

Aldeyra Therapeutics, Inc.  
Form POS AM  
June 12, 2015  
Table of Contents

As filed with the Securities and Exchange Commission on June 12, 2015

Registration No. 333-203078

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**Post-Effective**  
**Amendment No. 2**  
**to**  
**FORM S-1 on FORM S-3**  
**REGISTRATION STATEMENT**  
***UNDER***  
***THE SECURITIES ACT OF 1933***

**ALDEYRA THERAPEUTICS, INC.**

**(Exact name of registrant as specified in its charter)**

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>2834</b> (Primary Standard Industrial Classification Code Number) <b>131 Hartwell Avenue, Suite 320</b>	<b>20-1968197</b> (I.R.S. Employer Identification Number)
--	---	---

**Lexington, MA 02421**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Todd C. Brady, M.D., Ph.D.**

**President and Chief Executive Officer**

**Aldeyra Therapeutics, Inc.**

**131 Hartwell Avenue, Suite 320**

**Lexington, MA 02421**

**(781) 761-4904**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Jay K. Hachigian**

**Keith J. Scherer**

**Gunderson Dettmer Stough Villeneuve**

**Franklin & Hachigian, LLP**

**One Marina Park Drive, Suite 900**

**Boston, MA 02210**

**(617) 648-9100**

**Approximate date of commencement of proposed sale to public:** As soon as practicable after this Registration Statement is declared effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**EXPLANATORY NOTE**

On March 27, 2015, Aldeyra Therapeutics, Inc. ( Aldeyra , the Company , we ) filed a registration statement with the Securities and Exchange Commission, or the SEC, on Form S-1 (File no. 333-203078). The registration statement was declared effective by the SEC on April 7, 2015 to initially register for resale by the selling stockholder identified in the prospectus of up to 211,528 shares of our common stock that we sold to the selling stockholder and 211,528 shares of common stock that are issuable upon the exercise of an outstanding warrant to purchase our common stock issued to the selling stockholder in connection with a private placement completed on January 21, 2015.

On May 14, 2015, we subsequently filed Post-Effective Amendment No. 1 to the registration statement on Form S-1 with the SEC (File no. 333-203078) to (i) incorporate by reference our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 and (ii) update certain other information in the prospectus.

This Post-Effective Amendment No. 2 to Form S-1 on Form S-3 is being filed to convert the registration statement on Form S-1 (File No. 333-203078) into a registration statement on Form S-3, and contains an updated prospectus relating to the offering and sale of the shares that were registered for resale on the Form S-1.

No additional securities are being registered under this Post-Effective Amendment. All applicable filing fees were paid at the time of the original filing of the Registration Statement on March 27, 2015.

**Table of Contents**

**The information in this prospectus is not complete and may be changed. The selling stockholder named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholder named in this prospectus is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED JUNE 12, 2015**

**PROSPECTUS**

**Aldeyra Therapeutics, Inc.**

**423,056 Shares of Common Stock**

This prospectus relates to the resale by the selling stockholder identified in this prospectus of up to 211,528 shares of our common stock that we sold to the selling stockholder and 211,528 shares of common stock that are issuable upon the exercise of an outstanding warrant to purchase our common stock issued to the selling stockholder in connection with a private placement completed on January 21, 2015. We will not receive any proceeds from the sale of these shares by the selling stockholder.

We are not selling any shares of common stock and will not receive any proceeds from the sale of the shares under this prospectus. Upon the exercise of the warrant for 211,528 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrant, which is \$9.50 per share.

We have agreed to bear all of the expenses incurred in connection with the registration of these shares. The selling stockholder will pay or assume brokerage commissions and similar charges, if any, incurred for the sale of shares of our common stock.

The selling stockholder identified in this prospectus, or its pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. For additional information on the methods of sale that may be used by the selling stockholder, see the section entitled **Plan of Distribution** on page 28. For a list of the selling stockholder, see the section entitled **Selling Stockholder** on page 27.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Our common stock is traded on The NASDAQ Capital Market under the symbol **ALDX**. On June 11, 2015, the closing sale price of our common stock on The NASDAQ Capital Market was \$8.30 per share. You are urged to obtain current market quotations for the common stock.

