Aldeyra Therapeutics, Inc. Form S-1/A April 25, 2014 Table of Contents

As filed with the Securities and Exchange Commission on April 25, 2014.

Registration No. 333-193204

#### **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 5

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 (State or Other Jurisdiction of 2834 (Primary Standard Industrial 20-1968197 (I.R.S. Employer **Incorporation or Organization**)

Classification Code Number) 15 New England Executive Park **Identification Number**)

Burlington, MA 01803

**Telephone: (781) 270-0630** 

(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.

**15 New England Executive Park** 

Burlington, MA 01803

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(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 "Smaller reporting company x (Do not check if a smaller reporting company)

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

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

#### PRELIMINARY PROSPECTUS

**SUBJECT TO COMPLETION** 

**DATED APRIL 25, 2014** 

1,200,000 Shares

**Common Stock** 

This is the initial public offering of shares of common stock of Aldeyra Therapeutics, Inc. No public market currently exists for our shares. We are offering all of the shares of common stock offered by this prospectus. We expect the public offering price of our shares of common stock to be between \$10.00 and \$12.00 per share.

All common share and per-common-share figures in this prospectus have been adjusted to reflect a 1-for-12 reverse stock split of our outstanding common stock to be effected prior to the consummation of this offering.

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol ALDX.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, we have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> beginning on page 9 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

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.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount and commissions <sup>(1)</sup>	\$	\$
Offering proceeds to us before expenses	\$	\$

(1) Does not include a non-accountable expense allowance equal to 1% of the gross proceeds of this offering payable to Aegis Capital Corp., the representative of the underwriters. See Underwriting for a description of compensation payable to the underwriters.

We have granted a 45-day option to the representative of the underwriters to purchase up to 180,000 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver our shares to purchasers in the offering on or about , 2014.

# Aegis Capital Corp

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from	
contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made availa	ble to

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 logo are our pending trademarks that are used in this prospectus. 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 <sup>®</sup> 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.

#### **PROSPECTUS SUMMARY**

This summary highlights selected information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information you should consider before investing in our common stock. You should read this prospectus carefully, especially the risks set forth under the heading Risk Factors and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. References in this prospectus, unless the context otherwise requires, to Aldeyra, our company, we, us and our and other similar references refer to Aldeyra Therapeutics, Inc. during the periods presented unless the context requires otherwise.

#### ALDEYRA THERAPEUTICS, INC.

#### Overview

We are a biotechnology company focused primarily on the development of products to treat immune-mediated, inflammatory, orphan, and other diseases that are thought to be related to a naturally occurring toxic chemical species known as free aldehydes. We discovered and are developing NS2, a product candidate that is designed to trap and allow for disposal of free aldehydes, for the treatment of Sjögren-Larsson Syndrome (SLS), a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes, and acute anterior uveitis, an inflammatory eye disease.

We believe there is significant unmet medical need for the therapies we intend to develop. We are not aware of any therapy that has been approved by the United States Food and Drug Administration, or the FDA, for SLS. Acute anterior uveitis is often treated with corticosteroids (commonly used anti-inflammatory agents), but prolonged use of corticosteroids can lead to significant morbidity. In addition, SLS and acute anterior uveitis are rare conditions. We intend to request orphan drug designation from the FDA for the drugs that we are developing to treat rare diseases.

NS2 has been tested in a variety of *in vitro* and preclinical models, and has demonstrated the ability to trap free aldehydes, diminish inflammation, reduce healing time, protect key cellular constituents from aldehyde damage, and lower the potential for scarring or fibrosis. NS2 has been tested in a variety of toxicity studies in animals and appears to be generally safe and well tolerated. We are also developing aldehyde traps distinct from NS2 that have the potential to treat diseases other than those described above.

We have evaluated NS2 in a Phase I clinical trial in 48 healthy volunteers where NS2 was observed to be safe and well tolerated when administered as an eye drop up to four times per day over seven days. In 2014, we plan to initiate the following clinical trials, the data from all of which are expected to be available in the second half of 2015:

· Phase II clinical trial with our NS2 eye drop in acute anterior uveitis; and

• Phase II/III clinical trial in SLS with a topical dermatologic formulation of NS2.

