the design and operation of our internal controls over financial reporting for non-routine complex transactions, stock-based compensation transactions, and the disclosure requirements relating to these transactions. Under the Exchange Act, a material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company s annual or interim financial statements will not be prevented or detected on a timely basis by the company s internal controls. Specifically, as neither of our employees at the time were accountants or had served as corporate financial or accounting officers, our internal controls over the accounting and financial reporting of non-routine complex transactions and stock-based compensation transactions did not meet all standards applicable to companies with publicly traded securities.

We have since hired a full time chief financial officer, have implemented the process of formally documenting, reviewing, and improving our internal controls over financial reporting and have made efforts to improve our internal controls and accounting policies and procedures and believe that as of December 31, 2014

Table of Contents

that we have remediated the material weakness. 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.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

Our offices are located in Lexington, Massachusetts, consisting of approximately 3,700 square feet of office space. Our lease for this facility expires in 2017. Management believes that the leased facilities are 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.

52

Table of Contents

PART II

ITEM 5. *MARKET FOR REGISTRANT S COMMON EQUITY, RELATED SHAREHOLDER 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, 2014	High	Low
Second quarter 2014 (from May 1, 2014)	$ 8.22	$ 6.00
Third quarter 2014	$ 7.63	$ 3.00
Fourth quarter 2014	$ 11.99	$ 5.39

Holders of Record

As of December 31, 2014 there were 10 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.

Use of Proceeds from Public Offering of Common Stock

On May 7, 2014, we closed our Initial Public Offering of 1,500,000 shares of common stock at a public offering price of $8.00 per share. The aggregate offering price for shares sold in the offering was approximately $12.0 million. The offer and sale of all of the shares in the Initial Public Offering were registered under the Securities Act of 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 remainder of the information required by this item regarding the use of our Initial Public Offering proceeds has been omitted pursuant to SEC rules because such information has not changed since our last periodic report was filed.

ITEM 6. *SELECTED FINANCIAL DATA*

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

Table of Contents

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 Information 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 products to treat immune-mediated, inflammatory, orphan, and other diseases that are related to free aldehydes, a naturally occurring toxic chemical species. We discovered and are developing NS2, a novel product candidate that is designed to trap and allow for the disposal of free aldehydes, for the treatment of Sjögren-Larsson Syndrome (SLS), a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes, and noninfectious anterior uveitis, an inflammatory eye disease. NS2 has been tested in a variety of in vitro and preclinical models, and has demonstrated efficacy in trapping free aldehydes, diminishing inflammation, reducing healing time, protecting key cellular constituents from aldehyde damage, and lowering the potential for scarring or fibrosis. NS2 has completed a variety of toxicity studies in animals and appears generally safe and well-tolerated. We are also in the early stages of developing aldehyde traps different from NS2 that have the potential to treat diseases other than those described above.

We have evaluated NS2 in a Phase I clinical trial in 48 healthy volunteers where NS2 was observed to be safe and well tolerated when administered as an eye drop up to four times per day over seven days. In 2014, we filed two Investigational New Drug (IND) applications to initiate a Phase II clinical trial in SLS and a Phase II trial in noninfectious anterior uveitis. Data from all of these clinical trials are currently expected to be available in the second half of 2015.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. 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 May 2014, we closed our initial public offering (Initial Public Offering) whereby we received net proceeds of approximately $10.1 million, after underwriter discounts, expenses and commissions, through the sale of 1,500,000 shares of our common stock at $8.00 per share.

In January 2015, we sold an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share in a private placement. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. In a subsequent private placement in January 2015, 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. We received net proceeds of approximately $9.1 million, after placement agent fees and expenses from these two private placements.

We will need to raise additional capital in the form of debt or equity to fund additional development of NS2 or 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.

54

Table of Contents

Research and development expenses

We expense all 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.

Substantially all of our research and development expenses to date have been incurred in connection with NS2. We expect our research and development expenses to increase for the foreseeable future as we advance NS2 through clinical development, including the conduct of our planned clinical trials. 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 NS2. 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 candidate.

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 NS2 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, 2014 and 2013. 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 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.

Table of Contents

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts, interest expense incurred on our outstanding debt and changes in the fair value of our derivative liabilities. There were no derivative liabilities outstanding as of December 31, 2014.

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 reporting 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 prospectus, 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

Table of Contents

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.

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 a public market for the trading of our common stock and a lack of company specific historical and implied volatility data, 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 past four years. The resulting volatility estimate was 89%, and we have employed this value throughout our calculations. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. 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 2014 and 2013 were as follows:

	December 31, 2014	December 31, 2013
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	$4.99 - $8.00	$10.56 - $11.03
Exercise price	$4.99 - $8.00	$0.552 - $4.56
Expected life (years)	6.00 - 6.25	5.47 - 7.85
Risk free interest rate	1.92% - 2.03%	1.71% - 2.34%

Other Information

Net Operating Loss Carryforwards

As of December 31, 2014 we have Federal and State income tax net operating loss (NOL) carryovers of approximately $16.2 million and $13.4 million, respectively, which will expire at various dates through 2034. As of December 31, 2014 we have Federal and State tax carryovers of credits for increasing research activities (R&D tax credits) of approximately $392,000 and $45,000, respectively, which will expire at various dates through 2034.

Table of Contents

As of December 31, 2013 we had Federal and State income tax NOL carryovers of approximately $10.9 million and $9.8 million, respectively, which will expire at various dates through 2033. As of December 31, 2013 we have Federal and State tax carryovers of R&D tax credits of approximately $233,000 and $25,000, respectively, which will expire at various dates through 2033.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company believes it underwent a change in ownership during 2008, as defined by Internal Revenue Code Section 382, and the net operating losses and research and development credits could be subject to limitation. However, we do not believe any of our NOLs and R&D tax credits are limited by this potential ownership change.

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, *Going Concern* (ASU 2014-15). ASU 2014-15 provides GAAP guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company s ability to continue as a going concern within one year from the date the financial statements are issued. The standard will be effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. Upon adoption the Company will use the guidance in ASU 2014-15 to assess going concern.

Accounting Standards Update (ASU) No. 2014-10 Development Stage Entities (Topic 915); Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities, Guidance in Topic 810, Consolidation (ASU 2014-10). In June 2014, the Financial Accounting Standards Board (FASB) amended its guidance on development stage entities. The amendment removed all incremental financial reporting requirements from GAAP for development stage entities. This guidance is effective for interim and annual periods beginning after December 15, 2014, with early adoption permitted. We adopted this guidance in the quarterly period ended June 30, 2014. Prior to our adoption of this guidance, we were a development stage entity because we devoted substantially all of our efforts to research and development of products to treat diseases for which planned principal operations had not commenced. The adoption of this guidance did not have a material impact on our financial position, results of operations or cash flows other than the removal of inception-to-date information about income statement line items, cash flows, and equity transactions.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). The amendments in ASU 2014-09 provide for a single, principles-based model for revenue recognition that replaces the existing revenue recognition guidance. ASU 2014-09 is effective for annual and interim periods beginning on or after December 15, 2016 and will replace most existing revenue recognition guidance under GAAP when it becomes effective. It permits the use of either a retrospective or cumulative effect transition method and early adoption is not permitted. As we have not generated revenues, we have not yet selected a transition method and is in the process of evaluating the effect this standard will have on our financial statements and related disclosures.

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

Table of Contents

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 related possible regulatory approvals. 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, 2014 and 2013

Net (loss) income attributable to common stockholders. Net (loss) income attributable to common stockholders for the years ended December 31, 2014 and 2013 was approximately $(9.6) million and $1.1 million, respectively. As of December 31, 2014, we had total stockholders equity of $6.3 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses.

Research and development expenses. Research and development expenses were $3.7 million for the year ended December 31, 2014 compared to $1.5 million for the same period in 2013. The increase of $2.2 million is primarily related to the increase in our external research and development expenditures, including preclinical, manufacturing and clinical efforts and an increase in personnel costs associated with an increase in headcount.

General and administrative expenses. General and administrative expenses were $3.6 million for the year ended December 31, 2014, compared to $2.1 million for the year ended 2013. The increase of $1.5 million is primarily related to an increase in insurance costs, legal costs and personnel costs due to increased headcount.

Other income (expense). Total other income (expense) was $2.1 million for the year ended December 31, 2014 and consisted of the change in fair market value of preferred stock warrant liabilities. Total other income (expense) was $16.7 million for the same period in 2013 and primarily consisted of the change in fair market value of warrants to purchase preferred stock warrant liabilities, convertible preferred stock rights and rights option liabilities, which were converted to common stock in connection with our Initial Public Offering.

Upon our Initial Public Offering in May 2014, all redeemable convertible preferred stock was converted into common stock and the derivative warrant liabilities reflected on our balance sheet at December 31, 2013 were net exercised and converted into common stock.

Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and convertible equity securities and borrowings under our loan and security agreement. 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, 2014, we had total stockholders equity of approximately $6.3 million and cash and cash equivalents of $8.5 million. In addition, we received net proceeds of approximately $9.1 million, after placement agent fees and expenses, from two private placement transactions in January 2015. During the year

Table of Contents

ended December 31, 2014, we had net loss attributable to common stockholders of approximately $9.6 million, which includes non-cash items of a deemed dividend on preferred securities of $4.1 million and the effect of a change in fair value of preferred stock warrant liabilities of approximately $2.3 million. We expect to generate operating losses for the foreseeable future.

In April 2012, we entered into a loan and security agreement (the Credit Facility) with Square 1 Bank (Square 1) with availability in the amount of $500,000 to help fund our operations. The Credit Facility was subsequently amended in November 2013 to provide us with an additional $1.0 million of available funds. We received an advance payment of $1.0 million in November 2013 through a term loan. The amended Credit Facility called for interest only payments at a 6.50% interest rate from November 2013 through November 2014 for all amounts outstanding, inclusive of those amounts originally drawn during 2012 prior to the amendment, at which point, we are required to make principal payments of $58,160 plus interest through the maturity date of the term loans in November 2016. As of December 31, 2013, $1,395,833 was outstanding under the Credit Facility. In November 2014, we amended the Credit Facility. Pursuant to the Credit Facility, Square 1 agreed 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 Square 1, 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 in November 2014; and (ii) $3,000,000 (the Tranche B Loan) is to be made available to us following the satisfaction of certain conditions, including receipt of positive phase 2 data in either Sjögren-Larsson Syndrome (SLS) or noninfectious anterior uveitis. As of December 31, 2014, $1,395,833 was outstanding under the Credit Facility. 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. Any term loan made is payable as interest-only prior to November 2015 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. The Credit Facility is collateralized by our assets, including our intellectual property.

On May 7, 2014, we closed our Initial Public Offering whereby we received net proceeds of approximately $10.1 million, after underwriter discounts, expenses and commissions, through the sale of 1,500,000 shares of our common stock at $8.00 per share.

We believe that our cash and cash equivalents as of December 31, 2014, together with the net proceeds from our January 2015 private placements and amounts available under the Credit Facility, will be adequate to fund operations through approximately the end of 2016. 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 NS2. 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 initiation, progress, costs, results of and timing of our clinical development program for NS2 and our other product candidates, including our planned clinical trials expected to be initiated in 2015 to assess NS2 when administered topically to patients with SLS and noninfectious anterior uveitis;

- the need for, and the progress, costs and results of, any additional clinical trials of NS2 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 NS2;

our ability to satisfy the conditions for the Tranche B Loan;

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 NS2 for clinical trials and other studies and, if approved, for commercial sale;

Table of Contents

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 NS2;

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,	
	2014	2013
Net cash used in operating activities	$ (4,775,994)	$ (1,706,601)
Net cash used in investing activities	(14,062)	
Net cash provided by financing activities	10,055,006	3,745,317
Net increase (decrease) in cash and cash equivalents	$ 5,264,950	$ 2,038,716

Operating Activities. Net cash used in operating activities was $4.8 million in 2014 compared to net cash used in operating activities of $1.7 million in 2013. The primary use of cash was to fund our operations. The increase in the amount of cash used in operating activities for 2014 as compared to 2013 was due to an increase in both research and development and general and administrative expenses.

Investing Activities. Net cash used in investing activities to purchase property and equipment was $14,062 for the year ended December 31, 2014.

Financing Activities. Net cash provided by financing activities was $10.1 million for the year ended December 31, 2014 compared to net cash provided by financing activities of $3.7 million for year ended 2013. The net cash provided by financing activities in 2014 was related to our Initial Public Offering, while the net cash provided by financing activities 2013 was from the net proceeds we received from the issuance of our Series B redeemable convertible preferred stock partially offset by certain payments on our Credit Facility.

Table of Contents

Off-Balance Sheet Arrangements

Through December 31, 2014, 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.