**Investing in our common stock involves risks. See Risk Factors beginning on page 5.**

We are an emerging growth company under applicable Securities and Exchange Commission rules and are eligible for reduced public company disclosure requirements.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is \_\_\_\_\_, 2015.**

**Table of Contents**

We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. The selling stockholder is not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

	<b>Page</b>
<u>SUMMARY</u>	1
<u>THE OFFERING</u>	4
<u>RISK FACTORS</u>	5
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA</u>	26
<u>USE OF PROCEEDS</u>	27
<u>SELLING STOCKHOLDER</u>	27
<u>PLAN OF DISTRIBUTION</u>	28
<u>LEGAL MATTERS</u>	29
<u>EXPERTS</u>	29
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	29
<u>INCORPORATION OF DOCUMENTS BY REFERENCE</u>	29

**Table of Contents**

**SUMMARY**

*This summary highlights information contained or incorporated by reference elsewhere in this prospectus. You should read the following summary together with the more detailed information appearing or incorporated by reference in this prospectus, including our consolidated financial statements and related notes, and in Risk Factors beginning on page 5, before deciding whether to purchase shares of our common stock. Unless the context otherwise requires, we use the terms Aldeyra, the company, we, us and our in this prospectus to refer to Aldeyra Therapeutics, Inc.*

**Company 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 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 prospectus 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 compounds 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 began 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).

In March of 2015, we initiated a clinical trial of NS2 applied topically to skin for the treatment of the dermatologic symptoms 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 caused by mutations in an enzyme, fatty aldehyde dehydrogenase, 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, delay in mental development, spasticity, and, in some patients, retinal dysfunction. In preclinical studies, NS2 traps fatty aldehydes in cells lacking the enzyme that is mutated in SLS. 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 preventing water loss from tissue.

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 March of 2015, we initiated a Phase II clinical trial 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, pain, 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).

We intend to initiate other clinical trials with NS2 in SLS and ocular inflammation, as well as in other diseases thought to be mediated in part by free aldehydes, and we may initiate development of injectable formulations of NS2 for diseases for which we believe systemic aldehyde trapping may provide therapeutic benefit. Specifically, we plan to finance additional trials of topically applied NS2 in SLS and uveitis or other forms of ocular inflammation; the formulation of NS2 for subcutaneous and intravenous administration; the completion of Phase I safety and tolerability testing of injectable formulations of NS2 in preparation for potential Phase II clinical trials for systemic treatment of SLS, autoimmune diseases that lead to severe inflammatory crises, and another genetic disease (succinic semi-aldehyde dehydrogenase deficiency) where an aldehyde dehydrogenase is dysfunctional and high aldehyde levels are thought to mediate neurological disease; the synthesis and formulation of novel aldehyde traps other than NS2; and the expansion our clinical development and regulatory infrastructure.

**Table of Contents**

**Risks Related to Our Business**

An investment in our common stock involves a high degree of risk. Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors". These risks represent challenges to the successful implementation of our strategy and to the growth and future profitability of our business. Some of these risks include the following:

We have incurred significant operating losses since our inception, and we expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

Our business is dependent in large part on the success of a single product candidate, NS2. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, NS2.

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.

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.

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.

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.

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

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.

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.

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.

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 are currently highly dependent on the services of our three senior employees and certain key consultants.

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.

For further discussion of these and other risks you should consider before making an investment in our common stock, see the section titled "Risk Factors" beginning on page 5 of this prospectus.

### **Recent Developments**

In May 2015, we issued and sold a total of 2,822,500 shares of our common stock, including 122,500 shares upon the underwriter's partial exercise of their overallotment option, at a public offering price of \$7.50 per share in an underwritten offering. Net proceeds from the offering was approximately \$19.9 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

### **Our Corporate Information**

Our principal executive offices are located at 131 Hartwell Avenue, Suite 320, Lexington, Massachusetts 02421, and our telephone number is (781) 761-4904. On March 17, 2014, we changed our name from Aldexa Therapeutics, Inc. to Aldeyra Therapeutics, Inc. Our website address is [www.aldeyra.com](http://www.aldeyra.com). Our website and the information contained in, or accessible through, our website will not be deemed to be incorporated by reference into this prospectus and does not constitute part of this prospectus. You should not rely on any such information in making your decision whether to purchase our common stock.

**Table of Contents**

**Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in gross revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

exemption from complying with the auditor attestation requirements under Section 404 of the Sarbanes-Oxley Act, regarding the effectiveness of our internal controls over financial reporting;

reduced disclosure obligations regarding the company's executive compensation arrangements in our periodic reports, proxy statements and registration statements;

exemptions from the requirements of holding a non-binding advisory vote on executive compensation; and

stockholder approval of any golden parachute arrangements not previously approved.

