

Aldeyra Therapeutics, Inc.  
Form S-1/A  
May 05, 2015  
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As filed with the Securities and Exchange Commission on May 5, 2015

Registration No. 333-203536

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

**Amendment No.1 to**  
**Form S-1**  
**REGISTRATION STATEMENT**  
***UNDER***  
***THE SECURITIES ACT OF 1933***

**ALDEYRA THERAPEUTICS, INC.**

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

**Delaware**

**2834**

**20-1968197**

**(State or other jurisdiction of  
incorporation or organization)**

**(Primary Standard Industrial  
Classification Code Number)  
131 Hartwell Avenue, Suite 320**

**(I.R.S. Employer  
Identification No.)**

**Lexington, MA 02421**

**Telephone: (781) 761-4904**

**(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**

**Telephone: (781) 761-4904**

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

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

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, please 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 post-effective amendment filed pursuant to Rule 462(d) 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.

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

The registrant is an "emerging growth company" as defined in Section 2(a) of the Securities Act. This registration statement complies with the requirements that apply to an issuer that is an emerging growth 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.**



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

**PRELIMINARY PROSPECTUS (Subject to Completion)**

**Dated May  
5, 2015**

**3,000,000 Shares**

**Aldeyra Therapeutics, Inc.**

**Common Stock**

We are offering 3,000,000 shares of our common stock. Our common stock is listed on The NASDAQ Capital Market under the symbol ALDX. On May 4, 2015, the last reported sale price of our common stock on The NASDAQ Capital Market was \$9.27 per share.

**Investing in our common stock involves risk. See Risk Factors beginning on page 8.**

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be 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.

|  | <i>Per Share</i> | <i>Total</i> |
|--|------------------|--------------|
| <b>Public offering price</b>                 | <b>\$</b>        | <b>\$</b>    |
| <b>Underwriting discount(1)</b>              | <b>\$</b>        | <b>\$</b>    |
| <b>Proceeds to Aldeyra (before expenses)</b> | <b>\$</b>        | <b>\$</b>    |

(1) See Underwriting for additional disclosure regarding underwriting commissions and expenses. The underwriters may also purchase up to an additional 450,000 shares from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallotments.

The underwriters expect to deliver the shares against payment in New York, New York on \_\_\_\_\_, 2015

***Joint Book-Running Managers***

**Cowen and Company**

**Canaccord Genuity**

***Co-Managers***

**Janney Montgomery Scott**  
, 2015

**Laidlaw & Company (UK) Ltd.**

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus or in any free writing prospectus that we may authorize to be delivered or made available to you. Neither the delivery of this prospectus nor the sale of our common stock means that the information contained in this prospectus or any free writing prospectus is correct after the date of this prospectus or such free writing prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy the shares of common stock in any circumstances under which the offer or solicitation is unlawful.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in

Risk Factors. These and other factors could cause our future performance to differ materially from our assumptions and estimates. See Special Note Regarding Forward-Looking Statements.

Aldeyra Therapeutics and our design logo used in this prospectus are the property of Aldeyra. This prospectus may also include other trademarks, tradenames and service marks that are the property of their respective holders. Solely for convenience, trademarks and tradenames referred to in this prospectus may appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable holder will not assert its rights, to these trademarks and tradenames.

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**PROSPECTUS 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 8, 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.*

**ALDEYRA THERAPEUTICS, INC.**

**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





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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 raise sufficient capital 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.

## **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:

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



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- n 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.
- n 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.
- n 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.
- n 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.
- n We are currently highly dependent on the services of our three senior employees and certain key consultants.
- n 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 8 of this prospectus.

## **Recent Developments**

On January 14, 2015 we completed a private placement for the issuance and sale of 1,113,080 shares of our common stock and warrants to purchase up to 1,113,080 shares of our common stock to a number of institutional and other accredited investors, for gross proceeds of approximately \$7.8 million. On January 21, 2015, we completed a private placement for the issuance and sale of 211,528 shares of our common stock and a warrant to purchase up to 211,528 shares of our common stock to an accredited investor, for gross proceeds of approximately \$2.0 million. As a result, as of March 31, 2015, we had approximately \$15.7 million in cash and cash equivalents.

## **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.

## **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:

- n 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;



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- n 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;
- n reduced disclosure obligations regarding the company's executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- n exemptions from the requirements of holding a non-binding advisory vote on executive compensation; and
- n 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.

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**THE OFFERING**

Common stock offered by us 3,000,000 shares

Common stock to be outstanding after this offering 9,890,021 shares

Overallotment option 450,000 shares

Use of proceeds We intend to use the net proceeds of this offering for research and development activities, including current and additional clinical trials of topically administered NS2, to develop systemic formulations of NS2, to develop novel aldehyde traps distinct from NS2, to expand clinical development and regulatory infrastructure, and for working capital and other general corporate purposes. See Use of Proceeds.

Risk factors You should read the Risk Factors section of this prospectus for a discussion of factors that you should 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 and excludes the following:

- n 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;
- n 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); and
- n 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.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- n no exercise of the outstanding options or warrants; and
- n no exercise by the underwriters of their option to purchase additional shares of our common stock to cover overallotments, if any.





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The following table summarizes our historical financial data as of the dates indicated and for the periods then ended. We have derived the following statement of operations data for the years ended December 31, 2014 and 2013 from our audited financial statements, which are incorporated by reference into this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary of our financial data set forth below should be read together with our financial statements and the related notes to those statements, and the information under Management's Discussion and Analysis of Financial Condition and Results of Operations, which is incorporated by reference into this prospectus.