Our long-term debt obligation consists of amounts we are obligated to repay under our Credit Facility with Square 1, of which $1.4 million was outstanding as of December 31, 2014. On November 10, 2014, we amended our Credit Facility with Square 1. Pursuant to the amended Credit Facility, Square 1 agreed 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 Square 1, 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) $3,000,000 is to be made available to us following the satisfaction of certain conditions, including receipt of positive phase 2 data in either SLS or 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. Any term loan we draw is payable as interest-only prior to November 2015 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, 2014:

	Total	Less than 1 Year	Years 1 - 3	Years 3 - 5	More than 5 Years
Credit facility	$ 1,395,833	$ 77,546	$ 930,556	$ 387,731	$
Operating lease obligations	188,000	68,000	120,000		
Total	$ 1,583,833	$ 145,546	$ 1,050,556	$ 387,731	$

In February 2010, we entered into a license and supply agreement providing us with an exclusive license to certain technology and access to purchase materials at certain costs. Under the terms of the license and supply agreement, we are obligated to make milestone payments up to an aggregate of $2.15 million upon reaching certain development and regulatory milestones in the development of the applicable product. Upon commercialization of the product containing the licensed technology, we would be obligated to pay royalties based on net sales subject to an annual cap. The license and supply agreement runs through the 7th anniversary of the expiration of all patents licensed under the agreement, which we estimate to be April 2036, unless terminated earlier. The amounts payable pursuant to this agreement are not included in the table above as the timing of the payments is uncertain.

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. 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 $1.3 million.

Table of Contents

ITEM 7A. ***QUALITATIVE AND QUANTITATIVE 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.

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 85 through 107 of this report 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.

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.

Table of Contents

Management s Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies

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 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

None.

Table of Contents

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Our executive officers and directors, and their ages and positions as of March 15, 2015, are set forth below:

Name	Age	Position(s)
Todd C. Brady, M.D., Ph.D.	43	Chief Executive Officer and Director
Stephen J. Tulipano	55	Chief Financial Officer
Scott L. Young	52	Chief Operating Officer
Ben Bronstein, M.D.	65	Director
C. Boyd Clarke [3]	66	Chairman of the Board
Martin J. Joyce [1, 2]	61	Director
Gary Phillips, M.D. [1, 2]	48	Director
Jesse I. Treu, Ph.D. [3]	67	Director
Neal Walker, D.O. [1]	45	Director

(1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of nominating and governance committee.

Todd C. Brady, M.D., Ph.D. has served as our President and Chief Executive Officer since January of 2012 and as a member of our board of directors since 2005. From April 2013 to December 2013, Dr. Brady also served as Entrepreneur in Residence at Domain Associates, LLC, a leading healthcare venture capital firm, where he was a Principal from November 2004 to March 2013. From 2002 to 2004, Dr. Brady was Senior Director of business development at Aderis Pharmaceuticals, Inc., a late-stage biotechnology company sold to Schwarz Pharma Mfg., Inc. (now UCB, Inc.). From 2001 to 2002, Dr. Brady was Executive Vice President of Corporate Development and Strategy at Xanthus Life Sciences, Inc., an oncology drug development biotechnology company subsequently acquired by Antisoma plc. From 2000 to 2001, Dr. Brady was Chief Executive Officer of Phenome Sciences, which was acquired by Xanthus Life Sciences, Inc. Earlier in his career, Dr. Brady was a Senior Associate at CB Health Ventures, LLC (now Excel Venture Management LLC), a healthcare venture capital fund. Dr. Brady has had broad experience in biotechnology corporate development, and has worked in all facets of drug development from preclinical testing to Phase III and IV clinical trials, including the development of a new chemical entity now marketed for the treatment of Parkinson s Disease. Dr. Brady is a member of the Board of Directors of Evoke Pharma, Inc., a publicly held specialty pharmaceutical company, where he is Chairman of the Nominating and Governance Committee and a member of the Compensation Committee. He is also a member of the Board of Directors of Cantex Pharmaceuticals, Inc., Novadigm Therapeutics, Inc., and Oncobioloigics, Inc., all privately held biotechnology companies. Dr. Brady holds a Ph.D. in pathology from Duke University Graduate School (and serves on the School s Board of Visitors), a M.D. from Duke University Medical School, and an A.B. from Dartmouth College in Philosophy and Psychology. Dr. Brady s extensive knowledge of our business, as well as his years of experience in the biotechnology industry, including executive leadership in several biotechnology companies, contributed to our conclusion that he should serve as a director of our company.

Stephen Tulipano has served as our Chief Financial Officer and Treasurer since June 2014. He has nearly 27 years of accounting and financial experience, of which 14 years were focused on the pharmaceutical industry. Prior to joining Aldeyra, Mr. Tulipano provided accounting and management advisory services with Three Tulips, Inc. from 2011 to

2014. Prior to that, he served as Chief Financial Officer of Javelin Pharmaceuticals from 2006 to 2010 until its acquisition by Hospira. Prior to that, from 1998 to 2006, Mr. Tulipano was at Biogen Idec, Inc. where he served as Director of Corporate Accounting. He has also held several accounting roles both within companies and accounting firms. Mr. Tulipano holds a B.S. in Business Administration and Accounting from Salem State College and an M.B.A. in Finance from the Sawyer School of Management at Suffolk University. He is also a Certified Public Accountant.

Table of Contents

Scott L. Young has served as our Chief Operating Officer since December 2011. Mr. Young has over 25 years of preclinical and clinical experience in both large and small pharmaceutical firms. Prior to joining Aldeyra, Mr. Young was Chief Operating Officer for Link Medicine Corporation, a biotechnology company developing novel pharmaceuticals to treat neurodegenerative diseases including Alzheimer s Disease and Parkinson s Disease, from 2006 to 2011. While at Link Medicine Corporation, Mr. Young and colleagues successfully raised more than $40 million in financing, advanced the lead program to clinical development, and subsequently out-licensed the technology to AstraZeneca UK Limited. Mr. Young was previously Chief Operating Officer of OXiGENE, Inc., a publicly traded oncology therapeutics development company, where from 1999 through 2006 he was instrumental in advancing a pharmaceutical candidate from laboratory testing into Phase III clinical trials and led the development of a compound in an orphan ophthalmology indication. Mr. Young has also held positions in clinical and regulatory affairs, cGMP manufacturing operations, and R&D and process development at Genzyme Corporation, RepliGen Corporation and Genetics Institute, Inc. (now Pfizer, Inc.). He holds a B.S. in biochemistry from the University of Massachusetts, Amherst.

Ben Bronstein, M.D. has served as a member of our board of directors since 2010, and from 2010 to 2011 served as Chief Executive Officer of Aldeyra Therapeutics, then known as Neuron Systems. Dr. Bronstein is a Visiting Scholar at the Wyss Institute of Biologically Inspired Engineering at Harvard Medical School and an active advisor to life science companies. He is a board-certified pathologist and dermatopathologist, with over 20 publications.
Dr. Bronstein began his professional career on the staff of the Massachusetts General Hospital and on the faculty of Harvard Medical School. He has spent the past 25 years in entrepreneurial roles in life science companies and venture capital firms. Dr. Bronstein has founded or held senior management positions at several venture-backed life science firms, including BioSurface Technologies Corporation, a regenerative medicine company; Peptimmune, Inc., an immunotherapeutics company (a spinout from Harvard and MIT); and Vidus Ocular, Inc., a Yale University spinout developing an implantable device for the treatment of glaucoma. Most recently he has served as a founder and senior vice president of Access BridgeGap Ventures, the life science investment unit of Access Industries, Inc. Dr. Bronstein serves on the boards of directors of several privately held life science companies. He is also a member of the Weill Cornell Medical College Faculty Industry Council and the Coulter Oversight Committee at Boston University.
Dr. Bronstein received his M.D. and M.B.A. from Boston University. Dr. Bronstein s extensive knowledge of our business and history, experience as a board member of biotechnology companies and expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies contributed to our conclusion that he should serve as a director of our company.

C. Boyd Clarke has served as chairman of our board of directors since October 2013. Mr. Clarke s original training in the pharmaceutical and vaccine industry was received at Merck and Company, where he held a number of positions including Vice President of the Merck Vaccine Division and the founding President of Pasteur-Merieux MSD, a European joint venture that commercialized vaccines in the European Union. Since leaving Merck in 1996, his career has focused on leading and advising smaller developmental biotechnology and vaccine companies. Mr. Clarke was previously President and Chief Executive Officer of three biotechnology companies: Neose Technologies, a protein therapeutics company; Aviron, a vaccine company; and U.S. Bioscience, an oncology company. MedImmune acquired both Aviron (in 2002) and U.S. Bioscience (in 1999) for a combined value of $2 billion. Mr. Clarke has served as Chairman of the Board of QLT (an ocular company) and Mersana Therapeutics (an oncology company), and as Executive Chairman of LigoCyte Pharmaceuticals (a vaccine company), in which capacity he oversaw the sale of the company to Takeda Pharmaceuticals in 2012. He has also served as a board member or advisor to OraVax (a vaccine company) and Rib-X (an antibiotic company). In these capacities, he has developed significant expertise in the challenges of small company leadership, strategic management, business development and mergers and acquisitions. Currently, he is on the board of Novadigm Therapeutics (a vaccine company). Mr. Clarke s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies, and expertise in developing, financing and providing strong executive leadership to numerous

biopharmaceutical companies contributed to our conclusion that he should serve as a director of our company.

Table of Contents

Martin J. Joyce has served as member of our board of directors since October 2013. Mr. Joyce s professional background includes leadership roles in public and private, medical device, biotechnology and pharmaceutical companies from start-up stage to over $500 million in annual revenue. He has experience in public equity financings, business development, SEC reporting, strategic planning, mergers, acquisitions, investor relations and biotechnology operations. Since 2012, Mr. Joyce has served as a consultant to the life science industry assisting biotechnology and pharmaceutical companies in strategic planning, fund raising and operations. From March 2011 to July 2012, Mr. Joyce was chief financial officer at Lucid Inc., an early stage skin cancer diagnostic company. Previously, Mr. Joyce served as Executive Vice President and Chief Financial Officer of BioSphere Medical from January 2006 through September 2010. He served as BioSphere s Chief Financial Officer and Vice President from September 2004 to January 2006. From January 2001 to September 2004, Mr. Joyce served as Managing Partner of Stratex Group LLC, a provider of biopharmaceutical executive services to early-stage companies and venture investors. From 1996 to January 2001, Mr. Joyce was North American Chief Financial Officer for Serono Inc. a biotechnology company. From April 1987 to 1996, Mr. Joyce held a variety of senior level positions within Serono in finance, sales, marketing and manufacturing. Mr. Joyce was previously employed at Millipore Corporation, a high technology bioscience company. Mr. Joyce received a B.S. in finance from Northeastern University and a M.B.A. from Suffolk University, Boston, Massachusetts. Mr. Joyce s extensive knowledge of our business and history, experience in multiple publicly-traded and privately-held companies, and expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies contributed to our conclusion that he should serve as a director of our company.

Gary Phillips, M.D. has served as Senior Vice President and Chief Strategy Officer at Mallinckrodt Pharmaceuticals plc since October 2013 and has been a member of our Board of Directors since May 2009. Before joining our company, he was President of Reckitt Benckiser Pharmaceuticals, Inc. from 2011 to 2012. He served as President of U.S. Surgical and Pharmaceuticals at Bausch & Lomb Incorporated from 2002 to 2008. Dr. Phillips has also held executive roles at Merck Serono SA (a division of Merck KGaA) from 2008 to 2011, Novartis Corporation from 2000 to 2002, and Wyeth Pharmaceuticals, Inc. (now Pfizer, Inc.) from 1999 to 2000. He was most recently Head of Global Health & Healthcare Industries at the World Economic Forum in Geneva from January 2012 to September 2013. Dr. Phillips was also healthcare strategy managing consultant at Towers Perrin Forster & Crosby, Inc. (now Towers Watson & Co) from 1997 to 1999, and practiced as a general medicine clinician/officer in the US Navy, from which he was honorably discharged as a lieutenant commander. Dr. Phillips was educated at the University of Pennsylvania, where he received an M.D. (Alpha Omega Alpha) from the School of Medicine in 1992, an MBA from the Wharton School in 1991, and B.A. (summa cum laude, Phi Beta Kappa) in biochemistry from the College of Arts and Sciences in 1987. He completed postgraduate medical education at Naval Medical Center San Diego and maintains an active medical license. Dr. Phillip s extensive knowledge of our business and history, and his experience in pharmaceutical strategy at multiple multinational companies, contributed to our conclusion that he should serve as a director of our company.