We may take advantage of these provisions until December 31, 2019, or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual gross revenue, the date at which we become a large accelerated filer, or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

**Private Placement of Common Stock and Warrant**

On January 21, 2015, we completed a private placement of 211,528 shares of common stock, \$0.001 par value per share, and a warrant to purchase 211,528 shares of our common stock at an exercise price per share of \$9.50, with a term of three years from the date of issuance resulting in net proceeds of approximately \$2.0 million. We are using the proceeds from the private placement for working capital and general corporate purposes. As part of this private placement, we entered into a registration rights agreement with the purchasers pursuant to which we agreed to file a registration statement to register for resale the shares of common stock sold in the private placement, including the

shares underlying the warrant sold in the private placement, within 75 days following the closing of the private placement. We are required to use our commercially reasonable best efforts to cause the registration statement to be declared effective under the Securities Act of 1933, as amended, as soon as practicable, but in no event later than 120 days after the closing date (or 150 days in the event of a full review of the shelf registration statement by the Securities and Exchange Commission). We agreed to keep the registration statement effective until all registrable securities may be sold pursuant to Rule 144 under the Securities Act of 1933, without the need for current public information or other restriction. The issuance of the shares of common stock and the warrant in connection with the private placement was exempt from registration under the Securities Act of 1933, as amended, pursuant to the exemption for transactions by an issuer not involving a public offering under Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder.

**Table of Contents**

**THE OFFERING**

Common stock offered by the selling stockholder	423,056 shares, including 211,528 shares of our common stock issuable upon exercise of a warrant at an exercise price of \$9.50 per share
Common stock outstanding	6,890,021 shares
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering.
Risk Factors	You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

NASDAQ Capital Market symbol ALDX

The number of shares of our common stock outstanding is based on 6,890,021 shares of our common stock outstanding as of March 31, 2015, including the 211,528 shares of our common stock issued to the selling stockholder in January 2015 in a private placement and excludes the following:

874,032 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of approximately \$3.10 per share;

583,427 shares of common stock reserved for future grants under our 2014 Equity Incentive Plan as of March 31, 2015 (subject to automatic annual adjustment in accordance with the terms of the plan);

1,384,608 shares of our common stock issuable upon exercise of warrants at a weighted average exercise price of approximately \$9.52 per share; and

2,822,500 shares of our common stock sold pursuant to our registration statement on Form S-1 (File no. 333-203536) in May 2015.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above.

**Table of Contents**

**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained or incorporated by reference in this prospectus, including our consolidated financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment.*

**Risks Related to our Business**

***We have incurred significant operating losses since inception, and we expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.***

We have incurred significant operating losses since we were founded in 2004 and expect to incur significant losses for the next several years as we continue our clinical trial and development programs for NS2 and our other product candidates. Net loss attributable to common stockholders for the three months ended March 31, 2015 and 2014 was approximately \$2.1 million and \$13,237, respectively. As of March 31, 2015, we had total stockholders' equity of \$13.8 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. 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 current and planned clinical trials of NS2. 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;

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

the results of later phases 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;

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 for marketing approval required by the FDA, or comparable foreign regulatory bodies;

patients in our clinical trials may suffer other adverse effects or die 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 varying levels of 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.



**Table of Contents**

*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.

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. Prior to our SLS Phase II clinical trial which commenced in March 2015, NS2 had 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 in humans 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 delay in mental development, 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 if it is approved.

***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 extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other jurisdictions.

We are not permitted to initiate clinical trials of a new drug under an 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.

***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;

**Table of Contents**

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 must submit the results of preclinical testing to the FDA as part of an IND, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. We may rely in part on preclinical, clinical, and quality data generated by contract research organization (CROs) and other third parties for obtaining the data for and preparing 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



## **Table of Contents**

authorities, the IRB, other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for a product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of 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, including those relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for 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.

## **Table of Contents**

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;

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.



## **Table of Contents**

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

***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 March 31, 2015, 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 parties and may occur on substantially different timing from our estimates. Specifically, we use CROs to conduct our clinical trials and also rely on medical institutions, clinical investigators, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that 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.

**Table of Contents**

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

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

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

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

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

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

The manufacturing of compounds is extremely susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

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. 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

**Table of Contents**

efforts to establish development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

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

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

our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;

we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and

we will bear all of the risk related to the development of any such product candidates.