|   | <b>As of December 31,</b> |                     |                 |
|---|---------------------------|---------------------|-----------------|
|   | <b>2014</b>               | <b>2013</b>         | <b>Change %</b> |
| <b>Financial assets:</b>  |                           |                     |                 |
| Cash and cash equivalents   | \$ 8,527,304              | \$ 3,262,354        | 161%            |
| <b>Total assets</b>   | <b>\$ 8,787,103</b>       | <b>\$ 3,743,233</b> | <b>135%</b>     |
| Accounts payable and accrued expenses   | \$ 1,250,018              | \$ 459,726          | 172%            |
| Notes payable   | 1,253,027                 | 1,187,175           | 6%              |
| <b>Total liabilities</b>  | <b>\$ 2,503,045</b>       | <b>\$ 5,647,261</b> | <b>-56%</b>     |
| Total redeemable convertible preferred stock  |                           | 38,317,298          | -100%           |
| Total stockholders' equity (deficit)  | 6,284,058                 | (40,221,326)        | -116%           |
| <b>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b> | <b>\$ 8,787,103</b>       | <b>\$ 3,743,233</b> | <b>135%</b>     |
| <b>Working capital:</b>   |                           |                     |                 |
| Current assets  | \$ 8,759,872              | \$ 3,270,766        | 168%            |
| Current liabilities   | (1,327,564)               | (605,011)           | 119%            |
| <b>Total working capital</b>  | <b>\$ 7,432,308</b>       | <b>\$ 2,665,755</b> | <b>179%</b>     |
| <b>Cash flows:</b>  |                           |                     |                 |
| Net cash used in operating activities   | \$ (4,775,994)            | \$ (1,706,601)      | 180%            |
| Net cash used in investing activities   | (14,062)                  |                     |                 |
| Net cash provided by financing activities   | 10,055,006                | 3,745,317           | 168%            |
| <b>Net increase (decrease) in cash and cash equivalents</b>   | <b>\$ 5,264,950</b>       | <b>\$ 2,038,716</b> | <b>158%</b>     |
| <b>Income statement:</b>  |                           |                     |                 |
| Research and development  | \$ 3,707,544              | \$ 1,541,681        | 140%            |
| General and administrative  | 3,563,046                 | 2,134,726           | 67%             |
| <b>Loss from operations</b>   | <b>(7,270,590)</b>        | <b>(3,676,407)</b>  | <b>98%</b>      |

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|   |           |            |       |
|---|-----------|------------|-------|
| Change in fair value of preferred stock warrant liabilities                               | 2,327,502 | 720,785    | 223%  |
| Change in fair value of convertible preferred stock rights and rights options liabilities |           | 16,175,386 | -100% |
| Interest income   | 3         | 31         | -90%  |
| Interest expense  | (244,174) | (159,323)  | 53%   |
| Total other income, net   | 2,083,331 | 16,736,879 | -88%  |

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|  | As of December 31, |              | Change % |
|--|--------------------|--------------|----------|
|  | 2014               | 2013         |          |
| Net (loss) income and comprehensive (loss) income                | (5,187,259)        | 13,060,472   | -140%    |
| Accretion of preferred stock                                     | (333,082)          | (822,550)    | -60%     |
| Allocation of undistributed earnings to preferred stockholders   |                    | (11,128,012) | -100%    |
| Deemed dividend  | (4,053,570)        |              |          |
| Net (loss) income attributable to common stockholders            | \$ (9,573,911)     | \$ 1,109,910 | -963%    |
| Net (loss) income per share attributable to common stockholders: |                    |              |          |
| Basic  | \$ (2.51)          | \$ 3.49      | -172%    |
| Diluted  | \$ (3.09)          | \$ (17.61)   | -82%     |
| Weighted average common shares outstanding:                      |                    |              |          |
| Basic  | 3,818,157          | 318,429      |          |
| Diluted  | 3,850,612          | 855,508      |          |

|                            | As of December 31, 2014 |                |
|----------------------------|-------------------------|----------------|
|                            | Actual                  | As Adjusted(1) |
| <b>Balance Sheet Data:</b> |                         |                |
| Cash, cash equivalents     | \$ 8,527,304            | \$ 43,447,452  |
| Working capital            | 7,432,308               | 42,366,694     |
| Total assets               | 8,787,103               | 43,693,013     |
| Additional paid-in capital | 52,790,090              | 87,705,913     |
| Total stockholder s equity | 6,284,058               | 41,204,206     |

(1) The as adjusted column in the balance sheet data as of December 31, 2014 reflects (i) our sale of 3,000,000 shares of common stock in this offering at the assumed public offering price of \$9.27 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the sale by us of an aggregate of 1,324,608 shares of our common stock and warrants to purchase an aggregate of 1,324,608 shares of our common stock in private placements completed in January 2015.

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**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, as of December 31, 2014, we had an accumulated deficit \$46.5 million, and we expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.***

We have incurred significant operating losses since we were founded in 2004 and expect to incur significant losses for the next several years as we continue our clinical trial and development programs for NS2 and our other product candidates. Net (loss) income attributable to common stockholders for the years ended December 31, 2014 and 2013 was approximately \$(9.6) million and \$1.1 million, respectively. As of December 31, 2014, we had total stockholders equity of \$6.3 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if NS2 or any of our other product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

We currently generate no revenue from sales, and we may never be able to commercialize NS2 or our other product candidates. We do not currently have the required approvals to market any of our product candidates and we may never receive them. We may not be profitable even if we or any of our future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***Our business is dependent in large part on the success of a single product candidate, NS2. 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

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future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- n we may not have sufficient financial and other resources to complete the necessary clinical trials for NS2;
- n 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;
- n we may not be able to provide evidence of safety and efficacy for NS2;
- n 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;
- n there may be variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- n 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;
- n patients in our clinical trials may suffer other adverse effects or die for reasons that may or may not be related to NS2;
- n 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
- n we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a New Drug Application (NDA) to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market NS2, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that NS2 will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval for or, if approved, successfully commercialize, NS2, we may not be able to generate sufficient revenue to continue our business.

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

We commenced our first clinical trial in 2010, and we have limited experience developing clinical-stage compounds upon which you can evaluate our business and prospects. In addition, as an early-stage clinical development company, we have limited experience in conducting clinical trials, and we have never conducted clinical trials of a size required for regulatory approvals. Further, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan we will need to successfully:

- n execute our product candidate development activities, including successfully completing our product design and formulation and our clinical trial programs;
- n obtain required regulatory approvals for our product candidates;



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- n 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;
- n secure substantial additional funding;
- n develop and maintain successful strategic relationships;
- n build and maintain a strong intellectual property portfolio;
- n build and maintain appropriate clinical, sales, distribution, and marketing capabilities on our own or through third parties; and
- n 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





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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.

***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

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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:

- n such authorities may disagree with the design or implementation of our or any of our future development partners' clinical trials;
- n 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;
- n 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;
- n the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- n 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;
- n such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- n 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
- n 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

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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:

- n the FDA failing to grant permission to proceed or placing the clinical trial on hold;
- n subjects failing to enroll or remain in our trial at the rate we expect;
- n subjects choosing an alternative treatment for the indication for which we are developing NS2 or other product candidates, or participating in competing clinical trials;
- n lack of adequate funding to continue the clinical trial;
- n subjects experiencing severe or unexpected drug-related adverse effects;
- n 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;
- n any changes to our manufacturing process that may be necessary or desired;
- n 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;
- n 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;
- n 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

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one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of NS2 or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, the FDA or other regulatory authorities, the IRB, other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for a product candidate may be harmed and our ability to generate 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.