Jesse I. Treu, Ph.D. has served on our board of directors since June 2013. Dr. Treu has been a Managing Member of Domain Associates, L.L.C. since its inception in 1986. He has been a director of over 35 early-stage healthcare companies. Dr. Treu currently serves as a member of the boards of directors of Afferent Pharmaceuticals, Inc., CoLucid Pharmaceuticals, Inc., Regado Biosciences, Inc., Tandem Diabetes Care, Inc., RightCare Solutions, Inc. and Veracyte, Inc. He has also served as a founder, president and chairman of numerous venture-stage companies. Prior to the formation of Domain Associates, Dr. Treu had twelve years of experience in the healthcare industry. He was Vice President of the predecessor organization to The Wilkerson Group and its venture capital arm, CW Ventures. While at CW Ventures, he served as President and CEO of Microsonics, Inc., a pioneer in computer image processing for cardiology. From 1977 through 1982, Dr. Treu led new product development and marketing planning for immunoassay and histopathology products at Technicon Corporation, which is now part of Siemens Diagnostics. Dr. Treu began his career with General Electric Company in 1973, initially as a research scientist developing thin film

optical sensors for immunoassay testing, and later serving on the corporate staff with responsibility for technology assessment and strategic planning. Dr. Treu received his B.S. in Physics from Rensselaer Polytechnic Institute and his M.A. and Ph.D. in physics

Table of Contents

from Princeton University. Dr. Treu s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies and expertise in developing and financing contributed to our conclusion that he should serve as a director of our company.

Neal Walker, D.O. has served on our board of directors since June 2013. Dr. Walker is the President and Chief Executive Officer at Aclaris Therapeutics, Inc., a privately held dermatological drug development company. He is a board certified dermatologist and serial entrepreneur with over 18 years of experience in the biopharmaceutical industry. Prior to founding Aclaris Therapeutics, Inc. in 2012, he was co-founder, President and CEO of Vicept Therapeutics, Inc. (acquired by Allergan, Inc.) from 2009 to 2012. Dr. Walker has co-founded and led a number of life science companies: Octagon Research Solutions, Inc., a software and services provider to biopharmaceutical companies (acquired by Accenture plc); Trigenesis Therapeutics, Inc., a specialty dermatology company where he served as Chief Medical Officer (acquired by Dr. Reddy s Laboratories Ltd); Cutix Inc., a commercial dermatology company that markets PreSun®, a sunscreen brand acquired from Bristol-Myers Squibb Co. He began his pharmaceutical industry career at Johnson and Johnson, Inc. Dr. Walker currently is on the Board of Directors of Sebacia, Inc and Follica, Inc (Executive Chairman). Dr. Walker previously served on the Board of Directors for Octagon, a contract research organization. He is also on the Advisory Board of Flexible Medical Systems LLC, a privately held medical device company. Dr. Walker received his MBA from The Wharton School, University of Pennsylvania, his D.O. from Philadelphia College of Osteopathic Medicine and a B.A. in Biology from Lehigh University. Dr. Walker s experience as a founder of two private pharmaceutical firms, strong background in clinical and product development in dermatology and other fields, and substantial knowledge of the pharmaceutical industry contributed to our conclusion that he should serve as a director of our company.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our executive officers and directors and persons who own more than 10% of our common stock, file reports of ownership and changes of ownership with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

SEC regulations require us to identify in this annual report anyone who filed a required report late during the most recent fiscal year. Based on our review of forms we received, or written representations from reporting persons, we believe that during fiscal 2014, all Section 16(a) filing requirements were satisfied on a timely basis.

Code of Conduct

Our board of directors adopted a code of 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 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.

Stockholder Recommendations for Nominations to the Board of Directors

Pursuant to our amended and restated bylaws, or nominations or other business to be properly brought before an annual meeting by a stockholder, (1) the stockholder must have given timely notice thereof in writing to our Corporate Secretary, (2) such business must be a proper matter for stockholder action under the Delaware General Corporation

Law, (3) if the stockholder, or the beneficial owner on whose behalf any such proposal or nomination is made, has provided us with a Solicitation Notice, as defined below, such stockholder or beneficial owner must, in the case of a proposal, have delivered prior to the meeting a proxy statement and form of proxy to

Table of Contents

holders of at least the percentage of our voting shares required under applicable law to carry any such proposal, or, in the case of a nomination or nominations, have delivered prior to the meeting a proxy statement and form of proxy to holders of a percentage of our voting shares reasonably believed by such stockholder or beneficial holder to be sufficient to elect the nominee or nominees proposed to be nominated by such stockholder, and must, in either case, have included in such materials the Solicitation Notice and (4) if no Solicitation Notice relating thereto has been timely provided pursuant to this section, the stockholder or beneficial owner proposing such business or nomination must not have solicited a number of proxies sufficient to have required the delivery of such a Solicitation Notice under this section.

To be timely, a stockholder s notice shall be delivered to our Corporate Secretary at our principal executive offices not less than forty-five (45) or more than seventy-five (75) days prior to the first anniversary (the Anniversary) of the date on which we first mailed our proxy materials for the preceding year s annual meeting of stockholders; provided, however, that if no proxy materials were mailed by us in connection with the preceding year s annual meeting, as is the case with our 2015 annual meeting of stockholders, or if the date of the annual meeting is advanced more than thirty (30) days prior to or delayed by more than thirty (30) days after the anniversary of the preceding year s annual meeting, notice by the stockholder to be timely must be so delivered not later than the close of business on the later of (x) the 90th day prior to such annual meeting or (y) the 10th day following the day on which public announcement of the date of such meeting is first made. Such stockholder s notice shall set forth (a) as to each person whom the stockholder proposes to nominate for election or reelection as a director all information relating to such person as would be required to be disclosed in solicitations of proxies for the election of such nominees as directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the Exchange Act), and such person s written consent to serve as a director if elected; (b) as to any other business that the stockholder proposes to bring before the meeting, a brief description of such business, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made; and (c) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (i) the name and address of such stockholder, as they appear on our books, and of such beneficial owner, (ii) the class and number of shares of our Company that are owned beneficially and of record by such stockholder and such beneficial owner, and (iii) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of our voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of our voting shares to elect such nominee or nominees (an affirmative statement of such intent, a Solicitation Notice).

Stockholder Communications with the Board of Directors

Stockholders wishing to communicate with the board of directors or with an individual member of the board of directors may do so by writing to the board of directors or to the particular member of the board of directors, care of the Corporate Secretary by mail to our principal executive offices, Attention: Corporate Secretary. The envelope should indicate that it contains a stockholder communication. All such stockholder communications will be forwarded to the director or directors to whom the communications are addressed.

Board Composition

Our business affairs are managed under the direction of our board of directors, which is currently composed of seven members. Six of our directors are independent within the meaning of the listing rules of The NASDAQ Stock Market (NASDAQ). Our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three

classes as follows:

the Class I directors are Jesse I. Treu, Ph.D. and Ben Bronstein, M.D., and their terms will expire at the annual meeting of stockholders to be held in 2015;

Table of Contents

the Class II directors are Gary Phillips, M.D. and Neal Walker, D.O., and their terms will expire at the annual meeting of stockholders to be held in 2016; and

the Class III directors are Todd C. Brady, M.D., Ph.D., C. Boyd Clarke and Martin J. Joyce, and their terms will expire at the annual meeting of stockholders to be held in 2017.

Directors in a particular class will be elected for three-year terms at the annual meeting of stockholders in the year in which their terms expire. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each director s term continues until the election and qualification of his or her successor, or the earlier of his or her death, resignation or removal. The classification of our board of directors may have the effect of delaying or preventing changes in our control or management.

Director Independence

Our common stock is listed on The NASDAQ Capital Market. The listing rules of this stock exchange generally require that a majority of the members of a listed company s board of directors be independent. In addition, the rules of the NASDAQ require that, subject to specified exceptions, each member of a listed company s audit, compensation, and nominating and corporate governance committees be independent. The NASDAQ director independence definition includes a series of objective tests, such as that the director is not also one of our employees and has not engaged in various types of business dealings with us. In addition, as further required by the NASDAQ rules, our board of directors has made a subjective determination as to each independent director that no relationships exist which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our directors reviewed and discussed information provided by the directors and us with regard to each director s business and personal activities as they may relate to us and our management.

Our board of directors has determined that none of our non-employee directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined under the rules of the NASDAQ. The independent members of our board of directors will hold separate regularly scheduled executive session meetings at which only independent directors are present.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries. Each of Martin J. Joyce, Gary Phillips, M.D. and Neal Walker, D.O. qualify as an independent director pursuant to Rule 10A-3.

Board Leadership Structure

Our board of directors is currently led by its chairman, Mr. Clarke. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for the company and the day-to-day leadership and performance of the company, while the

chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

Table of Contents

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. The composition of these committees meet the criteria for independence under, and the functioning of these committees comply with the applicable requirements of SOX, the current rules of The NASDAQ Capital Market and SEC rules and regulations. We intend to comply with future requirements as they become applicable to us. Each committee has the composition and responsibilities described below.

Audit Committee

During our year ended December 31, 2014, our audit committee held 4 meetings and acted by written consent once. The members of our audit committee are Martin J. Joyce, Gary Phillips, M.D. and Neal Walker, D.O., each of whom is a non-employee member of the board of directors. Mr. Joyce serves as the chair of the audit committee. The audit committee s main function is to oversee our accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. Pursuant to the audit committee charter, the functions of the committee include, among other things:

appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;

overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;

reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;

monitoring our internal control over financial reporting and our disclosure controls and procedures;

meeting independently with our registered public accounting firm and management;

preparing the audit committee report required by SEC rules;

reviewing and approving or ratifying any related person transactions; and

overseeing our risk assessment and risk management policies.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and The NASDAQ Capital Market. Our board of directors has determined that Mr. Joyce is an audit committee financial expert as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable NASDAQ rules and regulations.

Compensation Committee

During our year ended December 31, 2014, our compensation committee held 1 meeting and acted by written consent 3 times. The members of our compensation committee are Gary Phillips, M.D. and Martin J. Joyce. Dr. Phillips serves as the chair of the compensation committee. Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. Pursuant to the compensation committee charter, the functions of this committee include:

evaluating the performance of our chief executive officer and determining the chief executive officer s salary and contingent compensation based on his or her performance and other relevant criteria;

identifying the corporate and individual objectives governing the chief executive officer s compensation;

Table of Contents

- in consultation with the chief executive officer, determining the compensation of our other officers;
- making recommendations to our board of directors with respect to director compensation;
- reviewing and approving the terms of material agreements with our executive officers;
- overseeing and administering our equity incentive plans and employee benefit plans;
- reviewing and approving policies and procedures relating to the perquisites and expense accounts of our executive officers;
- if and as applicable, furnishing the annual compensation committee report required by SEC rules; and
- conducting a review of executive officer succession planning, as necessary, reporting its findings and recommendations to our board of directors, and working with the board of directors in evaluating potential successors to executive officer positions.

Our board of directors has determined that each of Gary Phillips, M.D. and Martin J. Joyce is independent under the applicable rules and regulations of NASDAQ, is a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the United States Internal Revenue Code of 1986, as amended, or Section 162(m).

Our chief executive officer and chief financial officer assist our compensation committee in carrying out its functions, although they do not participate in deliberations or decisions with respect to their own compensation. In January 2015, our compensation committee engaged the services of Pearl Meyer, Inc., a compensation consulting firm, to advise the compensation committee regarding the amount and types of compensation that we provide to our executives and directors and how our compensation practices compared to the compensation practices of other companies. Pearl Meyer reports directly to the compensation committee. Pearl Meyer does not provide any services to us other than the services provided to the compensation committee. The compensation committee believes that Pearl Meyer does not have any conflicts of interest in advising the compensation committee under applicable SEC rules or NASDAQ listing standards.

Nominating and Governance Committee

Our nominating and governance committee was established in connection with our initial public offerings and did not hold any meetings in year ended December 31, 2014. The members of our nominating and governance committee are Jesse Treu, Ph.D. and C. Boyd Clarke. Dr. Treu serves as the chair of the nominating and corporate governance committee. Pursuant to the nominating and corporate governance committee charter, the functions of this committee include, among other things:

identifying, evaluating, and making recommendations to our board of directors and our stockholders concerning nominees for election to our board of directors, to each of its committees and committee chairs;

annually reviewing the performance and effectiveness of our board of directors and developing and overseeing a performance evaluation process;

annually evaluating the performance of management, the board of directors and each board committee against their duties and responsibilities relating to corporate governance;

annually evaluating adequacy of our corporate governance structure, policies, and procedures; and

providing reports to our board of directors regarding the committee s nominations for election to the board of directors and its committees.

Table of Contents

Meetings of the Board of Directors

The full board of directors met 4 times during our year ended December 31, 2014. No director attended fewer than 75% of the total number of meetings of the board of directors and of any committees of the board of directors of which he or she was a member during our year ended December 31, 2014.

It is our policy that directors are invited and encouraged to attend our annual meetings of stockholders. We expect to schedule our annual meetings on the same day as a regularly scheduled board of directors meeting in order to facilitate attendance by the members of our board of directors.

Director Compensation

The following table sets forth information about the compensation of the non-employee members of our board of directors who served as a director during our year ended December 31, 2014. Other than as set forth in the table and described more fully below, during our year ended December 31, 2014, we did not pay any fees to, make any equity awards or non-equity awards to or pay any other compensation to the non-employee members of our board of directors. Dr. Brady, our chief executive officer, receives no compensation for his service as a director, and is not included in the table below. Mr. Clarke currently serves as chair of our board of directors.