***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 corticosteroids, some of which are generic. Our potential competitors in these diseases may be developing novel immune modulating therapies that may be safer or more effective than 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 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

**Table of Contents**

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.

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 hazardous waste insurance coverage and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

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

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

**Table of Contents**

***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 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.

## Table of Contents

### **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 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 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.

**Table of Contents**

***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 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

## **Table of Contents**

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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 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.

**Table of Contents**

**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.

***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 March 31, 2015. As of March 31, 2015 and December 31, 2014, 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

## **Table of Contents**

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 Ownership of Our Common Stock**

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

We have a limited history as a public company. An active trading market for our shares may never develop or be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price they paid or at the time that they would like to sell. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could harm our business.

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

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

our ability to enroll patients in our planned clinical trials;

results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;

regulatory developments in the United States and foreign countries;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems, especially in light of current reforms to the United States healthcare system;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;

sales of our stock by insiders and 5% stockholders;

trading volume of our common stock;

general economic, industry and market conditions other events or factors, many of which are beyond our control;

additions or departures of key personnel; and

intellectual property, product liability or other litigation against us.

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

***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 March 31, 2015, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 67.0% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and 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;

**Table of Contents**

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.

***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

## Table of Contents

governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years from our Initial Public Offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When and if we are a large accelerated filer or an accelerated filer and are no longer an emerging growth company, each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff.

Historically, we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate formally documented accounting policies and procedures to support, effective internal controls. As we grow, we will hire additional personnel and engage in external temporary resources and may implement, document and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered in the future, could

cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If other securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

This prospectus contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are contained principally in Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business. In some cases, you can identify forward-looking statements by terms such as may, might, will, objective, intend, should, could, can, would, expect, project, target, design, estimate, predict, potential, plan or the negative of these terms, and similar expressions intended to 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. Forward-looking statements include, but are not limited to, statements about:

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 clinical trials and 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 or sufficiency of our cash or cash equivalents.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

Any forward-looking statement made by us in this prospectus speaks only as of the date on which it is made. Except as required by law, we assume no obligation to update these statements publicly, or to update the reasons actual results could differ materially from those anticipated in these statements, even if new information becomes available in the future.

We discuss many of these risks in this prospectus in greater detail under the heading Risk Factors. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus.

Unless required by United States federal securities laws, we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

**Table of Contents**

**USE OF PROCEEDS**

We are filing the registration statement of which this prospectus is a part to permit the holder of the shares of our common stock described in the section entitled "Selling Stockholder" to resell such shares. We will not receive any proceeds from the resale of any shares offered by this prospectus by the selling stockholder. Upon the exercise of the warrant for 211,528 shares of our common stock by payment of cash, however, we will receive the exercise price of the warrant, which is \$9.50 per share. The warrant covered by the registration statement of which this prospectus is a part do not have a net exercise provision. We will use any cash received from the exercise of the warrant for the funding of our research and development programs and otherwise for general corporate purposes.

The selling stockholder will pay any underwriting discounts and commissions and expenses incurred by such selling stockholder for brokerage, accounting, tax or legal services or any other expenses incurred by such selling stockholder in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, NASDAQ Capital Market listing fees and fees and expenses of our counsel and our auditors.

**SELLING STOCKHOLDER**

The shares of common stock being offered by the selling stockholder include those issued to the selling stockholder pursuant to the purchase agreement we entered into with the selling stockholder and shares of common stock issuable upon exercise of the warrant purchased pursuant to the purchase agreement. For additional information regarding the issuance of the common stock and warrant, see "Private Placement of Common Stock and Warrant" above. We are registering the shares of common stock in order to permit the selling stockholder to offer the shares for resale from time to time. Except for the ownership of the shares of common stock and the warrant issued pursuant to, or in connection with, the purchase agreement, the selling stockholder has not had any material relationship with us within the past three years.

The table below lists the selling stockholder and other information regarding the beneficial ownership of the shares of common stock by the selling stockholder. The second column lists the number of shares of common stock beneficially owned by the selling stockholder, based on its ownership of the common stock and warrant, as of May 1, 2015, assuming exercise of the warrant held by the selling stockholder on that date, without regard to any limitations on exercise.

The third column lists the shares of common stock being offered by this prospectus by the selling stockholder.