We are raising capital to fund these clinical trials with NS2 as well as to develop different aldehyde traps for the treatment of other diseases, and for general corporate purposes. We believe that NS2 has the potential to be the first in class of aldehyde traps for the diseases described above and potentially for inflammatory and other diseases generally. None of our products have been approved for sale in the United States or elsewhere.

### **Risks Related to Our Business**

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

- We have incurred significant operating losses since our inception, and we expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.
- Our business is dependent in large part on the success of a single product candidate, NS2, which has not entered a clinical trial to demonstrate efficacy in humans. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, NS2.
- Because we have limited experience developing clinical-stage compounds, there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects.
- If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize NS2 and our other product candidates.
- The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials, including NS2, may not have favorable results in later clinical trials, if any, or receive regulatory approval.
- Because NS2 and our other product candidates are, to our knowledge, new chemical entities, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of these product candidates and obtain the necessary regulatory approvals for commercialization.
- Aldehyde trapping is an unproven approach, the safety and efficacy of which has not been demonstrated in humans.
- NS2 and our other product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.
- Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

- Any product candidate we or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.
- If our competitors develop treatments for the target indications of our product candidates that are approved more quickly than ours, marketed more successfully or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.
- We are currently highly dependent on the services of our two senior employees and certain key consultants.
- Even if we receive regulatory approval for NS2 or any other product candidate, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, could be limited. For further discussion of these and other risks you should consider before making an investment in our common stock,

see the section titled Risk Factors beginning on page 8 of this prospectus.

### **Our Corporate Information**

Our principal executive offices are located at 15 New England Executive Park, Burlington, MA 01803, and our telephone number is (781) 270-0630. On March 17, 2014, we changed our name from Aldexa Therapeutics, Inc. to Aldeyra Therapeutics, Inc. Our website address is 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 JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- exemption from complying with the auditor attestation requirements under Section 404 of the Sarbanes-Oxley Act, regarding the effectiveness of our internal controls over financial reporting;
- reduced disclosure obligations regarding the company s executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute arrangements not previously approved.
   We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which such fifth anniversary will occur in 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.

## The Offering

Common stock offered by us	1,200,000 shares of our common stock.
Common stock to be outstanding after this offering	5,170,164 shares of our common stock.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 180,000 additional shares of our common stock at the public offering price, less underwriting discounts and commissions.
Use of proceeds	We intend to use the net proceeds of this offering for research and development activities, including our planned clinical trials of NS2, to develop aldehyde traps for the treatment of other diseases and for working capital and other general corporate purposes. See Use of Proceeds.
Dividend policy	We do not currently intend to declare dividends on shares of our common stock. See Dividend Policy.
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

The number of shares of our common stock to be outstanding after this offering is based on 3,970,164 shares of our common stock outstanding as of December 31, 2013 assuming the anticipated conversion of all then outstanding shares of Series A convertible preferred stock and Series B convertible preferred stock into common stock, and excludes:

ALDX

- 609,842 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013, at a weighted-average exercise price of approximately \$1.4795 per share;
- 14,649 shares of common stock reserved for issuance under our 2010 equity incentive plan;

- 625,000 shares of common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, which became effective in October 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan;
- 2,571 shares of common stock to be issued upon the net exercise of outstanding warrants to purchase shares of our Series A convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus and the subsequent conversion of such shares of Series A convertible preferred stock into shares of common stock;
- 108,076 shares of common stock to be issued upon the net exercise of outstanding warrants to purchase shares of our Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus and the subsequent conversion of such shares of Series B convertible preferred stock into shares of common stock;
- 48,000 shares of common stock issuable upon exercise of warrants to be issued to the representative of the underwriters in connection with this offering, at an exercise price per share equal to 125% of the public offering price, as described in the Underwriting Representative s Warrants section of this prospectus; and
- 15,454 shares of common stock issuable upon conversion of a convertible promissory note issued in the original principal amount of \$170,000 at the public offering price per share assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus.

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

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the closing of this offering;
- the automatic conversion of all outstanding shares of our Series A convertible preferred stock into 2,326,118 shares of our common stock immediately prior to the closing of the offering;
- the automatic conversion of all outstanding shares of our Series B convertible preferred stock into 1,316,681 shares of our common stock immediately prior to the closing of the offering;
- a one-for-12 reverse stock split of our common stock to be effected before the completion of this offering;
- no exercise of the outstanding options or the warrants to be issued to the representative of the underwriters described above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock to cover over-allotments, if any.