	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)(3)	Total ($)
Ben R. Bronstein, M.D.	$ 13,125	$ 71,791	$ 84,916
C. Boyd Clarke	27,564	107,693	$ 135,257
Martin J. Joyce	20,625	71,791	$ 92,416
Gary Phillips, M.D.	19,689	71,791	$ 91,480
Jesse I. Treu, Ph.D.	15,750(4)	71,791	$ 87,541
Neal S. Walker, D.O.	15,939	71,791	$ 87,730

(1) The amounts in this column represent the aggregate grant date fair value of option awards granted to the director during our fiscal year ended December 31, 2014, computed in accordance with FASB ASC Topic 718. See Note 9 to our financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion of our assumptions in determining the ASC 718 values of our option awards. Amount consists of: (a) $71,791 with respect to the options granted to Drs. Bronstein, Philips, Treu and Walker and Mr. Joyce on May 7, 2014, and (b) $107,693 with respect to the option granted to Mr. Clarke on May 7, 2014.

(2) As of December 31, 2014, our non-employee directors held outstanding stock options as follows: Drs. Bronstein and Walker, 21,770 options; Mr. Clarke, 18,250 options; Mr. Joyce and Dr. Treu, 12,166 options; and Dr. Phillips, 21,769 options.

(3) On May 7, 2014, each of our directors (other than Mr. Clarke) was granted an option to purchase 12,166 shares of our common stock, and as non-employee chair of our board of directors, Mr. Clarke was granted an option to purchase 18,250 shares of our common stock, in each case at an execise price per share of $8.00. All of these options granted were made pursuant to our non-employee director compensation program.

(4) Approximately $10,500 of these fees were paid to the management company of the venture capital fund affiliated with Dr. Treu in 2014.

Non-Employee Director Compensation

Each member of our board of directors who is not our employee will receive the following cash compensation for board services, as applicable

$17,500 per year for service as member of the board of directors.

$17,500 per year for service as chairman of the board of directors.

Table of Contents

$7,500 per year for service as chairman of the Audit Committee;

$5,000 per year for service as chairman of the Compensation Committee;

$3,500 per year for service as chairman of the Nominating and Corporate Governance Committee;

$3,750 per year for service as non-chairman member of the Audit Committee;

$2,500 per year for service as non-chairman member of the Compensation Committee; and

$1,750 per year for service as non-chairman member of the Nominating and Corporate Governance Committee.

Non-employee members of our board of directors will also receive automatic grants of non-statutory stock options under our 2013 Equity Incentive Plan. For purposes of our automatic director grant program, a non-employee director is a director who is not employed by us and who does not receive compensation from us or have a business relationship with us that would require disclosure under certain Securities and Exchange Commission rules. Each non-employee director joining our board of directors will automatically be granted a non-statutory stock option to purchase 12,166 shares of common stock with an exercise price equal to the fair market value of our common stock on the grant date. This initial option will vest ratably in annual installments over 3 years of service following the date of grant.

In addition, on the date of each annual meeting of our stockholders, each non-employee director will automatically be granted a non-statutory stock option to purchase 6,083 shares of our common stock on that date with an exercise price equal to the fair market value of our common stock on the grant date. A non-employee director who receives an initial award will not receive the additional annual award in the same calendar year. Automatic annual grants vest in full on the one-year anniversary of the grant date.

If we are subject to a change in control, then all of the director s automatic grants will become fully vested. All automatic director options have a maximum term of ten years.

We will also reimburse our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

ITEM 11. ***EXECUTIVE COMPENSATION***

Summary Compensation Table

The following table provides information concerning the compensation paid to our Chief Executive Officer and our next two most highly compensated executive officers for our year ended December 31, 2014. We refer to these individuals as our named executive officers.

Name and Principal Position	Year	Salary ($)(1)	Stock Awards ($)(2)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Todd C. Brady, M.D., Ph. D.	2014	$ 377,500	$	$ 454,871	234,000(3)	9,013	$ 1,075,384
President and Chief Executive Officer	2013	70,833	136,732	3,480,256			3,687,821
Stephen J. Tulipano	2014	135,000(5)		246,994	44,898(3)		426,892
Chief Financial Officer							
Scott L. Young	2014	322,679			132,300(3)		454,979
Chief Operating Officer	2013	300,000		1,240,727		30,410	1,571,137

Table of Contents

(1) The salary amount represents the salary earned from January 1 through December 31 of the applicable year.
(2) Reflects the aggregate grant date fair value of stock awards and option awards granted during the applicable year calculated in accordance with FASB ASC Topic 718. For a discussion of valuation assumptions, see Note 9 to our audited consolidated financial statements included in this Annual Report on Form 10-K. In accordance with SEC rules, the grant date fair value of an award subject to performance conditions is based on the probable outcome of the conditions.
(3) Represents amounts paid under our 2014 management cash incentive plan paid in 2015.
(4) Represents $16,640 in relocation expenses and $8,872 in reimbursement of healthcare premiums.
(5) Officer s employment with us commenced on June 23, 2014. The amount reported represents the pro rata portion of the officer s salary from commencement of employment through December 31, 2014.

Narrative Explanation of Certain Aspects of the Summary Compensation Table

Employment Letters

In November 2013, we entered into a letter agreement with Dr. Brady that became effective upon our initial public offering in May 2014. We and Dr. Brady amended such letter agreement in February 2014. Pursuant to such amended letter, Dr. Brady s annual base salary was increased from $340,000 to $400,000 and his cash bonus opportunity for each of our fiscal years increased from 30% to 45% of his base salary.

In June 2014, we entered into a letter agreement with Mr. Tulipano in connection with the commencement of his employment. Mr. Tulipano s offer letter provides for an initial base salary of $260,000 per year, a cash bonus opportunity for each of our fiscal years of 30% of his base salary, a stock option grant of 67,642 shares of our common stock pursuant to the terms and conditions of our 2013 Equity Plan which will vest over four years of employment with us, and other employee benefit plans and programs.

In November 2013, we entered into a letter agreement with Mr. Young that became effective upon our initial public offering in May 2014. We and Mr. Young amended such letter agreement in February 2014. Pursuant to such amended letter, Mr. Young s annual base salary was increased from $300,000 to $315,000 and his cash bonus opportunity for each of our fiscal years increased from 25% to 35% of his base salary.

Except as described below under Severance and Change in Control Benefits, each of our named executive officers must remain employed with us through the date of payment to receive a bonus.

Each of our named executive officers is eligible to receive certain benefits in the event of a change in control or if his employment is terminated under certain circumstances, as described under Severance and Change in Control Benefits below.

Equity Compensation

We offer stock options and restricted shares to our named executive officers as the long-term incentive component of our compensation program. We typically grant equity awards to new hires upon their commencing employment with us. Stock options allow employees to purchase shares of our common stock at a price per share equal to the fair market value of our common stock on the date of grant and may or may not be intended to qualify as incentive stock options for United States federal income tax purposes. Generally, the equity awards we grant vest in equal monthly installments over 48 months, subject to the employee s continued employment with us on the vesting date.

In 2014, Dr. Brady was granted an option to purchase shares of common stock effective as of our initial public offering and Mr. Tulipano was granted an option to purchase shares of common stock pursuant to his offer letter in

connection with the commencement of his employment. The table below provides details regarding the foregoing grants.

Name	Grant Date	Number of Shares Underlying Option Grants	Exercise Price ($)
Todd C. Brady, M.D., Ph.D.	5/7/14	76,068(1)	8.00
Stephen J. Tulipano	7/21/14	67,642(2)	4.99

Table of Contents

(1) Option vests in equal quarterly installments over four years of service following May 7, 2014 provided Dr. Brady provides continuous service to us through each such vesting date.
(2) Option vests with respect to 25% of the shares on June 23, 2015, with the balance vesting in equal monthly installments over the next 36 months provided Mr. Tulipano provides continuous service to Aldeyra through each such vesting date.

As discussed below under Severance and Change in Control Benefits, stock options granted to our named executive officers are generally subject to accelerated vesting in the event such officer is subject to an involuntary termination or if we experience a change in control.

Outstanding Equity Awards at Fiscal 2014 Year-End

The following tables show certain information regarding outstanding equity awards held by our named executive officers as of December 31, 2014.

Except as indicated in the footnotes below, options granted to our named executive officers are generally immediately exercisable with respect to all of the option shares (whether vested or unvested), subject to our repurchase right in the event that the executive s service terminates before vesting in such shares. For information regarding the vesting acceleration provisions applicable to the options held by our named executive officers, please see Severance and Change in Control Benefits below.

		Option Awards				
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Vested	Number of Securities Underlying Unexercised Options (#) Unvested	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Todd C. Brady	9/8/2013	80,035(1)	112,049		0.552	9/7/2023
	9/8/2013	32,953(2)			0.552	9/7/2023
	9/8/2013	16,007(3)		32,014	0.552	9/7/2023
	10/30/2013	24,010(4)	72,032		4.56	10/29/2023
	5/7/2014	0(5)	76,068		8.00	5/6/2024
Scott L. Young	6/22/2012	20,923(6)	7,772		3.24	6/21/2022
	9/8/2013	40,017(1)	56,025		0.552	9/7/2023
	9/8/2013	16,007(3)		32,014	0.552	9/7/2023
Stephen J. Tulipano	7/21/2014	0(7)	67,642		4.99	7/20/2024

(1) Option vests over four years of service following April 15, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.
(2) Option vested in equal monthly installments over six months of service following April 1, 2013.
(3)

16,007 of the shares vested upon the effective date of our initial public offering and 16,007 of the shares vest upon the date on which our closing market capitalization equaled at least $55.0 million for 10 consecutive trading days. The remaining shares vest on the date on which our closing market capitalization equals at least $70.0 million for 10 consecutive trading days, provided that the officer remains in continuous service with us through such date.

(4) Option vests in equal quarterly installments over four years of service following October 30, 2013.

(5) Option vests in equal annual installments over four years of service following May 7, 2014.

(6) Option vests over four years of service following January 1, 2012, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.

(7) Option vests with respect to 25% of the shares after 12 months of continuous service with us following June 23, 2014, with the balance becoming exercisable in equal monthly installments over the next 36 months of continuous service provided thereafter.

Table of Contents

Severance and Change in Control Benefits

Pursuant to their letter agreements and offer letters, if we terminate the employment of any of our named executive without cause or if such executive resigns for good reason, then he will be eligible to receive:

- continued payment of base salary for 12 months (9 months in the case of Mr. Tulipano);
- a lump-sum cash payment equal to the greater of such executive s target bonus for the year in which such termination occurs or the actual bonus paid to the executive with respect to our most recently completed fiscal year;
- payment by us of the monthly premiums under COBRA for such executive and their eligible dependents for up to 12 months (9 months in the case of Mr. Tulipano) following the termination of such executive s employment; and
- In the case of Dr. Brady and Mr. Young, accelerated vesting and exercisability with respect to all equity or equity-based awards held by such executive officer as if such executive officer has completed an additional 12 months of service with us, and up to 12 months following such termination to exercise any then-outstanding stock options or stock appreciation rights.

Such payments are contingent on the officer s executing and not revoking a release of claims against us.

Cause means an officer s:

- unauthorized use or disclosure of our confidential information or trade secrets;
- material breach of any agreement with us;
- material failure to comply with our written policies or rules;
- conviction of, or plea of guilty or no contest to, a felony;
- gross negligence or willful misconduct;
- continuing failure to perform assigned duties after receiving written notification of such failure from our board of directors; or

failure to cooperate in good faith with a governmental or internal investigation of us or our directors, officers or employees if such cooperation has been requested.

Good Reason means a resignation within 12 months after one of the following conditions has come into existence with the officer s consent, but only if such officer has provided us with written notice of such condition within 90 days after it has come into existence and we have failed to cure such condition within 30 days after we receive such notice:

a reduction in such executive officer s base salary or target bonus by more than 10%;

a material reduction of such executive officer s authority, duties or responsibilities; or

a relocation of such executive officer s principal workplace by more than 50 miles.

In addition, in the event that we are subject to a change in control, all of the equity or equity-based awards granted to each of Dr. Brady and Mr. Young will become fully vested and exercisable other than the option to purchase 28,695 shares granted to Mr. Young in 2012, which will so accelerate only upon his involuntary termination within 12 months of such change in control. A change in control means the consummation of a transaction in which any person acquires 50% or more of our voting stock; a sale of all or substantially all of our assets; our merger or consolidation; or replacement of a majority the members of our board of directors.

The option granted to Mr. Tulipano in July 2014 will become fully vested and exercisable if he is subject to a termination without cause by us or voluntarily resigns for good reason, in each case as defined above, within

Table of Contents

12 months after our change in control. A change in control means the consummation of a transaction in which any person acquires 60% or more of our voting stock; a sale of all or substantially all of our assets; our merger or consolidation; or replacement of a majority the members of our board of directors.

Employee Benefits and Perquisites

Our named executive officers will be eligible to participate in our health and welfare plans to the same extent as all full-time employees. We do not provide our named executive officers with perquisites or other personal benefits other than reimbursement of certain healthcare premiums, as described in the Summary Compensation Table.