Under the terms of the warrant, the selling stockholder may not exercise the warrant to the extent such exercise would cause such selling stockholder, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 9.99% of the then-outstanding shares of our common stock following such exercise without giving 60 days prior notice to us, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrant which has not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholder may sell all, some or none of its shares in this offering. See "Plan of Distribution."

Name of Selling Stockholder	Number of Shares	
	Common Stock Owned	Maximum Number of Shares of Common Stock Owned After

	<b>Prior to Offering</b>	<b>to be Sold Pursuant to this Prospectus</b>	<b>Offering (1)</b>
Cowen Investments LLC	423,056(2)	423,056	0

- (1) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (ii) no other shares of common stock will be acquired or sold by the selling stockholder before completion of this offering. However, the selling stockholder may sell all, part or none of its shares of common stock offered pursuant to this prospectus and may sell all, part or none of its common stock pursuant to one or more exemptions from the registration provisions of the Securities Act of 1933, as amended (the Securities Act ).
- (2) Includes 211,528 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of \$9.50 per share, which may be exercised after July 21, 2015 and expires on January 21, 2018. RCG LV Pearl, LLC is the sole member of Cowen Investments LLC. RCG LV Pearl, LLC disclaims beneficial ownership of the shares held by Cowen Investments LLC. Cowen Group, Inc. is the sole member of RCG LV Pearl, LLC. Cowen Group, Inc. disclaims beneficial ownership of the shares held by Cowen Investments LLC. Peter A. Cohen, the Chairman and Chief Executive Officer of Cowen Group, Inc., has voting and investment control over the shares held by Cowen Investments LLC. Mr. Cohen disclaims beneficial ownership of these shares. An affiliate of Cowen Investments LLC is a FINRA member. However, this affiliate will not sell any shares to be offered by Cowen Investments LLC through the prospectus and will receive no compensation whatsoever in connection with sales of shares by Cowen Investments LLC through the prospectus. The address for Cowen Investments LLC is 599 Lexington Avenue, New York, NY 10022.

**Table of Contents**

**PLAN OF DISTRIBUTION**

The selling stockholder, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from the selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholder may use any one or more of the following methods when disposing of shares or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales effected after the date the registration statement of which this Prospectus is a part is declared effective by the SEC;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted by applicable law.

The selling stockholder may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by it and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholder to include the pledgee, transferee or other successors in interest as selling stockholder under this prospectus. The selling stockholder also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholder may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholder from the sale of the common stock offered by it will be the purchase price of the common stock less discounts or commissions, if any. The selling stockholder reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrant by payment of cash, however, we will receive the exercise price of the warrant.

The selling stockholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that it meets the criteria and conform to the requirements of that rule.

## Edgar Filing: Aldeyra Therapeutics, Inc. - Form POS AM

The selling stockholder and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be underwriters within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. A selling stockholder who is an underwriter within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the name of the selling stockholder, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

## **Table of Contents**

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholder that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholder and its affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholder for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholder may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholder against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholder to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

## **LEGAL MATTERS**

The validity of the shares of common stock offered hereby is being passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Boston, Massachusetts.

## **EXPERTS**

The financial statements as of December 31, 2014 and 2013 and for each of the two years in the period ended December 31, 2014 incorporated by reference in this Prospectus and in the Post-Effective Amendment No. 2 to Registration Statement on Form S-1 on Form S-3 have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, appearing elsewhere herein and in the Registration Statement incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file reports and other information with the SEC as required by the Exchange Act. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at <http://www.sec.gov> or on our web site at <http://www.aldeyra.com>.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and the securities, including exhibits and schedules. You can obtain a copy of the registration statement from the SEC at any address listed above or from the SEC's web site.

## **INCORPORATION OF DOCUMENTS BY REFERENCE**

## Edgar Filing: Aldeyra Therapeutics, Inc. - Form POS AM

The SEC allows us to incorporate by reference into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ) (other than Current Reports on Form 8-K containing only information furnished under Item 2.02 or Item 7.01 of Form 8-K, unless otherwise indicated therein), including filings made after the date of the filing of this Post-Effective Amendment No. 2 to Registration Statement on Form S-1 on Form S-3, until the selling stockholder sells all of the securities covered by this prospectus or the sale of securities by the selling stockholder pursuant to this prospectus is terminated. The documents we incorporate by reference are:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on March 23, 2015;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed on May 14, 2015;

our Proxy Statement on Schedule 14A filed on April 27, 2015 (excluding those portions that are not incorporated by reference into our Annual Report);