## SUMMARY FINANCIAL DATA

The following tables set forth, for the periods and as of the dates indicated, our summary financial data. The statements of operations data for the years ended December 31, 2012 and 2013 and the cumulative period from August 13, 2004 (inception) to December 31, 2013 are derived from our audited financial statements included elsewhere in the prospectus. You should read the following information together with the more detailed information contained in Selected Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes included elsewhere in the prospectus. Our historical results are not indicative of the results to be expected in the future.

	Years Ended	Cumulative for the Period from August 13, 2004 (Inception) to December 31,	
	2012	2013	2013
Statements of Operations:			
Operating expenses:			
Research and development(1)	\$ 469,270	\$ 1,541,681	\$ 12,847,149
General and administrative(1)	644,941	2,134,726	6,359,850
Loss from operations	(1,114,211)	(3,676,407)	(19,206,999)
Other income (expenses):			
Change in fair value of preferred stock warrant liabilities	(9,000)	720,785	711,785
Change in fair value of convertible preferred stock rights			
and rights option liabilities	(125,500)	16,175,386	15,539,486
Value provided in excess of issuance price of Series B			
convertible preferred stock	(21,484,762)	-	(21,484,762)
Other income	871	-	250,756
Interest income	101	31	188,738
Other expenses	-	-	(42,566)
Interest expense	(342,014)	(159,323)	(989,151)
Total other income (expenses), net	(21,960,304)	16,736,879	(5,825,714)
Net income (loss) and comprehensive income (loss)	(23,074,515)	13,060,472	(25,032,713)
Accretion of issuance costs on preferred stock	(389,487)	(822,550)	(1,936,637)
Allocation of undistributed earnings to preferred stockholders	-	(11,128,012)	(11,128,012)
Deemed dividend to Series A preferred stockholders	(15,661,898)	-	(15,661,898)
Net income (loss) attributable to common stockholders	\$ (39,125,900)	\$ 1,109,910	\$ (53,759,260)

Net income (loss) per share attributable to common stockholders:			
Basic (2)	\$ (124.44)	\$ 3.49	
Diluted	\$ (124.44)	\$ (17.58)	
Weighted average common shares outstanding:			
Basic (2)	314,419	318,429	
Diluted	314,419	857,183	
Pro forma net income (loss) per share attributable to common stockholders (unaudited): Basic		\$ 2.70	
Diluted		\$ (0.71)	
Pro forma weighted average common shares outstanding (unaudited)			
Basic		4,071,875	
Diluted		4,412,887	

Footnotes on page 8

	As of December 31, 2013				
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)		
Balance Sheet Data:					
Cash and cash equivalents	\$ 3,262,354	\$ 3,262,354	\$ 14,256,354		
Working capital	2,665,755	2,665,755	13,659,755		
Total assets	3,743,233	3,743,233	14,264,766		
Credit facility (net of discount)	1,187,175	1,187,175	1,187,175		
Accrued deferred offering costs	394,368	394,368	-		
Convertible preferred stock warrant					
liabilities	3,518,867	-	-		
Redeemable convertible preferred stock	38,317,298	-	-		
Total stockholders equity (deficit)	(40,221,326)	1,614,839	12,608,839		

The pro forma column in the balance sheet data table above reflects the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,642,799 shares of common stock and the issuance of 110,647 shares of common stock upon the net exercise of outstanding warrants to purchase shares of our Series A convertible preferred stock and Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus and the subsequent conversion of such shares of preferred stock into shares of common stock; and the related reclassification of liabilities related to convertible preferred stock warrant liability and convertible preferred stock warrant liabilities-related parties totaling \$3,518,867 to additional paid-in capital, a component of stockholders equity (deficit).