Director Compensation

See Item 10, Directors, Executive Officers and Corporate Governance for information regarding director compensation.

Board Oversight of Risk

Our board of directors has responsibility for the oversight of the company s risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand the company s risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating/corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is or has in the past served as an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Compensation Committee Report

The information contained in the following report of Aldeyra s compensation committee is not considered to be soliciting material, filed or incorporated by reference in any past or future filing by us under the Securities Exchange Act of 1934 or the Securities Act of 1933 unless and only to the extent that Aldeyra specifically incorporates

it by reference.

The compensation committee has reviewed and discussed the section captioned Executive Compensation, included in this annual report, with management and, based on such review and discussion, the compensation

Table of Contents

committee has recommended to our board of directors that this Executive Compensation section be included in our annual report on Form 10-K.

Submitted by the compensation committee of the board of directors:

Gary Phillips, M.D. (Chair)

Martin J. Joyce

ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 15, 2015 for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each stockholder known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock based on currently available Schedules 13D and 13G filed with the SEC.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 6,890,024 shares of common stock outstanding at March 15, 2015. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable or releasable within 60 days of March 15, 2015. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Aldeyra Therapeutics, Inc., 131 Hartwell Avenue, Suite 320, Lexington, Massachusetts 02421.

Name and Address of Beneficial Owner	Number of shares beneficially	Percentage of shares beneficially

	owned	owned
5% Stockholders:		
Funds Affiliated with Domain Associates	1,982,597(1)	28.8%
Johnson & Johnson Innovation-JJDC, Inc.	1,750,292(2)	25.4%
FMR LLC	834,811(3)	12.1%
Directors and Named Executive Officers:		
Todd C. Brady, M.D., Ph.D.	209,111(4)	3.0%
Stephen Tulipano	0	*
Scott L. Young	98,944(5)	1.4%
Ben Bronstein, M.D.	20,503(6)	*
C. Boyd Clarke	15,500	*
Martin J. Joyce	13,500	*
Gary Phillips, M.D.	18,071(7)	*
Jesse Treu, Ph.D.	1,982,597(8)	28.8%
Neal Walker, D.O.	13,052(9)	*
All current executive officers and directors as a group (9 persons)	2,371,278(10)	32.9%

Table of Contents

* Less than 1% of the outstanding shares of common stock.

(1) Consists of 10,358 shares of common stock held by Domain Associates LLC, 1,973,389 shares of common stock held by Domain Partners VI, L.P. and 9,208 shares of common stock held by DP VI Associates, L.P. The managing members of One Palmer Square Associates VI, L.L.C., the general partner of Domain Partners VI, L.P. and DP VI Associates, L.P., share voting and investment power with respect to these shares. The managing members of Domain Associates LLC are James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak and Kim Kamdar. Each of James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak and Kim Kamdar share voting and investment power with respect to the securities held by Domain Associates LLC. Each of James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak, and Kim Kamdar disclaims beneficial ownership of the securities held by Domain Associates LLC except to the extent of his or her pecuniary interest therein, if any.

(2) Linda Vogel, Investment Portfolio Manager, of Johnson & Johnson Innovation-JJDC, Inc. (JJDC) exercises voting and dispositive power over the shares held by JJDC. The address of JJDC is: 410 George St., New Brunswick, NJ 08901.

(3) Consists of (a) 556,516 shares held by Fidelity Select Biotechnology Portfolio and (b) 278,295 shares held by Fidelity Advisor Biotechnology Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (Fidelity Funds) advised by Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds Boards of Trustees. The address for Fidelity Select Portfolios: Biotechnology Portfolio is c/o Brown Brothers Harriman & Co., 525 Washington Blvd, Jersey City, NJ 07310. The address for Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund is c/o State Street Bank & Trust, P.O. Box 5756, Boston, MA 02206.

(4) Includes options to purchase 194,022 shares of common stock that may be exercised within 60 days of March 15, 2015.

(5) Includes options to purchase 98,944 shares of common stock that may be exercised within 60 days of March 15, 2015.

(6) Includes options to purchase 8,003 shares of common stock that may be exercised within 60 days of March 15, 2015.

(7) Includes options to purchase 8,696 shares of common stock that may be exercised within 60 days of March 15, 2015.

(8) Includes securities beneficially owned by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC as set forth in footnote 1 above, for which Dr. Treu may be deemed to share voting and investment power. Dr. Treu disclaims beneficial ownership of the securities held by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC except to the extent of his pecuniary interest therein, if any.

(9) Includes options to purchase 6,802 shares of common stock that may be exercised within 60 days of March 15, 2015.

(10)

Includes options to purchase 316,467 shares of common stock that may be exercised within 60 days of March 15, 2015.

Table of Contents

Equity Compensation Plan Information

The following table provides information as of December 31, 2014, 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) and our 2004 Employee, Director and Consultant Stock Plan (2004 Plan).

Plan Category	A Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights	B Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights	C 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	874,032(1)	$ 3.10	360,810(2)
Equity compensation plans not approved by security holders			
Total	874,032	$ 3.10	360,810

(1) Of these shares, 264,190 were subject to options then outstanding under the 2013 Plan, 585,888 were subject to options then outstanding under the 2010 Plan and 23,954 were subject to options then outstanding under the 2004 Plan.

(2) Represents 360,810 shares of common stock available for issuance under our 2013 Plan. No shares are available for future issuance under the 2010 Plan or 2004 Plan. In addition, 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) 2,000,000 shares of our common stock; (2) 4% of the shares of common stock outstanding at that time; and (3) such other amount as our board of directors may determine. On January 1, 2015, an additional 222,617 shares became available for future issuance under our 2013 Plan in accordance with the annual increase.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

In addition to the compensation arrangements with our directors and executive officers described elsewhere in this annual report, the following is a description of each transaction since January 1, 2014 and each currently proposed transaction in which:

we have been or are to be a participant;

the amount involved exceeds or will exceed $120,000; and

any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals (other than tenants or employees), had or will have a direct or indirect material interest.

Amended and Restated Investors Rights Agreement

In connection with the initial closing of the Series B convertible preferred stock financing described above, we entered into an amended and restated investors rights agreement with the holders of all of our outstanding shares of convertible preferred stock, including entities affiliated with Domain Associates, L.L.C and Johnson & Johnson Development Corporation. Pursuant to this agreement, we granted such stockholders certain registration rights with respect to shares of our common stock.

Table of Contents

Convertible Promissory Note

In October 2013, we issued a convertible promissory note to Domain Partners VI, L.P., in a principal amount of $170,000, which was amended in February 2014 to extend its maturity date. The note accrued interest at a rate of 6% per annum. The note converted into 21,250 shares of our common stock in connection with our initial public offering.

Employment Agreements

We have entered into offer letters with our named executive officers. For more information regarding these agreements, see the section of this prospectus entitled Executive Compensation Narrative Disclosure to Compensation Tables.

Indemnification Agreements

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for certain expenses, judgments, fines and settlement amounts, among others, incurred by this person in any action or proceeding arising out of this person s services as a director or executive officer in any capacity with respect to any employee benefit plan or as a director, partner, trustee or agent of another entity at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the section entitled Management Director Compensation and Executive Compensation.

Participation in our Initial Public Offering

Certain of our directors purchased an aggregate of 65,625 shares of our common stock in our initial public offering at the initial public offering price. The following table presents the number of shares issued to these related parties at the initial public offering price of $8.00 per share:

Participants(1)	Shares of Common Stock
Todd C. Brady, M.D., Ph.D.	12,500
Ben Bronstein, M.D.	12,500
C. Boyd Clarke	12,500
Martin J. Joyce	12,500
Gary Phillips, M.D	9,375
Neal Walker, D.O .	6,250

(1) Additional details regarding these stockholders and their equity holdings is provided in Principal Stockholders.

Warrant Conversion Agreement

In December 2012 and August 2013, in connection with our Series B convertible preferred stock financing, we issued warrants to the investors in such financing, including entities affiliated with Domain Associates, L.L.C and Johnson & Johnson Development Corporation, which warrants were immediately exercisable for an

Table of Contents

aggregate of 193,842 shares of our Series B convertible preferred stock, at an exercise price of $5.1588 per share. We entered into an agreement with the warrant holders whereby such holders net exercised the warrants effective upon the consummation of this offering for an aggregate of 68,840 shares of our common stock.

Policies and Procedures for Related Party Transactions

Pursuant to our code of conduct and audit committee charter, any related party transaction or series of transactions with an executive officer, director, or any of such persons immediate family members or affiliates, in which the amount, either individually or in the aggregate, involved exceeds $120,000 must be presented to our audit committee for review, consideration and approval. All of our directors and executive officers are required to report to our audit committee any such related party transaction. In approving or rejecting the proposed transactions, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable, the impact on a director s independence. Our audit committee shall approve only those transactions that, in light of known circumstances, are not inconsistent with Aldeyra s best interests, as our audit committee determines in the good faith exercise of its discretion.

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Information required under this item will be contained in the Company s Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, under the caption Ratification of Selection of Independent Registered Public Accounting Firm and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

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 85. 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.

Table of Contents

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 23, 2015.

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 23, 2015
Todd C. Brady, M.D., Ph.D.	(principal executive officer)	
/s/ Stephen J. Tulipano	Chief Financial Officer	March 23, 2015
Stephen J. Tulipano	(principal financial and accounting officer)	
/s/ C. Boyd Clarke	Chairman of the Board of Directors	March 23, 2015
C. Boyd Clarke		
/s/ Ben Bronstein, M.D.	Director	March 23, 2015
Ben Bronstein, M.D.		
/s/ Martin J. Joyce	Director	March 23, 2015
Martin J. Joyce		
/s/ Gary Phillips, M.D.	Director	March 23, 2015
Gary Phillips, M.D.		
/s/ Jesse Treu, Ph.D.	Director	March 23, 2015
Jesse Treu, Ph.D.		

/s/ Neal Walker, D.O.	Director	March 23, 2015

Neal Walker, D.O.

Table of Contents

ALDEYRA THERAPEUTICS, INC.

INDEX TO FINANCIAL STATEMENTS

		Page
ITEM 1.	Report of Independent Registered Public Accounting Firm	86
	Balance Sheets at December 31, 2014 and 2013	87
	Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2014 and 2013	88
	Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit) for the years ended December 31, 2014 and 2013	89
	Statements of Cash Flows for the years ended December 31, 2014 and 2013	90
	Notes to Financial Statements	91

Table of Contents

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. (formerly known as Aldexa Therapeutics, Inc.) (the Company) as of December 31, 2014 and 2013 and the related statements of operations and comprehensive income (loss), redeemable convertible preferred stock and stockholders equity (deficit), and cash flows for each of the two years in the period ended December 31, 2014. 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 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, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014**,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

March 23, 2015

Table of Contents

ALDEYRA THERAPEUTICS, INC.

BALANCE SHEETS

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,527,304	$ 3,262,354
Prepaid expenses and other current assets	232,568	8,412
Total current assets	8,759,872	3,270,766
Deferred offering costs	14,238	472,467
Fixed assets, net	12,993	
Total assets	$ 8,787,103	$ 3,743,233
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 341,294	$ 341,853
Convertible notes payable related parties		85,000
Accrued interest on convertible notes payable related parties		2,125
Accrued expenses	908,724	117,873
Current portion of credit facility	77,546	58,160
Total current liabilities	1,327,564	605,011
Credit facility, net of current portion and debt discount	1,175,481	1,129,015
Accrued deferred offering costs		394,368
Convertible preferred stock warrant liability		253,247
Convertible preferred stock warrant liabilities related parties		3,265,620
Total liabilities	2,503,045	5,647,261
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock:		
Series A Preferred Stock, $0.001 par value, none authorized, issued and outstanding as of December 31, 2014 and 24,000,000 shares authorized; 980,391 shares issued and outstanding as of December 31, 2013		29,291,865
Series B Preferred Stock, $0.001 par value, none authorized, issued and outstanding as of December 31, 2014 and 38,000,000 shares authorized; 1,316,681 shares issued and outstanding as of December 31, 2013		9,025,433
Total redeemable convertible preferred stock		38,317,298
Stockholders equity (deficit):		

Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding as of December 31, 2014; none authorized, issued or outstanding as of December 31, 2013		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 5,565,415 shares issued and outstanding as of December 31, 2014; 65,000,000 shares authorized; 327,365 shares issued and outstanding as of December 31, 2013	5,565	327
Common stock, non-voting, $0.001 par value; none authorized, issued and outstanding as of December 31, 2014; 65,000,000 authorized, none issued and outstanding as of December 31, 2013		
Additional paid-in capital	52,790,090	1,102,685
Accumulated deficit	(46,511,597)	(41,324,338)
Total stockholders equity (deficit)	6,284,058	(40,221,326)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 8,787,103	$ 3,743,233