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*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:

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

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

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

In addition, if NS2 or any of our other product candidates is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label





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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:

- n demonstration of clinical efficacy and safety compared to other more-established products;
- n the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- n acceptance of a new formulation by health care providers and their patients;
- n the prevalence and severity of any adverse effects;
- n 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;
- n pricing and cost-effectiveness;
- n the effectiveness of our or any future collaborators' sales and marketing strategies;
- n 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;
- n unfavorable publicity relating to the product candidate; and
- n 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:

- n a covered benefit under its health plan;

- n safe, effective, and medically necessary;
- n appropriate for the specific patient;
- n cost-effective; and
- n neither experimental nor investigational.

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Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of the applicable product candidate to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Further, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only in limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for 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.



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

As of December 31, 2014, we had only six full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis, manufacturing, financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

***We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on third parties to conduct the clinical trials for NS2 and clinical trials for our other future product candidates and, therefore, the timing of the initiation and completion of these trials is controlled by such third 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.

***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



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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:

- n 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.
- n 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.
- n 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.



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

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

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

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



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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.

***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:

- n we may not be able to attract and build an effective marketing department or sales force;
- n 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
- n 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

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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.



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

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

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

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:

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



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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.

***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



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successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- n decreased demand for NS2 or our other product candidates;
- n injury to our reputation;
- n withdrawal of clinical trial participants;
- n costs to defend the related litigation;
- n a diversion of management's time and our resources;
- n substantial monetary awards to trial participants or patients;
- n product recalls, withdrawals or labeling, marketing or promotional restrictions;
- n loss of revenue;
- n the inability to commercialize NS2 or our other product candidates; and
- n 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

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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.

***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:

- n issue equity securities that would dilute our current stockholders' percentage ownership;
- n incur substantial debt that may place strains on our operations;
- n spend substantial operational, financial and management resources in integrating new businesses, technologies and products; and
- n 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.



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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce NS2 and our other product candidates. Our ability to obtain clinical supplies of NS2 or our other product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

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

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

## **Risks Relating to Our Intellectual Property**

### ***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent 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.





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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:

- n 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;
- n patent applications may not result in any patents being issued;
- n 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;
- n 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;
- n 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
- n 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 confidentiality 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.



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***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:

- n result in costly litigation;
- n divert the time and attention of our technical personnel and management;
- n cause development delays;
- n 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;
- n require us to develop non-infringing technology; or
- n 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

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prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

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

We are a party to a technology license that is important to our business and we may enter into additional licenses in the future. We currently hold a license from Ligand Pharmaceuticals Incorporated that covers use of an excipient in our eye drops. This license imposes various commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would lose valuable rights under our collaboration agreements and our ability to develop product candidates.

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

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

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

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

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

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

We may not be able to protect our

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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





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costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

### **Risks Related to Our Financial Position and Need for Capital**

*If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize 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:

- n 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;
- n 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;
- n the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- n 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;
- n the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;
- n the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us;
- n costs associated with any other product candidates that we may develop, in-license or acquire;
- n the effect of competing technological and market developments;
- n our ability to establish and maintain partnering arrangements for development; and
- n 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

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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 December 31, 2014. As of December 31, 2014 and December 31, 2013, the outstanding principal balance under the Credit Facility was approximately \$1.4 million. The term loans under the Credit Facility are to be made available to us upon the following terms: (i) \$2,000,000 was made available on November 10, 2014; and (ii) \$3,000,000 (the Tranche B Loan) is to be made available to us following the satisfaction of certain conditions, including receipt of positive phase 2 data in either SLS or noninfectious anterior uveitis. However, we can provide no assurances that we will satisfy the conditions for the Tranche B Loan. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, restrictions on transferring any part of our business or property, changing our business, including changing the composition of our executive team or board of directors, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets and other financial covenants, in each case subject to customary exceptions. If we default under the terms of the loan agreement, including failure to satisfy our operating covenants, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the loan agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments may be limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of our Initial Public Offering.***

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

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### **Risks Related to Our Common Stock and this Offering**

*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:

- n our ability to enroll patients in our planned clinical trials;
- n results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- n regulatory developments in the United States and foreign countries;
- n variations in our financial results or those of companies that are perceived to be similar to us;
- n changes in the structure of healthcare payment systems, especially in light of current reforms to the United States healthcare system;
- n announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- n market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- n sales of our stock by insiders and 5% stockholders;
- n trading volume of our common stock;
- n general economic, industry and market conditions other events or factors, many of which are beyond our control;
- n additions or departures of key personnel; and
- n 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:

- n variations in the level of expenses related to our clinical trial and development programs;
- n addition or termination of clinical trials;
- n any intellectual property infringement lawsuit in which we may become involved;
- n regulatory developments affecting NS2 and our other product candidates;

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- n our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- n nature and terms of stock-based compensation grants; and
- n derivative instruments recorded at fair value.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

***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, including the net proceeds from this offering, 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, including the net proceeds from this offering. 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,



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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.

***You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase.***

The public offering price of our common stock is substantially higher than the net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately \$5.10 per share in net tangible book value of the common stock assuming a public offering price of \$9.27 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015. In the past, we issued options and warrants to acquire common stock at prices significantly below the public offering price. To the extent these outstanding options and warrants are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see Dilution.

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

As of December 31, 2014, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 84.0% of our outstanding common stock. As a result, such persons, acting 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:

- n 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;
- n limiting the removal of directors by the stockholders;
- n creating a staggered board of directors;
- n prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- n eliminating the ability of stockholders to call a special meeting of stockholders;
- n permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- n 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

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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.