The pro forma as adjusted column in the balance sheet data table above reflects (1) the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2013 into an aggregate of 3,642,799 shares of common stock upon completion of this offering, (2) the issuance of 110,647 shares of common stock upon the net exercise of outstanding warrants to purchase shares of our Series A convertible preferred stock and Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus and the subsequent conversion of such shares of preferred stock warrant liabilities related to convertible preferred stock warrant liabilities related to convertible preferred stock into shares of common stockholders equity (deficit), and (3) our sale of 1,200,000 shares of common stock in this offering at an assumed initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by approximately \$1.1 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase each of cash and cash equivalents, working capital, total assets and total stockholders equity by approximately \$10.1 million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

The following shares are excluded from the above calculations:

- 609,842 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013, at a weighted-average exercise price of \$1.4795 per share;
- 14,649 shares of common stock reserved for issuance under our 2010 equity incentive plan as of December 31, 2013;
- 625,000 shares of our common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, which became effective in October 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan;

- 48,000 shares of common stock issuable upon exercise of the warrant to be issued to the representative of the underwriters in connection with this offering, at an exercise price per share equal to 125% of the public offering price; and
- 15,454 shares of common stock issuable upon conversion of a convertible promissory note issued in the original principal amount of \$170,000 at the public offering price per share assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus.

*Footnotes from page 6:* 

(1) Includes stock-based compensation as follows:

	Year	Year Ended		
	December 31, 2012	De	cember 31, 2013	
Research and development	\$ 79,415	\$	481,598	
General and administrative	4,986		1,220,115	
Total	\$ 84,401	\$	1,701,713	

(2) Please see Notes 2 and 3 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our actual and pro forma basic and diluted net income (loss) per share attributable to common stockholders, and for the weighted-average number of shares used in the computation of per share amounts.

## **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 in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks is realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment.

#### **Risks Related to our Business**

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

We have incurred significant operating losses since we were founded in 2004 and expect to incur significant losses for the next several years as we continue our clinical trial and development programs for NS2 and our other product candidates. Net income for the year ended December 31, 2013 was approximately \$13.1 million, which includes non-cash income adjustments of \$16.9 million related to the change in fair value of our derivative instrument liabilities. Without these non-cash income adjustments, the net loss for the year ended December 31, 2013 would have been approximately \$3.8 million. As of December 31, 2013, we had a deficit accumulated during the development stage of of approximately \$41.3 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if NS2 or any of our other product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

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

# Our business is dependent in large part on the success of a single product candidate, NS2, which has not entered a clinical trial to demonstrate efficacy in humans. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, NS2.

Our product candidates are in the early stage of development and will require additional preclinical studies, substantial clinical development and testing, and regulatory approval prior to commercialization. We have 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 disposal of free aldehydes, toxic chemical species suspected to cause and exacerbate numerous diseases in humans and animals. We are largely dependent on successful continued development and ultimate regulatory approval of this product candidate for our future business success. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of NS2. We will need to raise sufficient funds for, and successfully enroll and complete, our planned clinical trials of NS2, which we intend to commence in 2014. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for NS2;
- we may not be able to provide evidence of safety and efficacy for NS2;
- the results of our planned clinical trials may not confirm the results of our Phase I trial of NS2 as an eye drop in healthy volunteers, particularly because the safety of NS2 has not been confirmed in a diseased population nor has NS2 been tested in humans in any other dosage form other than an eye drop;
- we have not demonstrated efficacy of NS2 in any clinical trial;
- there may be variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the United States Food and Drug Administration, or FDA, or comparable foreign regulatory bodies for marketing approval;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to NS2;
- if approved for certain diseases, NS2 will compete with well-established products already approved for marketing by the FDA, including corticosteroids and other agents that have demonstrated efficacy in some of the diseases for which we may attempt to develop NS2; and

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

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

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

- execute our product candidate development activities, including successfully completing our clinical trial programs;
- · obtain required regulatory approvals for our product candidates;
- manage our spending as costs and expenses increase due to the performance and completion of clinical trials, attempting to obtain regulatory approvals, manufacturing and commercialization;
- secure substantial additional funding;

- · develop and maintain successful strategic relationships;
- build and maintain a strong intellectual property portfolio;
- build and maintain appropriate clinical, sales, distribution, and marketing capabilities on our own or through third parties; and
- gain broad market acceptance for our product candidates.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business, or continue our operations.

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

Sjögren-Larsson Syndrome (SLS) is a rare disease afflicting an estimated 1 in 250,000 people worldwide, equivalent to approximately 1,000 patients in the United States and a larger number in Europe. SLS is caused by genetic

mutations in an enzyme, Fatty Aldehyde Dehydrogenase (FALDH), that converts long-chain aldehydes into fatty acids. In addition to manifesting what is believed to be severe aldehyde toxicity, SLS patients also have elevated levels of fatty alcohols and may manifest diminished levels of fatty acids.