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

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Years ended December 31,	
	2014	**2013**
Operating expenses:		
Research and development	$ 3,707,544	$ 1,541,681
General and administrative	3,563,046	2,134,726
Loss from operations	(7,270,590)	(3,676,407)
Other income (expense):		
Change in fair value of preferred stock warrant liabilities	2,327,502	720,785
Change in fair value of convertible preferred stock rights and rights option liabilities		16,175,386
Interest income	3	31
Interest expense	(244,174)	(159,323)
Total other income, net	2,083,331	16,736,879
Net (loss) income and comprehensive (loss) income	(5,187,259)	13,060,472
Accretion of preferred stock	(333,082)	(822,550)
Allocation of undistributed earnings to preferred stockholders		(11,128,012)
Deemed dividend	(4,053,570)	
Net (loss) income attributable to common stockholders	$ (9,573,911)	$ 1,109,910
Net (loss) income per share attributable to common stockholders:		
Basic	$ (2.51)	$ 3.49
Diluted	$ (3.09)	$ (17.61)
Weighted average common shares outstanding:		
Basic	3,818,157	318,429
Diluted	3,850,612	855,508

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

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

Redeemable Convertible Preferred Stock					Stockholders Equity (Deficit)				
Series A Preferred Stock		Series B Preferred Stock		Total Redeemable Convertible Preferred Stock	Common Voting Stock		Additional Paid-in Capital	Accumulated Deficit	S Eq
Shares	Amount	Shares	Amount		Shares	Amount			
980,391	$ 29,063,167	928,995	$ 166,667	$ 29,229,834	314,419	$ 314	$	$ (54,384,810)	$
							1,701,713		
			6,264,914	6,264,914					
		387,686	2,000,000	2,000,000					
							46,388		
					12,946	13	7,134		
228,698		593,852		822,550			(822,550)		
							170,000		

									13,060,472
980,391	29,291,865	1,316,681	9,025,433	38,317,298	327,365	327	1,102,685	(41,324,338)	
							2,037,073		
	78,037		255,045	333,082			(333,082)		
					1,500,000	1,500	9,975,407		
(980,391)	(29,369,902)	(1,316,681)	(9,280,478)	(38,650,380)	3,642,799	3,643	38,646,737		
					74,001	74	1,191,291		
					21,250	21	169,979		
								(5,187,259)	
	$		$	$	5,565,415	$ 5,565	$ 52,790,090	$ (46,511,597)	$

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

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (5,187,259)	$ 13,060,472
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	2,037,073	1,701,713
President and CEO contributed services		46,388
Amortization of debt discount non-cash interest expense	150,852	121,374
Change in fair value of warrant liability, purchase rights and warrant purchase rights	(2,327,502)	(16,896,171)
Depreciation	1,069	
Change in assets and liabilities:		
(Increase) decrease		
Prepaid expenses and other current assets	(224,156)	(5,462)
Accounts payable	(559)	269,315
Accrued interest on convertible notes related parties	(2,125)	2,125
Accrued expenses	776,613	(6,355)
Net cash used in operating activities	(4,775,994)	(1,706,601)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(14,062)	
Net cash used in investing activities	(14,062)	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	10,055,006	
Proceeds from convertible notes payable related parties		170,000
Proceeds from issuance of restricted common stock		7,147
Borrowings under credit facility, net	1,395,833	1,000,000
Repayments of credit facility	(1,395,833)	(104,167)
Cash paid for deferred offering costs		(78,099)
Net proceeds from issuance of Series B redeemable convertible preferred stock		2,750,436
Net cash provided by financing activities	10,055,006	3,745,317
NET INCREASE IN CASH	5,264,950	2,038,716
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,262,354	1,223,638
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 8,527,304	$ 3,262,354
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		

Cash paid during the period for:		
Interest	$ 96,794	$ 34,825
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Accretion of redeemable convertible preferred stock	$ 333,082	$ 822,550
Conversion of notes payable	$ 170,000	$
Conversion of Series A preferred stock upon closing initial public offering	$ 29,369,902	$
Conversion of Series B preferred stock upon closing initial public offering	$ 9,280,478	$
Net exercise of warrants into common stock	$ 1,191,365	$
Allocation of fair value of investor purchase rights to redeemable convertible preferred stock	$	$ 6,264,914
Warrants issued to underwriter in initial public offering	$ 315,388	$
Fair value warrants in connection with credit facility	$	$ 177,952
Offeratory costs in connection with Series B redeemable convertible preferred stock issuance in accrued expenses	$	$ 17,200
Deferred offering costs not yet paid	$ 14,238	$ 394,368
Exercise of Series B warrant purchase rights into warrants	$	$ 1,793,600

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

Table of Contents

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 developing a treatment for diseases related to high levels of free aldehydes, naturally occurring pro-inflammatory toxins. 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 At December 31, 2014, the Company had an accumulated deficit of approximately $46.5 million and cash and cash equivalents of approximately $8.5 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 offering commenced as of May 1, 2014 and did not terminate before all of the securities registered in the registration statement were sold. Aegis Capital Corp. acted as the sole manager of the offering and as representative of the underwriters. The Company raised approximately $10.1 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

Table of Contents

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.

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 $2.0 million in net proceeds in the private placement of common stock and a warrant to purchase common stock.

In addition, as discussed in Note 7, in November 2014, the Company amended its credit facility (the Credit Facility) with Square 1. Square 1 agreed 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 Square 1, 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) $3,000,000 (the Tranche B Loan) is to be made available to the Company following the satisfaction of certain conditions, including receipt of positive phase 2 data in either SLS or 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. Any term loan made is payable as interest-only prior to November 2015 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 funds obtained from the January 2015 private placements and amounts available under the Credit Facility, will provide sufficient funds to enable the Company to meet its obligations through at least the end of 2016. 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.

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, estimating the fair value of the Company s common and preferred stock, preferred stock warrants, purchase rights and warrant purchase rights, 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-

Table of Contents

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 free aldehydes.

Cash and Cash Equivalents The Company considers all investments purchased with an original maturity of three months or less when acquired to be cash equivalents.

Fair Value of Financial Instruments Financial instruments including cash and cash equivalents 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. The fair value of our derivative instruments, including warrants and forms of preferred stock purchase rights, are more fully described in Note 4.

Concentration of Credit Risk The Company s financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. Substantially all of the Company s cash is held at one financial institution that management believes to be of high-credit quality. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits; however, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

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, 2014 and 2013, 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, 2014 and 2013 were $184,517 and $189,965, respectively.

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 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 is recognized ratably 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.

Table of Contents

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) Income Comprehensive (loss) income is defined as the change in equity (deficit) during a period from transactions and other events and/or circumstances from non-owner sources. For all periods presented, comprehensive (loss) income is equal to net (loss) income.

Net (Loss) Income Applicable to Common Stock The Company computes net (loss) income per share in accordance with the two-class method. Under the two-class method, net income is allocated between common stock and other participating securities based on their participation rights. The Company has determined that their outstanding Series A and Series B Preferred Stock represents a participating security and as such the preferred shares are excluded from basic earnings per share. Net losses are not allocated to the preferred stockholders for computing net loss per share under the two-class method because preferred stockholders do not have contractual obligations to share in the losses of the Company. Basic earnings per share is calculated by dividing income allocable to common stockholders (after reduction for preferred stock dividends assuming current income for the period had been distributed) by the weighted average number of common stock outstanding.

Diluted net (loss) income per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method or treasury stock method, as applicable, to the potentially dilutive instruments. The Company allocates net income first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of common shares outstanding gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and restricted stock, warrants, rights to purchase additional shares of preferred stock, rights for warrants to purchase preferred stock and convertible debt.

Recent Accounting Pronouncements In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, Going Concern (ASU 2014-15). ASU 2014-15 provides GAAP guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company s ability to continue as a going concern within one year from the date the financial statements are issued. The standard will be effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. Upon adoption the Company will use the guidance in ASU 2014-15 to assess going concern.

In June 2014, the Financial Accounting Standards Board (FASB) amended its guidance on development stage entities ASU No. 2014-10 *Development Stage Entities (Topic 915); Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities, Guidance in Topic 810, Consolidation* (ASU 2014-10). The amendment removed all incremental financial reporting requirements from GAAP for development stage entities. ASU 2014-10 is effective for interim and annual periods beginning after December 15, 2014, with early adoption permitted. The Company adopted this guidance in the quarterly period ended June 30, 2014. Prior to the Company s adoption of this guidance, the Company was a development stage entity because it devoted substantially all

of its efforts to research and development of products to treat diseases for which planned principal operations have not commenced. The adoption of this guidance did not have a material impact on the Company s financial position, results of operations or cash flows other than the removal of inception-to-date information about income statement line items, cash flows, and equity transactions.

Table of Contents

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). The amendments in ASU 2014-09 provide for a single, principles-based model for revenue recognition that replaces the existing revenue recognition guidance. ASU 2014-09 is effective for annual and interim periods beginning on or after December 15, 2016 and will replace most existing revenue recognition guidance under GAAP when it becomes effective. It permits the use of either a retrospective or cumulative effect transition method and early adoption is not permitted. As the Company has not generated revenues, the Company has not yet selected a transition method and is in the process of evaluating the effect this standard will have on its financial statements and related disclosures.

3. NET (LOSS) INCOME ATTRIBUTABLE TO COMMON STOCKHOLDERS

Net (loss) income attributable to common stockholders

The following table summarizes the computation of basic and diluted net (loss) income per share attributable to common stockholders of the Company:

	Years Ended December 31,	
	2014	2013
Numerator:		
Basic		
Net (loss) income and comprehensive (loss) income	$ (5,187,259)	$ 13,060,472
Accretion of preferred stock	(333,082)	(822,550)
Allocation of undistributed earnings to preferred stockholders		(11,128,012)
Deemed dividend	(4,053,570)	
Net (loss) income attributable to common stockholders basic	$ (9,573,911)	$ 1,109,910
Diluted		
Net (loss) income attributable to common stockholders basic	(9,573,911)	1,109,910
Less: change in fair value of derivative liabilities	(2,327,502)	(16,175,386)
Net (loss) income available to common stockholders diluted	$ (11,901,413)	$ (15,065,476)
Denominator:		
Basic		
Weighted-average number of common shares basic	3,818,157	318,429
Diluted		
Weighted-average number of common shares basic	3,818,157	318,429
Rights (treasury stock)		429,663
Warrants (treasury stock)	32,455	
Warrants purchase rights (treasury stock)		107,416
Total weighted average number of common shares diluted	3,850,612	855,508
Net income (loss) per share:		

Basic	$	(2.51)	$	3.49
Diluted	$	(3.09)	$	(17.61)

For the year ended December 31, 2013, the Company corrected its calculation of weighted average common shares on a diluted basis from what the Company had disclosed previously for the same period which primarily consisted of stock options. The prospective modification resulted in a change to the weighted average number of common shares diluted from 857,183 on a reverse split adjusted basis to 855,508 which had a $(0.03) per share impact.

Table of Contents

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

	Years ended December 31,	
	2014	2013
Options to purchase common stock	180,939	1,675
Warrants to purchase Preferred Stock		83,454
Preferred Stock	1,207,615	2,789,532
Convertible note payable-related parties	7,393	7,053
Total of common stock equivalents	1,395,947	2,881,714

4. FAIR VALUE MEASUREMENTS

As of December 31, 2014 and 2013, the carrying amounts of cash and cash equivalents approximated their estimated fair values because of the short term nature of these financial instruments. The carrying value of the Company s credit facility and convertible notes related parties in current and long-term liabilities approximates fair value because the Company s interest rate yield (which is considered to be a level 2 input) is near current market rates available to the Company.

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.

There were no assets or liabilities measured at fair value at December 31, 2014. Liabilities measured at fair value on a recurring basis as of December 31, 2013 are as follows:

	Level 1	Level 2	Level 3	Total

December 31, 2013:					
Liabilities:					
Preferred Stock Warrant Liability	Series B Preferred Stock	$	$	$ 3,439,059	$ 3,439,059
Preferred Stock Warrant Liability	Series A Preferred Stock			79,808	79,808
Total		$	$	$ 3,518,867	$ 3,518,867

Table of Contents

The reconciliation of the Company s liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

Preferred stock warrant liability Series A Preferred Stock:

	Year Ended December 31, 2014	Year Ended December 31, 2013
Balance at beginning of period	$ 79,808	$ 87,600
Net exercise of Series A Warrants	(29,247)	
Change in fair value	(50,561)	(7,792)
Balance at end of period	$	$ 79,808

Preferred stock warrant liability Series B Preferred Stock:

	Year Ended December 31, 2014	Year Ended December 31, 2013
Balance at beginning of period	$ 3,439,059	$ 2,180,500
Net exercise of Series B Warrants	(1,162,118)	
Exercise of warrants purchase rights into Series B Warrants		1,793,600
Warrant liability Series B		177,952
Change in fair value	(2,276,941)	(712,993)
Balance at end of period	$	$ 3,439,059

The Company s preferred stock warrant liabilities were classified as level 3 and valued using the Black-Scholes-Merton (Black-Scholes) model. The fair values were derived by applying the assumptions described below. These liabilities increased or decreased each period based on the fluctuations of the fair value of the underlying preferred security.