Based on shares of common stock outstanding as of March 31, 2015, upon the closing of this offering, we will have outstanding a total of 9,890,021 shares of common stock after this offering, assuming no exercise of the underwriters overallotment option and no exercise of outstanding options and warrants. Of these shares, only the 1,324,608 shares sold by us in private placement transactions in January 2015, the 1,500,000 shares common stock sold by us in our initial public offering and the 3,000,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' overallotment option, will be freely tradable without restriction in the public market immediately following this offering. Up to an additional 4,005,413 of these shares of common stock are eligible for sale in the public market, of which 3,815,461 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, we have registered the 1,384,608 shares of our common stock underlying outstanding warrants and we have registered 1,457,459 shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans, which can be freely sold in the public market upon issuance and once vested, subject to the 90 day lock-up periods to the extent the holder thereof is subject to a lock-up agreement with the underwriters of this offering. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 3,642,799 shares of our outstanding common stock, or approximately 36.8% of our total outstanding common stock as of March 31, 2015 after giving effect



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to this offering, will be entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. Shares of our common stock held by our directors and executive officers will be restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the section of this prospectus titled Shares Eligible for Future Sale.

***In making your investment decision, you should not rely on information in public media that is published by third parties. You should rely only on statements made in this prospectus in determining whether to purchase our shares.***

You should carefully evaluate all of the information in this prospectus. We have in the past received, and may continue to receive, media coverage, including coverage that is not directly attributable to statements made by our officers and employees. We cannot confirm the accuracy of such coverage. You should rely only on the information contained in this prospectus in determining whether to purchase our shares of common stock.

***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



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the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years from our Initial Public Offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

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



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

We have since hired a full time chief financial officer, have implemented the process of formally documenting, reviewing, and improving our internal controls over financial reporting and have made efforts to improve our internal controls and accounting policies and procedures and believe that as of December 31, 2014 that we have remediated the material weakness. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

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

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

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

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



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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the information incorporated by reference in this prospectus contain forward-looking statements that are based on our beliefs and assumptions and on information currently available to us. 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 contained or incorporated by reference in this prospectus. Forward-looking statements include information concerning our possible or assumed future results of operations and expenses, business strategies and plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as may, might, will, objective, intend, should, could, can, would, expect, believe, anticipate, project, target, design, estimate, predict, potential, and other expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in Risk Factors and elsewhere in this prospectus. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our beliefs and assumptions only as of the date of this prospectus.

Meaningful factors which could cause actual results to differ include, but are not limited to:

- n the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- n the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- n the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- n the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- n our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- n the rate and degree of market acceptance of any of our product candidates;
- n our expectations regarding competition;
- n our anticipated growth strategies;

- n our ability to attract or retain key personnel;
- n our ability to establish and maintain development partnerships;
- n our expectations regarding federal, state and foreign regulatory requirements;
- n regulatory developments in the United States and foreign countries;
- n our ability to obtain and maintain intellectual property protection for our product candidates;
- n the anticipated trends and challenges in our business and the market in which we operate; and
- n the use of our cash or cash equivalents, including the expected proceeds from this offering.

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You should read this prospectus, the documents incorporated by reference in this prospectus and the documents that we have filed as exhibits to the registration statement or the documents incorporated by reference in 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.

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 disclaim any obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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**USE OF PROCEEDS**

We estimate that the net proceeds from the sale of shares of our common stock in this offering will be \$25.9 million, based on an assumed public offering price of \$9.27 per share (which was the last reported sale price of our common stock as reported on The NASDAQ Capital Market on May 4, 2015) and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds would be \$29.8 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase or decrease in the assumed public offering price of \$9.27 per share, which is the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015, would increase or decrease the net proceeds to us from this offering by approximately \$2.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each 1,000,000 share increase or decrease in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately \$8.7 million, assuming that the assumed price to the public remains the same, and after deducting estimated underwriting discounts and commissions payable by us. We do not expect that a change in the price to the public or the number of shares by these amounts would have a material effect on uses of the proceeds from this offering, although a decrease in the offering price without a corresponding increase in the number of shares offered may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to obtain additional capital to support our operations. We intend to use the net proceeds of this offering for research and development activities, including current and additional clinical trials of topically administered NS2, to develop systemic formulations of NS2, to develop novel aldehyde traps distinct from NS2, to expand clinical development and regulatory infrastructure, and for working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

Pending use of the proceeds as described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities or certificates of deposit.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development efforts for NS2 and other drug candidates, as well as the amount of cash used in our operations. We therefore cannot estimate the actual amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering.

**Table of Contents****MARKET PRICE OF OUR COMMON STOCK**

Our common stock has been listed on The NASDAQ Capital Market under the symbol **ALDX** since May 2, 2014. Prior to that, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Capital Market:

| <b>Year ending December 31, 2014</b>     | <b>High</b>     | <b>Low</b>     |
|--|-----------------|----------------|
| Second Quarter(1):                       | \$ 8.22         | \$ 6.00        |
| Third Quarter:                           | 7.63            | 3.00           |
| Fourth Quarter:                          | 11.99           | 5.39           |
| <br><b>Year ending December 31, 2015</b> | <br><b>High</b> | <br><b>Low</b> |
| First Quarter:                           | \$ 13.50        | \$ 6.90        |
| Second Quarter(2):                       | 11.79           | 9.15           |

(1) Represents the period from May 2, 2014, the date on which our common stock first began to trade on The NASDAQ Capital Market after the pricing of our initial public offering, through June 30, 2014, the end of our second fiscal quarter.

(2) Represents the period from April 1, 2015 through May 4, 2015.

On May 4, 2015, the closing price for our common stock was \$9.27 per share. As of December 31, 2014, there were 10 holders of record of our common stock.

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**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, and all currently available funds for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, unless waived, the terms of our loan and security agreement with Square 1 Bank do not allow us to pay cash dividends. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in our current or future financing instruments.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of December 31, 2014:

- n on an actual basis; and
- n on an adjusted basis to give effect to (i) the issuance and sale by us of 3,000,000 shares of common stock in this offering, and the receipt of the net proceeds from our sale of these shares at an assumed public offering price of \$9.27 per share, the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, (ii) the sale by us of an aggregate of 1,324,608 shares of our common stock and warrants to purchase an aggregate of 1,324,608 shares of our common stock in private placements completed in January 2015.

The as adjusted information below is illustrative only, and cash and cash equivalents, stockholders' equity and total capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this table in conjunction with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes incorporated by reference.

|   | <b>As of December 31, 2014</b> |                      |
|---|--------------------------------|----------------------|
|   | <b>Actual</b>                  | <b>As Adjusted</b>   |
| Cash and cash equivalents   | \$ 8,527,304                   | \$ 43,447,452        |
| Stockholders' equity:   |                                |                      |
| Preferred stock, \$0.001 par value; 15,000,000 shares authorized, no shares issued and outstanding, actual and as adjusted  |                                |                      |
| Common stock, \$0.001 par value; 150,000,000 shares authorized, 5,565,413 issued and outstanding, actual; 150,000,000 shares authorized, 9,890,021 shares issued and outstanding, as adjusted | 5,565                          | 9,890                |
| Additional paid-in capital  | 52,790,090                     | 87,705,913           |
| Accumulated deficit   | (46,511,597)                   | (46,511,597)         |
| <b>Total stockholders' equity</b>   | <b>\$ 6,284,058</b>            | <b>\$ 41,204,206</b> |

The table above excludes the following shares:

- n 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;
- n 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); and
- n 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.