The dermal pathology of SLS is thought to be due to aldehyde-mediated damage of lipids (fats) that contribute to the formation of the dermal moisture barrier. As a result, SLS patients are thought to lose water from skin, leading to compensatory mechanisms that include proliferation of the superficial layers of skin that may be 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, 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.

# 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 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. NS2 has not been administered to humans by any other route. Further, NS2 has not demonstrated efficacy in humans for any disease. Because NS2 is a novel chemical entity with limited use in humans, short and long-term safety, as well as prospects for efficacy, are poorly understood and difficult to predict due to our and the 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.

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

# Our dermatologic topical formulation of NS2 is unlikely to affect other clinical manifestations of SLS, which may decrease the likelihood of regulatory and commercial acceptance.

While the primary day-to-day complaint of SLS patients and their caregivers are symptoms associated with severe skin disease, SLS patients also manifest varying degrees of mental delay, spasticity 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 we are not able to test NS2 in SLS or in other diseases, we will not be able to initiate clinical trials necessary for demonstrating drug safety and efficacy in patients.

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

We have not submitted an Investigational New Drug (IND) application to investigate NS2 as a topical dermatologic in SLS and we have not amended our active IND for NS2 administered as an eye drop to include acute anterior uveitis. Submission of an IND for NS2 as a treatment for SLS will require new data, including dermatologic toxicity studies, that we have not yet generated. In addition, our active NS2 IND for ocular administration was originally submitted to test an eye disease (the dry form of age-related macular degeneration) other than uveitis and thus the FDA may require new data that we have not yet generated. We are not permitted to test a drug under a new IND in the United States until the FDA has no objection to the initial IND submission. To date, we have completed one Phase I clinical trial for NS2 administered as an eye drop in healthy volunteers. We will have to submit separate INDs for each of the other indications 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.

We currently plan to commence two clinical trials in 2014: a Phase II/III trial of NS2 administered as a topical dermatologic to patients with SLS, and a Phase II trial of NS2 administered as an eye drop to patients with acute anterior uveitis. There is no guarantee that these clinical trials or any other future trials will be allowed by the FDA to proceed or generate successful results, or that regulators will agree with our assessment of the clinical trials for NS2. In addition, we expect to rely on consultants and third party contract research organizations to assist us with regulatory filings and the conduct of our clinical trials. The FDA and other regulators have substantial discretion and may refuse to accept any application or may decide that our current data is insufficient for clinical trial initiation and require additional clinical trials, or preclinical or other studies.

# NS2 and our other product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the

products involved, as well as the target indications, and patient population. Approval policies or regulations may change and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

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

- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our future development partners from commercializing our product candidates.

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

Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing to the FDA as part of an IND application, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. We may rely in part on preclinical, clinical, and quality data generated by contract research organization (CROs) and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates 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, which may lead to additional delays and increase the costs of our preclinical 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 our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

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

- a facility manufacturing NS2, any of our other product candidates or any of their components being ordered by the FDA or other government or regulatory authorities, to temporarily or permanently shut down due to violations of current Good Manufacturing Practices, or cGMP, or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not
  performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol,
  Good Clinical Practice or regulatory requirements, or other third parties not performing data collection or
  analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or the finding of regulatory violations by the FDA or an institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of NS2 or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to 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.

# Even if we obtain marketing approval for NS2 or any other product candidate, it could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidate, when and if any of them are approved.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Following approval, if any, of NS2 or any other product candidates, such candidate will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for NS2 or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- · issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- · refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

• seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

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

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

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

we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

# Even if we receive regulatory approval for NS2 or any other product candidate, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, could be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, is also generally necessary for commercial success. The degree of market acceptance of our product candidates will depend on a number of factors, including:

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

the willingness of patients to pay out-of-pocket in the absence of third-party coverage. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Our efforts to educate the medical community and third-party payors on the benefits of NS2 or any of our other product candidates may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidate will depend on our ability to manufacture our products, differentiate our products from competing products and defend the intellectual property of our products.

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

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor s determination that use of a product candidate is:

• a covered benefit under its health plan;

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

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

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for 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 chose 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 acute anterior uveitis. However, we cannot guarantee that we will be able to receive orphan drug status from the FDA for NS2. If we are unable to secure orphan drug status for NS2 or our other product candidates, our regulatory and commercial prospects may be negatively impacted.