The table below shows the inputs used by instrument to determine the fair value measurements at December 31, 2013:

	December 31, 2013
Preferred stock warrant liability Series A	
Expected dividend yield	0%
Anticipated volatility	88.57%
Estimated stock price	$ 45.20
Exercise price	$ 12.24
Expected life (years)	5.28

Risk free interest rate			1.75%
Preferred stock warrant liabilities	***Series B***		
Expected dividend yield			0%
Anticipated volatility			88.57%
Estimated stock price		$	19.92
Exercise price		$	5.16
Expected life (years)		3.97	6.89
Risk free interest rate		0.78%	2.45%

Table of Contents

5. ACCRUED EXPENSES

Accrued expenses at December 31, 2014 and 2013 were:

	2014	2013
Legal expenses	41,985	38,102
Research and development expenses	313,642	4,410
Compensation accruals and payroll taxes	444,786	8,837
Accounting services, taxes and other	106,886	63,752
Interest	1,425	2,772
Total	$ 908,724	$ 117,873

6. CONVERTIBLE NOTES PAYABLE RELATED PARTIES

In October 2013, the Company issued a convertible promissory note to Domain Partners VI, L.P., a related party, in a principal amount of $170,000, which was amended in February 2014 to extend its maturity date. The amendment to the note was determined to be a modification in accordance with ASC 470, *Debt*, and did not result in extinguishment. The note accrued interest at a rate of 6% per annum, and was to become due and payable in June 2014 unless converted into shares of the Company s capital stock prior to such time pursuant to its terms.

The Company recorded the difference between the current Series B Preferred Stock Conversion price and the fair value of the Series B Preferred Stock at the date of issuance, limited to the face amount of the convertible promissory note of $170,000, as a beneficial conversion feature. This was reflected as a debt discount and was amortized to interest expense through the note s maturity date.

Upon the Company s Initial Public Offering in May 2014, the note automatically converted into 21,250 shares of the Company s common stock. As of that date the remaining beneficial conversion feature was expensed.

7. CREDIT FACILITY

In April 2012, the Company entered into a loan and security agreement (the Credit Facility) with Square 1 Bank (Square 1) with availability in the amount of $500,000 to help fund operations of the Company. The Credit Facility was subsequently amended in November 2013 to provide the Company with an additional $1.0 million of available funds. The Company received an advance payment of $1.0 million in November 2013 through a term loan. The amended Credit Facility called for interest only payments at a 6.50% interest rate from November 2013 through November 2014 for all amounts outstanding, inclusive of those amounts originally drawn during 2012 prior to the amendment, at which point, the Company is required to make principal payments of $58,160 plus interest through the maturity date of the term loans in November 2016. As of December 31, 2013, $1,395,833 was outstanding under the Credit Facility. In November 2014, the Company and Square 1 amended the Credit Facility. Pursuant to the Credit Facility, Square 1 agreed 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 Square 1, 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 in November 2014; and (ii) $3,000,000 (the Tranche B Loan) is to be made available to the Company following the satisfaction of certain

conditions, including receipt of positive phase 2 data in either Sjögren-Larsson Syndrome (SLS) or noninfectious anterior uveitis. As of December 31, 2014, $1,395,833 was outstanding under the Credit Facility. 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. Any term loan made is payable as interest-only prior to November 2015 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.

Table of Contents

Future maturities of the existing term loans under the Credit Facility as of December 31, 2014 are as follows:

Years	Amount
2015	$ 77,546
2016	465,278
2017	465,278
2018	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 11). The warrant was valued at $177,952 and, together with the fair value of the warrant issued in connection with the April 12, 2012 Credit Facility ($88,100), 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. The amendment to the credit facility was determined to be a modification in accordance with ASC 470, *Debt* and did not result in extinguishment.

At December 31, 2014 and 2013, the Credit Facility is shown net of a remaining debt discount of $142,806 and $208,659, respectively.

8. INCOME TAXES

No provision for federal 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, 2014, the Company had Federal and State income tax net operating loss (NOL) carryovers of approximately $16.2 million and $13.4 million, respectively, which will expire at various dates through 2034. As of December 31, 2014, the Company had Federal and State tax carryovers of credits for increasing research activities (R&D tax credits) of approximately $392,000 and $45,000, respectively, which will expire at various dates through 2034.

In December 2014, legislation was signed into law which retroactively reinstated various tax provisions which had previously expired January 1, 2014, principally related to the Federal R&D credit. The Company has generated a Federal R&D tax credit for 2014. The Company will not be able to generate Federal R&D tax credits in 2015 until and if legislation is enacted.

As of December 31, 2013, the Company had Federal and State income tax NOL carryovers of approximately $10.9 million and $9.8 million, respectively, which will expire at various dates through 2033. As of December 31, 2013 the Company had Federal and State tax carryovers of R&D tax credits of approximately $233,000 and $25,000, respectively, which will expire at various dates through 2033.

Table of Contents

Significant components of the Company s deferred tax assets and liabilities at December 31, 2014 and 2013 are as follows:

	Years ended December 31,	
	2014	**2013**
Federal & State NOL carryforward	$ 6,210,836	$ 4,206,982
Federal & State R&D credit carryforward	421,828	249,106
Intangibles net	1,163,905	1,395,749
Accounts payable and accrued expenses	402,062	336,324
Stock options	1,432,312	735,595
Other assets		(3,833)
Note discounts	(56,094)	(133,791)
Fixed assets	(97)	
Less valuation allowance	(9,574,752)	(6,786,132)
Net deferred tax assets (liabilities)	$	$

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company believes it underwent a change in ownership during 2008, as defined by Internal Revenue Code Section 382, and the net operating losses and R&D tax credits could be subject to limitation. However, the Company does not believe any of its NOLs and R&D tax credits are limited by this potential ownership change.

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,	
	2014	2013
Statutory tax rate	34.00%	34.00%
State taxes, net of federal benefits	5.82%	%
Mark to market items	15.26%	(42.85)%
Federal research and development credits	3.07%	(0.37)%
Change in valuation allowance	(53.76)%	8.99%
Other	(4.39)%	0.23%
Effective tax rate	0.00%	0.00%

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, 2014, options to purchase 23,954 shares of common stock at an exercise price of $3.24 per share remained outstanding under the 2004 Plan.

Table of Contents

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. As of December 31, 2014, there were no shares available for issuance under the 2010 Plan. However, grants made under the 2010 Plan are still governed by that plan. As of December 31, 2014, options to purchase 585,888 shares of common stock at a weighted average exercise price of $1.41 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, 2014, the number of shares of common stock authorized for issuance in connection with the 2013 Plan was 625,000. On January 1 of each year the aggregate number of common shares that may be issued under the Plan shall automatically increase by a number equal to the least of (a) 4% 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, 333,333 common shares, or (c) a number of common shares determined by the Company s board of directors. As of January 1, 2015, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 222,617 shares, increasing the number of shares of common stock available for issuance under the 2013 Plan to 847,617 shares. As of December 31, 2014, options to purchase 264,190 shares of common stock at a weighted average exercise price of $6.84 per share remained outstanding under the 2013 Plan.

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.

The following table summarizes option activity under the incentive plans:

	Stock Options Outstanding	Weighted-Average Exercise Price
Options outstanding at December 31, 2012	67,232	$ 3.24
Granted	542,610	$ 1.26
Options outstanding at December 31, 2013	609,842	$ 1.48
Granted	264,190	$ 6.84
Options outstanding at December 31, 2014	874,032	$ 3.10

Options granted for the year ended December 31, 2013 include two grants of options exercisable for a total of 32,014 common shares for which vesting is contingent on certain performance and market-based conditions. For options

granted containing performance conditions, the fair value is determined on the date of grant. For the year ended December 31, 2014, there was $340,372 expense recorded relating to the options as the performance conditions were satisfied in May 2014 and the shares vested.

In June 2013, the Company issued 12,948 restricted stock awards, the only restricted stock awards issued by the Company since inception, and then modified the terms on September 8, 2013 to fully vest the awards. Accordingly, the value of the award of $216,000 was fully expensed during the year ended December 31, 2013. The fair value of the award was determined on the grant date fair market value per share. The Company recorded a reduction to the contributed services expense of approximately $173,000 during the year ended December 31, 2013 related to this award as the individual holder of this award transferred 80% of the rights to this award to a stockholder of the Company during September 2013 (Note 12).

Table of Contents

The following table summarizes information about stock options outstanding at:

Period Ending	Number Exercisable	Outstanding Shares Weighted-Average Remaining Contractual Life	Exercisable Shares Weighted-Average Remaining Contractual Life
December 31, 2014	134,294	8.74	7.47
December 31, 2013	96,949	9.32	7.41

The Company records stock-based compensation related to stock options granted at fair value. During the years ended December 31, 2014 and 2013, 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 assumptions used in determining fair value of the employee stock options for the years ended December 2014 and 2013, are as follows:

	December 31, 2014	December 31, 2013
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	$ 4.99 - $8.00	$ 10.56 - $11.03
Exercise price	$ 4.99 - $8.00	$ 0.552 - $4.56
Expected life (years)	6.00 - 6.25	5.47 - 7.85
Risk free interest rate	1.92% - 2.03%	1.71% - 2.34%

The dividend yield of zero is based on the fact that we have 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 that are publicly traded since we don t have sufficient historical or implied data of our own. 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 since we don t have sufficient historical or implied data of our 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.

On June 21, 2013, the Company granted 300,147 employee options to purchase common stock each with an exercise price of $3.24 per share, which is equivalent to the grant date fair value. The awards had various vesting provisions through a period of up to four years. On September 8, 2013, the Company modified the awards. This modification did not affect the remaining service period. This modification reduced the exercise price from $3.24 per share to $0.552 per share. This modification resulted in an increased value from the original grant date of approximately $221,000. This incremental compensation cost is being recorded over the remaining vesting period of approximately four years. On October 30, 2013 the vesting provisions for certain of these options were revised and became based on the Company s Closing Market Capitalization, as defined. This modification resulted in an increased value from the original grant date of approximately $322,000 and was determined based on Monte Carlo simulations that estimated the timing and number of shares that are most likely to vest. This incremental compensation cost is being recorded over approximately four years, which is the approximate number of years that the Monte Carlo simulations predict that the Closing Market Capitalization could be reached.

At December 31, 2014, there is approximately $4.5 million of unrecognized compensation cost relating to stock options outstanding, which the Company expects to recognize over a weighted average period 2.6 years. Total unrecognized compensation cost will be adjusted for future forfeitures, if necessary.

The Company has also issued stock options to non-employees at various grant dates from inception. In determining the expense associated with their vesting, those non-employee stock options were valued using

Table of Contents

the Black-Scholes option-pricing model using the fair value of the common stock and the following assumptions:

	December 31, 2014	December 31, 2013
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	$ 7.22	$ 11.85
Exercise price	$ 0.552	$ 3.24
Expected life (years)	8.69	3.27 - 3.35
Risk free interest rate	2.17%	0.78%

There were 4,802 options issued to consultants during the year ended December 31, 2013. There were no options granted to consultants during the year ended December 31, 2014. The stock-based compensation is subject to remeasurement and is being expensed over the related service term.

There were no options exercised during the years ended December 31, 2014 and 2013. The total aggregate intrinsic value of stock options outstanding as of December 31, 2013 and 2014 was $6.3 million and $3.7 million, respectively. The intrinsic value of options vested as of December 31, 2013 and 2014 was $925,498 (total fair value of $1.1 million) and $1.4 million (total fair value of $1.8 million), respectively. The weighted average exercise price of fully vested shares as of December 31, 2013 and 2014 was $2.06 and $1.57, respectively. The total weighted average grant date fair value of stock options for the years ended December 31, 2013 and 2014 was $10.64 and $6.84 per share, respectively.

Stock-based compensation is recognized for stock options granted to employees and non-employees and has been reported in the Company s statement of operations as follows:

	Years Ended December 31,	
	2014	2013
Research and development expenses	$ 647,150	$ 481,598
General and administrative expenses	1,389,923	1,220,115
Total stock-based compensation expense	$ 2,037,073	$ 1,701,713

10. REDEEMABLE CONVERTIBLE PREFERRED STOCK

Series A Preferred Stock

In June 2008, the Company authorized a total of 13,764,706 shares of Series A redeemable, convertible preferred stock (Series A Preferred Stock) of which 490,197 shares were issued for $12.24 per share resulting in gross proceeds of $6.0 million and 241,883 shares were issued in connection with the conversion of $2.8 million of bridge notes and related $200,649 of accrued interest.

In connection with the sale of Series A Preferred Stock, in June 2008, the Company recorded a separate preferred stock liability as the investors received the right to purchase from the Company, on the same terms, 248,311 additional shares of Series A Preferred Stock in a second tranche (Series A Rights). The original purchasers of the Series A

Preferred Stock in the June transaction had the ability to sell some of the shares of the Series A Preferred Stock and still retained the ability to exercise the right to the future purchase of Series A Preferred Stock and, accordingly, the Series A Rights were determined to be a freestanding derivative liability instrument.