**Table of Contents****DILUTION**

If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of December 31, 2014 was \$6.3 million, or \$1.13 per share. Net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of December 31, 2014.

After giving effect to (i) the sale by us of an aggregate of 1,324,608 shares of our common stock and warrants to purchase an aggregate of 1,324,608 shares of our common stock in private placements completed in January 2015 and (ii) the sale by us of 3,000,000 shares of common stock in this offering at an assumed public offering price of \$9.27 per share, which is the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2014 would have been \$41.2 million, or \$4.17 per share. This amount represents an immediate increase in net tangible book value of \$3.04 per share to our existing stockholders and an immediate dilution in net tangible book value of \$5.10 per share to new investors purchasing shares of common stock in this offering at the assumed public offering price. The following table illustrates this dilution:

|  |         |         |
|--|---------|---------|
| Assumed public offering price per share  |         | \$ 9.27 |
| Net tangible book value per share as of December 31, 2014  | \$ 1.13 |         |
| Increase in net tangible book value per share attributable to new investors purchasing shares in this offering | 3.04    |         |
| As adjusted net tangible book value per share after this offering  |         | 4.17    |
| Dilution in net tangible book value per share to new investors in this offering                                |         | \$ 5.10 |

A \$1.00 increase or decrease in the assumed public offering price of \$9.27 per share, which is the last reported sale price of our common stock on The NASDAQ Capital Market on May 4, 2015, would increase or decrease our as adjusted net tangible book value per share after this offering by \$0.29 and would increase or decrease dilution per share to new investors by \$0.72, respectively, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. In addition, to the extent any outstanding options or warrants are exercised, new investors will experience further dilution. The information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase up to 450,000 additional shares of common stock at the assumed public offering price of \$9.27 per share, the as adjusted net tangible book value after this offering would be \$4.36 per share, representing an increase in net tangible book value of \$3.23 per share to existing stockholders and immediate dilution in net tangible book value of \$4.91 per share to investors purchasing our common stock in this offering at the assumed public offering price.

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 and excludes the following:



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The table above excludes the following shares:

- n 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;
- n 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); and
- n 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.

To the extent that any outstanding options or warrants are exercised, new investors will experience further dilution.

**Table of Contents****PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 31, 2015 for:

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

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

Applicable percentage ownership is based on 6,890,021 shares of common stock outstanding at March 31, 2015. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options or warrants held by that person or entity that are currently exercisable or that will become exercisable or releasable within 60 days of March 31, 2015. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Aldeyra Therapeutics, Inc., 131 Hartwell Avenue, Suite 320, Lexington, Massachusetts 02421.

| Name of Beneficial Owner                           | Shares Beneficially Owned<br>Prior to Offering |            | Percentage of Shares<br>Beneficially<br>Owned<br>After<br>Offering |
|--|--|------------|--|
|  | Number   | Percentage |  |
| <b>5% or Greater Stockholders</b>                  |  |            |  |
| Funds affiliated with Domain Associates,<br>L.L.C. | 1,992,955(1)                                   | 28.9%      | 20.2%  |
| Johnson & Johnson Development<br>Corporation       | 1,750,292(2)                                   | 25.4%      | 17.7%  |
| FMR LLC  | 834,811(3)                                     | 12.1%      | 8.4%   |
| <b>Executive Officers and Directors</b>            |  |            |  |
| Todd Brady, M.D., Ph.D .                           | 209,111(4)                                     | 3.0%       | 2.1%   |
| Stephen Tulipano                                   |  | *          | *  |
| Scott L. Young                                     | 98,944(5)                                      | 1.4%       | *  |
| Ben Bronstein, M.D .                               | 24,558(6)                                      | *          | *  |
| C. Boyd Clarke                                     | 21,583(7)                                      | *          | *  |
| Martin J. Joyce                                    | 17,555(8)                                      | *          | *  |
| Gary Phillips, M.D.                                | 22,126(9)                                      | *          | *  |
| Jesse Treu, Ph.D .                                 | 1,997,010(10)                                  | 29.0%      | 20.2%  |

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|  |               |       |       |
|--|---------------|-------|-------|
| Neal Walker, D.O .   | 17,307(11)    | *     | *     |
| All current executive officers and directors<br>as a group (9 persons) | 2,408,194(12) | 33.3% | 23.5% |

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

(1) Consists of 10,358 shares of common stock held by Domain Associates LLC, 1,973,389 shares of common stock held by Domain Partners VI, L.P. and 9,208 shares of common stock held by

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

- (2) Linda Vogel, Investment Portfolio Manager, of Johnson & Johnson Innovation-JJDC, Inc. ( JJDC ) exercises voting and dispositive power over the shares held by JJDC. The address of JJDC is: 410 George St., New Brunswick, NJ 08901.
- (3) Consists of (a) 556,516 shares held by Fidelity Select Biotechnology Portfolio and (b) 278,295 shares held by Fidelity Advisor Biotechnology Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ( Fidelity Funds ) advised by Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds Boards of Trustees. The address for Fidelity Select Portfolios: Biotechnology Portfolio is c/o Brown Brothers Harriman & Co., 525 Washington Blvd, Jersey City, NJ 07310. The address for Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund is c/o State Street Bank & Trust, P.O. Box 5756, Boston, MA 02206.
- (4) Includes options to purchase 194,022 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (5) Includes options to purchase 98,944 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (6) Includes options to purchase 12,058 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (7) Includes options to purchase 6,083 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (8) Includes options to purchase 4,055 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (9) Includes options to purchase 12,751 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (10) Includes options to purchase 4,055 shares of common stock that may be exercised within 60 days of March 31, 2015 and securities beneficially owned by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC as set forth in footnote 1 above, for which Dr. Treu may be deemed to share voting and investment power. Dr. Treu disclaims beneficial ownership



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of the securities held by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC except to the extent of his pecuniary interest therein, if any.