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

We currently have only two 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 Phase II and Phase III 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 rely on medical institutions, clinical investigators, CROs, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that any CROs, investigators, or other third parties on which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

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

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

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

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved, and will likely continue to be dependent on third-party manufacturers. Our dependence on

third parties to manufacture and supply us with clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

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

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

• The manufacturing of compounds is extremely susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Even minor deviations

from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.
- We and our contract manufacturers must comply with the FDA s cGMP regulations and guidelines. We and our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

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

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

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

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

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

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

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of NS2 or our other product candidates. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for NS2 or our other product candidate secure third parties may view the risk of success in our planned clinical trial as too significant or the commercial opportunity for our product candidate as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

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

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. With the exception of SLS, there are a variety of drug candidates in development for the indications that we intend to test. Please refer to the Business Competition section of this prospectus for more information. 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. Acute anterior uveitis may be treated with general immune suppressing therapies, including corticosteriods, some of which are generic. Our potential competitors in these diseases may be developing novel immune modulating therapies that may be safer or more effective than NS2 or our other product candidates.

### 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:

<sup>•</sup> we may not be able to attract and build an effective marketing department or sales force;

 the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by NS2 or any other product candidates that we may develop, in-license or acquire; and

#### our direct sales and marketing efforts may not be successful. We are highly dependent on the services of our two senior 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 two individuals: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer, and Scott L. Young, our Chief Operating Officer. In addition we rely on the services of a number of key consultants, including an IP consultant, a pharmacokinetic consultant, a chemistry consultant, a toxicology consultant, a dermatologic drug development consultant and an ocular drug development consultant. 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. Since our founding in 2004, we have had five employees, one of which left the company and two of which are no longer employees but continue to serve on our board of directors.

We expect to significantly 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 two full-time employees, we will need to grow our organization substantially to continue development and pursue the potential commercialization of NS2 and our other product candidates, as well as function as a public company. As we seek to advance NS2 and other product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, clinical and

regulatory, financial, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to so accomplish could prevent us from successfully growing our company.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates.

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

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

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

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

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

#### the availability of capital.

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed

healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formula managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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

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

We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product candidates. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

We face an inherent risk of product liability as a result of the clinical testing of NS2 and our other product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if NS2 or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

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

<sup>·</sup> decreased demand for NS2 or our other product candidates;

- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- $\cdot$  a diversion of management  $\,$  s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- $\cdot$  loss of revenue;

- · the inability to commercialize NS2 or our other product candidates; and
- a decline in our stock price.

Although we maintain product liability insurance with \$1.0 million in coverage, we plan to increase our product liability insurance coverage prior to initiating the clinical trials described in this prospectus. 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 would require that we and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We and any of our future development partners may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we and any of our future development partners fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

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

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

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

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

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

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed.

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

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

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

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

In addition, during the course of our operations our directors, executives, and employees may have access to material, nonpublic information regarding our business, our results of operations, or potential transactions we are considering. We may not be able to prevent a director, executive, or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive, or employee was to be investigated or an action was 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.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. While we have issued composition-of-matter patents in the United States and other countries for NS2, we cannot be certain that the claims in our patent applications covering composition-of-matter of our other product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are possibly methods that can be employed to trap aldehydes that we have not conceived of or attempted to patent, and other parties may discover and patent aldehyde trapping approaches and compositions that are similar to or different from ours.

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

the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

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

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

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of NS2 or our other product candidates. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- · divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing NS2 or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- · require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of patent infringement against us, others may hold proprietary rights that could prevent NS2 or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or processes could

subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market NS2 or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing NS2 or our other product candidates, which could harm our business, financial condition and operating results.

Any such claims against us could also be deemed to constitute an event of default under our loan and security agreement with Square 1 Bank. In the case of a continuing event of default under the loan, Square 1 Bank could, among other remedies, elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Square 1 Bank under the loan.