At the time of issuance, the Company recorded a liability for the initial fair value of the Series A Rights. The Series A Rights were valued at $1.5 million using the Black-Scholes pricing model with the following assumptions: two year expected term, a risk-free rate of 2.98% and volatility of 88.57%. The initial value assigned to the rights was recorded as a discount to the Series A Preferred Stock and the discount is being

Table of Contents

accreted over the period through the earliest redemption date of the Series A Preferred Stock as a non-cash dividend.

As the Series A Rights are exercisable for shares of a redeemable instrument, they are classified as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity,* and are subject to re-measurement at each balance sheet date and changes to fair value are recognized as a component of other income (expense) in the accompanying statement of operations and comprehensive loss.

In February 2010, the Series A Preferred Stock investors exercised their Series A Rights to purchase all of the additional shares of Series A Preferred Stock contemplated under the right in a second tranche sale of Series A Preferred Stock. In connection with the second tranche sale, there were 248,311 shares of Series A Preferred Stock issued, all of which were from the exercise of the Series A Rights. The second tranche sale resulted in gross proceeds to the Company of $3.0 million.

In connection with the exercise of the Series A Rights, the Company performed a final valuation of the Series A Rights immediately prior to exercise resulting in a valuation of approximately $1.9 million and reclassified the fair value on extinguishment to the Series A Preferred Stock purchased in the second tranche.

In connection with a December 2012 preferred stock transaction, certain features of the Series A Preferred Stock were modified. The significant changes included the following:

Liquidation preference increased from one times the original issue price of the Series A Preferred Stock to three times the original issue price.

Participation preference originally capped at three times the original issuance price to no cap on participation.

Conversion terms were modified to allow for the conversion price to fully ratchet down to the price on subsequent issuance of equity at a lower price. The terms previously only allowed for a partial ratchet to the lower conversion price.

The change in the terms of the Series A Preferred Stock were evaluated and the change was determined to be a modification. The Company recorded a deemed dividend of $15.7 million for the year ended December 31, 2012 calculated based on the difference in the fair value immediately before and immediately after the modification. This deemed dividend was recognized as an increase to the face value of Series A Preferred Stock with an offset to retained earnings.

Series B Preferred Stock

In December 2012, the Company authorized a total of 36,205,634 shares of Series B redeemable, convertible preferred stock (Series B Preferred Stock) of which 387,499 shares were issued for $5.16 per share resulting in gross proceeds of $2.0 million and 541,496 shares were issued in connection with the conversion of $2.2 million of convertible notes and related $593,474 of accrued interest.

Each investor participating in the December 2012 Series B financings, including those holding the Convertible Notes that were converted in connection with the December Series B Preferred Stock financing, received warrants

exercisable for a number of shares of Series B Preferred Stock (Series B Warrants) equal to the 25% of the shares of Series B Preferred Stock purchased in the financing transaction. There was a total of 96,921 shares underlying Series B Warrants issued in connection with the transaction. The Series B Warrants have an exercise price of $5.16 per share, are immediately exercisable and have a term of five years. As the Series B Warrants are exercisable for redeemable shares, the Company recorded a liability in accordance with ASC 480 for the initial fair value of the Series B Warrants. The Series B Warrants were valued at $2.2 million using the Black-Scholes pricing model with the following assumptions: a term of 5 years, a risk-free rate of 0.77%, volatility of 88.57% and fair value on date of issuance of $25.44 per share.

In connection with the sale of Series B Preferred Stock in December 2012, the Company recorded a separate preferred stock liability as the investors received the right to purchase from the Company, on the same

terms, 928,995 additional shares of Series B Preferred Stock, in a second tranche (Series B Rights). The Series B Right also provided for warrants (Series B Rights-Warrants) exercisable for Series B Preferred Stock to be issued with the shares exercised under Series B Rights with the same terms and conditions as those warrants issued to the purchasers of the Series B Preferred Stock in the first tranche (Series B Rights-Warrants). The Series B Rights provided warrants for 25% of the shares of the Series B Preferred Stock exercised under the right for purchase in the second tranche. The original purchasers of the Series B Preferred Stock in the December transaction had the ability to sell some of the shares of the Series B Preferred Stock and still retained the ability to exercise the right to the future purchase of Series B Preferred Stock and, accordingly, the Series B Rights were determined to be a freestanding derivative liability instrument.

The Company recorded a preferred stock liability in December 2012 for the initial fair value of the Company s obligation to sell the convertible preferred stock for the second tranche of Series B Preferred Stock and the associated warrants that would be provided. The Series B Rights preferred stock liability was valued at $18.9 million using the Black-Scholes pricing model with the following assumptions: a 10 month expected term, a risk-free rate of 0.15%, volatility of 88.57% and fair value on date of issuance of $25.44 per share. The Series B Rights-Warrants preferred stock liability was valued at $5.2 million using the Black-Scholes pricing model with the following assumptions: a 10 month expected term, a risk-free rate of 0.13% volatility of 88.57% and fair value on date of issuance of $22.44 per underlying warrant.

The initial values assigned to the Series B Rights, Series B Rights-Warrants and Series B Warrants were recorded as discounts to the Series B Preferred Stock to the extent of gross proceeds received in connection with the financing transaction and those discounts are being accreted over the period through the earliest redemption date of the Series B Preferred Stock via recordings of a non-cash dividend. The amount of value received in excess of issuance price of Series B Preferred Stock of $21.5 million was recorded as an expense in the statements of operations and comprehensive income (loss).

The Series B Rights, Series B Rights-Warrants and Series B Warrants are each exercisable into shares or share options for redeemable stock and are classified as liabilities in accordance with ASC 480 and are subject to re-measurement at each balance sheet date and changes to fair value are recognized as a component of other income (expense) in the statement of operations and comprehensive loss. See Note 4 for disclosure of changes in fair value and inputs used to calculate fair value using the Black-Scholes model.

In August 2013, the Series B investors exercised their right and purchased 387,686 additional shares of Series B Preferred Stock in connection with the second tranche. The second tranche sale resulted in gross proceeds of $2.0 million. The Company performed a final valuation of the exercised Series B Rights immediately prior to exercise resulting in a valuation of approximately $6.3 million and reclassified the fair value upon extinguishment to the Series B Preferred Stock purchased in the second tranche. The combination of the $2.0 million gross cash proceeds and the $6.3 million fair value of the Series B Rights resulted in an initial fair value of the Series B Preferred Stock issued in August 2013 of $8.3 million, prior to any discounts for direct costs associated with the transaction. The resulting warrants associated with the exercised Series B Rights were initially recorded at the final fair value of the Series B warrant purchase rights on the date of exercise and continued to be carried at fair value and those warrants remain outstanding as of December 31, 2013. The unexercised Series B Rights for 541,309 shares of Series B Preferred Stock and the associated Series B Rights-Warrants expired on October 1, 2013. As the unexercised Series B Rights and associated Series B Rights-Warrants had intrinsic value on the date of expiration, the Company recorded a gain of $10.5 million relating to the final fair value measurement adjustment on the date of expiration.

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 offering commenced as of May 1, 2014 and did not

Table of Contents

terminate before all of the securities registered in the registration statement were sold. Aegis Capital Corp. acted as the sole manager of the offering and as representative of the underwriters. The Company raised approximately $10 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.

In connection with the Initial Public Offering, holders of at least 67% of the respective outstanding Series A and Series B Preferred Stock (Series A and Series B voting as separate single classes) elected to automatically convert the Series A Preferred Stock and Series B Preferred Stock into 3,642,799 shares of common stock. The remaining unamortized discount was considered a deemed dividend of $4,053,570 for the year ended December 31, 2014.

11. STOCK PURCHASE WARRANTS

On April 12, 2012, in connection with the signing of the Credit Facility agreement, the Company granted warrants to purchase 2,042 shares of Series A Preferred Stock (Series A Warrants) at an exercise price of $12.24 per share to Square 1 Bank.

On December 20, 2012, in connection with the sale and issuance of Series B Preferred Stock on that date, the Company granted warrants to purchase 96,921 shares of Series B Preferred Stock at an exercise price of $5.16 per share to the Series B Preferred Stock investors.

On August 14, 2013, in connection with the sale and issuance of Series B Preferred Stock on that date, the Company granted warrants to purchase 96,921 shares of Series B Preferred Stock at an exercise price of $5.16 per share to the Series B Preferred Stock investors.

On November 20, 2013, the Company granted a warrant exercisable for 9,692 shares of Series B Preferred Stock at an exercise price of $5.16 to Square 1 Bank in connection with the amendment to the Credit Facility.

In connection with the Initial Public Offering, the holders of the outstanding Series A and Series B Preferred Stock Warrants elected to net exercise the warrants and the shares of Series A Preferred Stock and Series B Preferred Stock issued upon such net exercise were automatically converted into 74,001 shares of common stock.

Also 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 and are outstanding at December 31, 2014.

12. RELATED PARTY TRANSACTIONS

The Company entered into certain letter agreements with each of its executive officers. Pursuant to these letter agreements, if the Company terminates their employment without cause or if such executive resigns for good reason, then he will be eligible to receive: continued payment of base salary for a certain period of time; a lump-sum cash payment; payment by the Company of the monthly premiums under COBRA for such executive and their eligible dependents for a period of time; and, in the case of the Company s chief executive officer and chief operating officer, accelerated vesting and exercisability with respect to all equity or equity-based awards held by such executive officer as if such executive officer has completed an additional 12 months of service with the Company, and up to 12 months following such termination to exercise any then-outstanding stock options or stock appreciation rights. Such payments

are contingent on the officer s executing and not revoking a release of claims against the Company. As of December 31, 2014 and December 31, 2013, the Company assessed the likelihood for these events to occur and has determined that a liability related to these agreements is not likely to occur and therefore has not been recorded.

President and CEO contributed services The Company s President and Chief Executive Officer (CEO) was hired on January 6, 2012 on a half-time basis and on April 15, 2013, he began working full-time for the

Table of Contents

Company. During the period from January 6, 2012 through October 14, 2013, he was not paid a salary by the Company and was an employee and paid a salary by Domain Associates, LLC (Domain), a related party. The value of his services has been reflected in the statement of operations as an expense and recorded as a contribution of capital. For the year ended December 31, 2013, the value of his services was $219,167. The amount of contributed services for the year ended December 31, 2013 of $219,167 was then reduced by $172,779 as a result of vested shares of restricted stock issued to the CEO and then assigned to Domain during that same period. The value of restricted stock is included as a component of stock-based compensation expense for the year ended December 31, 2013.

Convertible Promissory Note In October 2013, the Company issued a convertible promissory note to Domain Partners VI, L.P., in a principal amount of $170,000, which was amended in February 2014 to extend its maturity date.

The note accrued interest at a rate of 6% per annum, and would have become due and payable in June 2014 unless it converted into shares of the Company s capital stock prior to such time pursuant to its terms.

Upon the Company s Initial Public Offering in May 2014, the note automatically converted into 21,250 shares of the Company s common stock.

13. COMMITMENTS AND CONTINGENCIES

Guarantees and Indemnifications As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company s request in such capacity. The term of the indemnification is for the officer s or director s lifetime. Through December 31, 2014, 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 In February 2010, the Company entered into a license and supply agreement providing the Company with an exclusive license to certain technology and access to purchase materials at certain costs. Under the terms of the license and supply agreement, the Company is obligated to make milestone payments up to an aggregate of $2.15 million upon reaching certain development and regulatory milestones in the development of the Company s product. Upon commercialization of the Company s product containing the licensed technology, the Company would be obligated to pay royalties based on net sales subject to an annual cap. The license and supply agreement runs through the 7th anniversary of the expiration of all patents licensed under the agreement, which the Company estimates to be April 2036, unless terminated earlier.

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 on or about September 12, 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. The following table outlines the Company s gross future minimum payments under all non-cancelable operating leases as of December, 2014

	Total	2015	2016	2017
Operating lease obligations	$ 188,000	$ 68,000	$ 69,000	$ 51,000

107

Table of Contents

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)
10.3	Offer Letter, effective as of July 15, 2013, between the Registrant and Scott L. Young (filed as Exhibit 10.3 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)
10.5	

Offer Letter, effective November 27, 2013, between the Registrant and Scott L. Young (filed as Exhibit 10.5 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)

Table of Contents

Exhibit Number	Exhibit Title
10.5(a)	Offer Letter Amendment, effective February 20, 2014 between the Registrant and Scott L. Young (filed as Exhibit 10.5(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)
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)
10.10	License and Supply Agreement dated as of February 19, 2010 between the Registrant and CyDex Pharmaceuticals, Inc. (filed as Exhibit 10.2 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-193204), as filed on January 27, 2014, and incorporated herein by reference)
10.11	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)
10.12	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)
10.13	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)
10.14	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)
10.15	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)
10.16	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)

109

Table of Contents

Exhibit Number	Exhibit Title
10.17	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)
10.18	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)
10.19	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)
10.20	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)
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.