- (11) Includes options to purchase 11,057 shares of common stock that may be exercised within 60 days of March 31, 2015.
- (12) Includes options to purchase 343,025 shares of common stock that may be exercised within 60 days of March 31, 2015.



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**SHARES ELIGIBLE FOR FUTURE SALE**

Future sales of shares of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect the market price of our common stock prevailing from time to time. As described below, only a limited number of shares are currently available for sale due to contractual and legal restrictions on resale. Nonetheless, sales of our common stock, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to raise equity capital in the future.

Based on the number of shares outstanding as of March 31, 2015, upon the closing of this offering, 9,890,021 shares of common stock will be outstanding, assuming no exercise of outstanding options or warrants and no exercise of the underwriters' option to purchase additional shares. Of the outstanding shares, all of the shares of common stock sold in this offering (including pursuant to the underwriters' exercise of their option to purchase additional shares), all of the shares of common stock sold in our January 2015 private placement and in our initial public offering, in each case not subject to any lock-up agreements as described below, will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

The remaining shares of our common stock outstanding after this offering are restricted securities, as that term is defined in Rule 144 under the Securities Act, or are subject to lock-up agreements with us as described below. Following the expiration of the lock-up period, restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or 701 promulgated under the Securities Act.

**Rule 144.** In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of ours who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of our common stock for at least six months, but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- n 1% of the number of shares of our common stock then outstanding, which will equal approximately 98,900 shares immediately after the closing of this offering based on the number of common shares outstanding as of March 31, 2015 and assuming no exercise of the underwriters' option to purchase additional shares of our common stock; or
- n the average weekly trading volume of our common stock on The NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.



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**Rule 701.** In general, under Rule 701 of the Securities Act, any of an issuer's employees, consultants or advisors who purchased shares from the issuer in connection with a qualified compensatory stock plan or other written agreement before the effective date of a registration statement under the Securities Act is eligible to resell those shares in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144, and a non-affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about the issuer.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act. In 2014, we filed a registration statement on Form S-1 under the Securities Act to register shares in connection with our initial public offering and a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and other awards issuable pursuant to our equity incentive plans. In 2015, we filed two registration statements on Form S-1 under the Securities Act to register for resale the common stock issued and the common stock underlying the warrants issued in our January 2015 private placements.

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701. However, all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

## **Lock-Up Agreements**

All of our directors and executive officers are subject to lock-up agreements or market standoff provisions that, subject to certain exceptions, prohibit them from offering for sale, selling, contracting to sell, granting any option for the sale of, transferring or otherwise disposing of any shares of our common stock, options or warrants to acquire shares of our common stock or any security or instrument related to our common stock, or entering into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock, for a period of 90 days following the date of this prospectus without the prior written consent of Cowen and Company, LLC. See the section of this prospectus titled "Underwriting."

## **Registration Rights**

Upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, the holders of 3,642,799 shares of our common stock will be entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration.

## **Equity Incentive Plans**

We have filed a Form S-8 registration statement under the Securities Act of 1933, as amended, to register shares of our common stock issued or reserved for issuance under our equity compensation plans and agreements. Accordingly, the shares covered by this registration statement are eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates.



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**MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following summary describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income and estate taxes and does not deal with foreign, state and local consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences other than income and estate taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or integrated investment or other risk reduction strategy, persons subject to the alternative minimum tax or Medicare contribution tax, partnerships and other pass-through entities, and investors in such pass-through entities. Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income and estate tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income and estate tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.

For the purposes of this discussion, a Non-U.S. Holder is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Holder, a partnership (or other entity treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation), nor an entity that is treated as a disregarded entity for U.S. federal income tax purposes (regardless of its place of organization or formation). A U.S. Holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

**Distributions**

Subject to the discussion below, distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally



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will be required to provide us with a properly executed applicable IRS Form W-8, or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If a Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, such Non-U.S. Holder may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce a Non-U.S. Holder's adjusted basis in our common stock, but not below zero, and then will be treated as gain to the extent of any excess, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

**Gain on Disposition of Our Common Stock**

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period. In general, we would be a United States real property holding corporation if interests in U.S. real estate comprised (by fair market value) at least half of our business assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. Even if we are treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will, or will continue to, qualify as regularly traded on an established securities market.

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A Non-U.S. Holder described in (a) above, will generally be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. An individual Non-U.S. Holder described in (b) above, will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though the individual is not considered a resident of the United States).

## **Information Reporting Requirements and Backup Withholding**

Generally, we must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed applicable IRS Form W-8 (and the payor does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed applicable IRS Form W-8 applicable or otherwise meets documentary evidence requirements for establishing Non-U.S. Holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts of tax withheld under the backup withholding rules may be allowed as a refund or credits against the tax liability of persons subject to backup withholding, provided that the required information is timely furnished to the IRS.

## **Foreign Accounts**

A U.S. federal withholding tax of 30% may apply on dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply on dividends and the gross proceeds of a disposition of our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. An intergovernment agreement between the United States and applicable foreign country may modify these requirements. Under certain



circumstances, a Non-U.S. Holder might be eligible for refunds

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or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of these rules for their investment in our common stock.

The IRS has issued guidance providing that the withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2017.

**Federal Estate Tax**

An individual Non-U.S. Holder who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise, even though such individual was not a citizen or resident of the United States at the time of his or her death.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

Table of Contents**UNDERWRITING**

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen and Company, LLC is the representative of the underwriters.

| <b>Underwriter</b>          | <b>Number of Shares</b> |
|-----------------------------|-------------------------|
| Cowen and Company, LLC      |                         |
| Canaccord Genuity Inc.      |                         |
| Janney Montgomery Scott LLC |                         |
| Laidlaw & Company (UK) Ltd. |                         |
| <b>Total</b>                |                         |

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the overallotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Overallotment Option to Purchase Additional Shares.** We have granted to the underwriters an option to purchase up to 450,000 additional shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the sale of common stock offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

**Discounts and Commissions.** The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

We estimate that the total expenses of the offering (which includes up to approximately \$30,000 that we have agreed to reimburse the underwriters for certain expenses incurred in connection with this offering), excluding underwriting discount, will be approximately \$        and are payable by us.

|                                       | <b>Per Share</b> | <b>Total<br/>Without Over-<br/>Allotment</b> | <b>With Over<br/>Allotment</b> |
|---------------------------------------|------------------|--|--------------------------------|
| Public offering price                 |                  |  |                                |
| Underwriting discount                 |                  |  |                                |
| Proceeds, before expenses, to Aldeyra |                  |  |                                |

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The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of \$        per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

**Discretionary Accounts.** The underwriters do not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Our common stock is listed on The NASDAQ Capital Market under the symbol ALDX.