**Table of Contents**

our Current Reports on Form 8-K, as filed with the SEC on January 1, 2015, January 13, 2015, January 15, 2015, January 20, 2015, January 22, 2015, March 2, 2015, March 13, 2015, March 17, 2015, March 19, 2015 and June 9, 2015; and

the description of our common stock contained in our Registration Statement on Form 8-A (File no. 001-36332) filed under the Exchange Act on March 4, 2014, including any amendment or report filed for the purpose of updating such description. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have furnished or may in the future furnish to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Investor Relations, Aldeyra Therapeutics, Inc. 131 Hartwell Avenue, Suite 320, Lexington, MA 02421, (781) 761-4904 email address: [dburke@theruthgroup.com](mailto:dburke@theruthgroup.com). In addition, copies of any or all of the documents incorporated herein by reference may be accessed at our website at [www.aldeyra.com](http://www.aldeyra.com). The information contained in, or accessible through, our website does not constitute part of this prospectus.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, all of which will be paid by the Registrant. All amounts are estimates except the SEC registration fee.

	<b>Amount</b>
Securities and Exchange Commission registration fee	\$ 528
Accountant's fees and expenses	\$ 25,000
Legal fees and expenses	\$ 50,000
Transfer agent's fees and expenses	\$ 2,500
Miscellaneous	\$ 11,972
Total expenses	\$ 90,000

**Item 14. Indemnification of Directors and Officers.**

The Registrant's amended and restated certificate of incorporation contains provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of the Registrant's directors for monetary damages for breach of their fiduciary duties as directors. The Registrant's amended and restated bylaws provide that the Registrant must indemnify its directors and officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

The Registrant has entered into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its amended and restated bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The securities purchase agreement and registration rights agreement entered into with the selling stockholder, provides for by the Registrant of the selling stockholder, for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

See also Undertakings set out in response to Item 17 herein.

**Item 16. Exhibits and Financial Statement Schedules.**

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - i. To include any prospectus required by section 10(a)(3) of the Securities Act;
  - ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in

**Table of Contents**

the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

- iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided however, that paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

- (4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) each prospectus filed pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale

prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Post-Effective Amendment No. 2 to the Registration Statement on Form S-1 on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the Commonwealth of Massachusetts, on this 12<sup>th</sup> day of June, 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 1933, this Post-Effective Amendment No. 2 to the Registration Statement on Form S-1 on Form S-3 has been signed by the following persons in the capacities held on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Todd Brady, M.D., Ph.D.	Director, President and Chief Executive Officer	June 12, 2015
Todd Brady, M.D., Ph.D.	(Principal Executive Officer)	
/s/Stephen Tulipano	Chief Financial Officer (Principal Financial and Accounting Officer)	June 12, 2015
Stephen Tulipano		
*	Chairman of the Board of Directors	June 12, 2015
C. Boyd Clarke		
*	Director	June 12, 2015
Ben Bronstein, M.D.		
*	Director	June 12, 2015
Martin J. Joyce		
*	Director	June 12, 2015
Gary Phillips, M.D.		
*	Director	June 12, 2015

Jesse Treu, Ph.D.

\*

Director

June 12, 2015

Neal Walker, D.O.

\* By: /s/ Stephen Tulipano  
Stephen Tulipano

Attorney-in-Fact

II-3

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Title</b>
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)
5.1	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (filed as Exhibit 5.1 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203078), as filed on March 27, 2015).
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)	



Edgar Filing: Aldeyra Therapeutics, Inc. - Form POS AM

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)

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Title</b>
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)
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)

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>
<b>Number</b>	<b>Title</b>
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)
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)
10.21	Third Amendment to Loan and Security Agreement, dated as of March 18, 2015, between Square 1 Bank and the Registrant (filed as Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203536), as filed on April 20, 2015, and incorporated herein by reference)
23.1*	Consent of BDO USA, LLP, independent registered public accounting firm
23.2	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1)
24.1	Power of Attorney. Reference is made to page II-5 of this Registration Statement
101.INS	XBRL Instance Document (incorporated by reference to Exhibit 101.INS to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)
101.SCH	XBRL Taxonomy Extension Schema Document (incorporated by reference to Exhibit 101.SCH to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (incorporated by reference to Exhibit 101.CAL to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (incorporated by reference to Exhibit 101.DEF to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (incorporated by reference to Exhibit 101.LAB to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (incorporated by reference to Exhibit 101.PRE to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2015)

Compensation Arrangement.

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