**Stabilization.** In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- n Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.
- n Overallotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing shares in the open market.
- n Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- n Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Stock Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

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In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the Nasdaq Stock Market in accordance with

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Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

**Lock-Up Agreements.** Pursuant to certain lock-up agreements, we and our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, for a period of 90 days after the date of the pricing of the offering.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The exceptions permit parties to the lock-up agreements, among other things and subject to restrictions, to: (a) make certain gifts, (b) if the party is a corporation, partnership, limited liability company or other business entity, make transfers to any shareholders, partners, members of, or owners of similar equity interests in, the party, or to an affiliate of the party, if such transfer is not for value, (c) if the party is a corporation, partnership, limited liability company or other business entity, make transfers in connection with the sale or transfer of all of the party's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the party's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by the lock-up agreement, (d) enter into any trading plan providing for the sale of common stock that meets the requirements of Rule 10b5-1(c) under the Exchange Act, provided that such plan does not provide for, or permit, the sale of any common stock during the lock-up period, and (e) transfers made pursuant to a third party tender offer, merger, consolidation or other similar transaction made to all holders of common stock involving a change of control of the company. In addition, the lock-up provision will not restrict broker-dealers from engaging in market making and similar activities conducted in the ordinary course of their business.

**United Kingdom.** Each of the underwriters has represented and agreed that:

- n it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended) (FSMA) except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority (FSA);
- n it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and

n

it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.



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**Switzerland.** The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

**European Economic Area.** In relation to each Member State of the European Economic Area (the "EEA") which has implemented the European Prospectus Directive (each, a "Relevant Member State"), an offer of our shares may not be made to the public in a Relevant Member State other than:

- n to any legal entity which is a qualified investor, as defined in the European Prospectus Directive;
  - n to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive), subject to obtaining the prior consent of the relevant dealer or dealers nominated by us for any such offer; or
  - n in any other circumstances falling within Article 3(2) of the European Prospectus Directive,
- provided that no such offer of our shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the European Prospectus Directive or supplement prospectus pursuant to Article 16 of the European Prospectus Directive.

For the purposes of this description, the expression an "offer to the public" in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the expression may be varied in that Relevant Member State by any measure implementing the European Prospectus Directive in that member state, and the expression "European Prospectus Directive" means Directive 2003/71/EC (and amendments hereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State. The expression "2010 PD Amending Directive" means Directive 2010/73/EU.

**Israel.** In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728-1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli



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and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

**Electronic Offer, Sale and Distribution of Shares.** A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

**Other Relationships.** Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

Laidlaw & Company (UK) Ltd. acted as the placement agent for our private placement completed on January 14, 2015.

On January 21, 2015, we completed a private placement for the issuance and sale of 211,528 shares of our common stock, at a purchase price of \$9.33 per share, and a warrant to purchase up to 211,528 shares of common stock, at a purchase price of \$0.125 per share subject to the warrant, to an affiliate of Cowen and Company, LLC. The purchase price per share of common stock represents the closing consolidated bid price per share of our common stock as reported on The NASDAQ Capital Markets on the trading day immediately preceding the execution of the purchase agreement for the private placement. The warrant is exercisable for cash at a per share exercise price of \$9.50 per share and expires on January 21, 2018, three years after the date on which it was issued and in compliance with FINRA Rule 5110(f)(2)(G)(i). The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of common stock at a price below the warrant exercise price. The common stock, the warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The affiliate of Cowen and Company, LLC (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate the common stock, the warrant or the securities underlying the warrant, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of these warrants or the underlying securities for a period of 180 days after the effective date of the registration statement for this offering.



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**INDUSTRY AND MARKET DATA**

We obtained the industry, market, and competitive position data throughout this prospectus from our own internal estimates and research, as well as from industry and general publications, in addition to research, surveys, and studies conducted by third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

**LEGAL MATTERS**

The validity of the common stock being offered will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of Boston, Massachusetts. Certain legal matters in connection with this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C., of Boston, Massachusetts. An affiliate of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C. owns an aggregate of 28,654 shares of our common stock.

**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 Registration Statement on Form S-1 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.

**INFORMATION INCORPORATED BY REFERENCE**

We incorporate by reference certain documents we file with the SEC, which means that we are disclosing important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and any information contained in this prospectus or in any document incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or free writing prospectus provided to you in connection with this offering, or in any other document we subsequently file with the SEC that also is incorporated by reference in this prospectus, modifies or supersedes the original statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to be a part of this prospectus.

The following documents filed with the SEC are hereby incorporated by reference in this prospectus:

- n our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 23, 2015 ( Annual Report );
- n our Proxy Statement on Schedule 14A filed with the SEC on April 27, 2015 (excluding those portions that are not incorporated by reference into our Annual Report);
- n our Current Reports on Form 8-K, as filed with the SEC on January 2, 2015, January 13, 2015, January 15, 2015, January 20, 2015, January 22, 2015, March 2, 2015, March 13, 2015, March 17, 2015 and March 19, 2015; and
- n the description of our common stock contained in our Registration Statement on Form 8-A filed 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.

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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.

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

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. The registration statement includes exhibits to which you should refer for additional information about us.

You may inspect a copy of the registration statement and the exhibits and schedules to the registration statement and documents incorporated by reference herein without charge at the offices of the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of the registration statement from the public reference section of the SEC, 100 F Street, N.E., Washington, D.C. 20549 upon the payment of the prescribed fees. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect our registration statement on this website.

We are subject to the information reporting requirements of the Securities Act and are required to file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at [www.aldeyra.com](http://www.aldeyra.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

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**3,000,000 Shares**

**Common Stock**

**PRELIMINARY PROSPECTUS**

*Joint Book-Running Managers*

**Cowen and Company**

**Canaccord Genuity**

*Co-Managers*

**Janney Montgomery Scott**

**Laidlaw & Company (UK) Ltd.**

, 2015

Until , 2015, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.



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

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The NASDAQ Capital Market listing fee.

|                                   |                   |
|-----------------------------------|-------------------|
| SEC registration fee              | \$ 4,300          |
| FINRA filing fee                  | 6,050             |
| NASDAQ Capital Market listing fee | 5,000             |
| Printing and engraving expenses   | 30,000            |
| Legal fees and expenses           | 150,000           |
| Accounting fees and expenses      | 50,000            |
| Transfer agent fees               | 5,000             |
| Miscellaneous fees and expenses   | 19,650            |
| <b>Total</b>                      | <b>\$ 270,000</b> |

**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.

Reference is made to the underwriting agreement contained in Exhibit 1.1 to this registration statement, indemnifying our directors and officers against limited liabilities.

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

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**Table of Contents****Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding the shares of common stock and preferred stock and the warrants issued, and options granted, by us in the three years preceding the filing of this registration statement that were not registered under the Securities Act of 1933.

- (1) Under the 2010 Employee, Director and Consultant Equity Incentive Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: (a) in 2012, we granted stock options to purchase 28,695 shares of our common stock at an exercise price of \$3.24 per share, (b) in 2013, we granted stock options to purchase an aggregate of 446,568 shares of our common stock at an exercise price of \$0.55 per share and (c) in 2013 we granted stock options to purchase an aggregate of 96,042 shares of our common stock at an exercise price of \$4.56 per share.
- (2) In 2013, we issued and sold an aggregate of 387,686 shares of Series B convertible preferred stock to investors for an aggregate purchase price of \$2.0 million.
- (3) In 2012, as consideration for entering into a debt facility, we issued a warrant to Square 1 Bank exercisable for an aggregate of 2,042 shares of our Series A convertible preferred stock at an initial exercise price of \$12.24 per share. This warrant became exercisable for an aggregate of 4,844 shares of our common stock immediately prior to the closing of our public offering.
- (4) In 2012, in connection with our Series B financing, we issued warrants to investors exercisable for an aggregate of 96,921 shares of our Series B convertible preferred stock at an initial exercise price of \$5.16 per share. These warrants became exercisable for an aggregate of 96,921 shares of our common stock immediately prior to the closing of our public offering.
- (5) In 2013, in connection with our Series B financing, we issued warrants to investors exercisable for an aggregate of 96,921 shares of our Series B convertible preferred stock at an initial exercise price of \$5.16 per share. These warrants became exercisable for an aggregate of 96,921 shares of our common stock immediately prior to the closing of our public offering..
- (7) In 2013 we sold an aggregate of 12,948 shares of our common stock to Todd C. Brady, M.D., Ph.D. pursuant to a restricted stock grant under our 2010 Employee, Director and Consultant Equity Incentive Plan.
- (8) In 2013 we issued a convertible promissory note in the principal amount of \$170,000 to Domain Partners VI, L.P. convertible into shares of our common stock in connection with our initial public offering. The note accrued interest at a rate of 6% per annum and converted into shares of our common stock at the initial public offering price per share of the common stock.
- (9) In 2013 as consideration for the amendment to our debt facility, we issued a warrant to Square 1 Bank exercisable for an aggregate of 9,692 shares of our Series B convertible preferred stock at an initial exercise price of \$5.16 per share. This warrant became exercisable for an aggregate of 9,692 shares of our common stock immediately prior to the closing of our public offering.
- (10) On January 14, 2015, we issued and sold 1,113,080 shares of our common stock at a price per share of \$7.00 and warrants to purchase approximately 1,113,080 shares of our common stock at an exercise price of \$9.50 per share in a private placement to accredited investors for an aggregate purchase price of approximately \$7.79 million.
- (11) On January 21, 2015, we issued and sold 211,528 shares of our common stock at a price per share of \$9.33 and a warrant to purchase approximately 211,528 shares of our common stock at an exercise price of \$9.50 per share in a private placement to an accredited investor for an aggregate purchase price of approximately \$2.00 million.

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The offers, sales, grants and issuances of the securities described in paragraphs (1) and (7) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701. The recipients

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of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our 2004 Employee, Director and Consultant Stock Plan and our 2010 Employee, Director and Consultant Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offer, sale, and issuance of the securities described in paragraphs (2), (3), (4), (5), (6), (8), (9), (10) and (11) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act in that the issuance of the security to the accredited investor did not involve a public offering. The recipients of the securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in this transaction. The recipient of the securities in this transaction was an accredited investor under Rule 501 of Regulation D.

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

- (a) **Exhibits.** We have filed, or incorporated into this registration statement on Form S-1 by reference, the exhibits listed on the accompanying Index to Exhibits.
- (b) **Financial Statement Schedules.** All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the consolidated financial statements or related notes.

## **Item 17. Undertakings.**

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 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.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the

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form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

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2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

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Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused Amendment No. 1 to this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on May 5, 2015.

ALDEYRA THERAPEUTICS, INC.

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

**POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

| <b>Signature</b>                                       | <b>Title</b>  | <b>Date</b> |
|--|---|-------------|
| /s/ TODD BRADY, M.D., PH.D.<br>Todd Brady, M.D., Ph.D. | Director, President and Chief<br>Executive Officer<br>(Principal Executive Officer) | May 5, 2015 |
| /s/ STEPHEN TULIPANO<br>Stephen Tulipano               | Chief Financial Officer (Principal<br>Financial and Accounting Officer)             | May 5, 2015 |
| *  | Chairman of the Board of Directors  | May 5, 2015 |
| C. Boyd Clarke   |   |             |
| *  | Director  | May 5, 2015 |
| Ben Bronstein, M.D.                                    |   |             |
| *  | Director  | May 5, 2015 |
| Martin J. Joyce  |   |             |



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| <b>Signature</b>    | <b>Title</b> | <b>Date</b> |
|---------------------|--------------|-------------|
| *                   | Director     | May 5, 2015 |
| Gary Phillips, M.D. |              |             |
| *                   | Director     | May 5, 2015 |
| Jesse Treu, Ph.D.   |              |             |
| *                   | Director     | May 5, 2015 |
| Neal Walker, D.O.   |              |             |

\* By: /s/ Stephen Tulipano  
Stephen Tulipano  
*Attorney-in-fact*

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| <b>Exhibit<br/>Number</b> | <b>Exhibit<br/>Title</b>  |
|---------------------------|---|
| 1.1*                      | Form of Underwriting Agreement  |
| 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  |
| 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)                   |   |

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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)

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| <b>Exhibit<br/>Number</b> | <b>Exhibit<br/>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)  |



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| <b>Exhibit<br/>Number</b> | <b>Exhibit<br/>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 10.20 to the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203536) filed on April 20, 2015)                  |
| 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 the Registrant's Registration Statement on Form S-1 (SEC File No. 333-203536) filed on April 20, 2015  |
| 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.

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