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

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

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

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

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

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of NS2 or other product candidates, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and

possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For instance, we have received correspondence from another company claiming that the prior name of our company may be confused with its name and registered marks, and as a result, they may consider challenging one of our trademark applications, and our use of the mark and company name. We did not believe that the name of our company or mark would be confused with the name of such other company or its marks, but recognized that if there is confusion, it may be difficult to protect our rights to such trademark and to build name recognition and our business could be adversely affected, and we could be at risk that such other company may choose to take formal action to try to stop us from using the name of our company or mark. There was also a risk that if there is confusion, the reputation, performance and/or actions of such other company may negatively impact our stock and our business. We therefore have, as of March 2014, adopted a new brand, Aldeyra Therapeutics. 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,

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which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

### If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize NS2 and our other product candidates.

We will require substantial future capital in order to complete the remaining clinical development for NS2 and our other product candidates and to potentially commercialize these product candidates. We expect our spending levels to increase in connection with our clinical trials of NS2, as well as other corporate activities. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our planned clinical trials of NS2 or any our other product candidates which we are pursuing or may choose to pursue in the future;
- the need for, and the progress, costs and results of, any additional clinical trials of NS2 and our other product candidates we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of NS2 and our other product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for NS2 and our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us;
- · costs associated with any other product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments;
- our ability to establish and maintain partnering arrangements for development; and
- the costs associated with being a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources together with the net proceeds from this offering 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. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we will be unable to complete the planned clinical trials for NS2 and our other product candidates and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or some of our technologies or otherwise agree to terms unfavorable to us.

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

We have a \$1.5 million loan and security agreement with Square 1 Bank that is secured by a lien covering all of our assets. As of December 31, 2012 and December 31, 2013, the outstanding principal balance of the Square 1 Bank loan was

approximately \$0.5 million and \$1.4 million, respectively. 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 or suffering a change in the composition of the board of directors such that a least one partner of Domain Associates L.L.C. or its affiliates no longer serves as a voting member any time prior to this offering, 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 the transactions contemplated by this 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 this offering, our preferred stock financings and other transactions, we have experienced, or may upon completion of this offering experience, 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, 2013, we had federal and state net operating loss carryforwards of approximately \$10.9 million and \$9.8 million, respectively, and federal and state research and development credits of approximately \$233,000 and \$25,000, respectively, which could be limited if we experience an ownership change. Any such limitations would generally be equal to our equity value at the time of the ownership change multiplied by a risk-free rate of return published monthly by the IRS.

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

#### An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on The Nasdaq Capital Market, an active trading market for our shares may never develop or be sustained following this offering. If the market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you or at all. 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 materially adversely affect our business.

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

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

- our ability to enroll patients in our planned clinical trials;
- results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;

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

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

#### Our quarterly operating results may fluctuate significantly.

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

- variations in the level of expenses related to our clinical trial and development programs;
- addition or termination of clinical trials;

- any intellectual property infringement lawsuit in which we may become involved;
- · regulatory developments affecting NS2 and our other product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- · nature and terms of stock-based compensation grants; and
- derivative instruments recorded at fair value.

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 after listing 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 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 the net proceeds from this offering, including for any of the purposes described in the section entitled Use of Proceeds, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering 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 the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering 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 initial 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 \$8.61 per share in net tangible book value of the common stock assuming an initial public offering price of \$11.00 per share, the midpoint of the range set forth on the cover of this prospectus. In the past, we issued options and warrants to acquire common stock at prices significantly below the initial 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.

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 70.7% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

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

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for

an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our loan and security agreement with Square 1 Bank currently prohibits us from paying dividends on our equity securities, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

# Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on shares of common stock outstanding as of December 31, 2013, upon the closing of this offering, we will have outstanding a total of 5,170,164 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 1,200,000 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. Aegis Capital Corp., however, may, in its sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, up to an additional 3,970,164 shares of common stock will be eligible for sale in the public market of which 3,655,746 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, 1,234,842 shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. 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 70.5% of our total outstanding common stock as of December 31, 2013, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See Description of Capital Stock Registration Rights. 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.

In addition, we are registering the 48,000 shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering as described in the Underwriting Representative s Warrants section of this prospectus.

# 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 this prospectus and 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 this prospectus and 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC, and The NASDAQ Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend 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 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, we expect these rules and regulations to 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 will be required to report upon the effectiveness of our internal control over financial reporting. When and if we are a large accelerated filer or an accelerated filer and are no longer an emerging growth company, each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company

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

Historically, we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate formally documented accounting policies and procedures to support, effective internal controls. We have 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 are accountants or have 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 commenced 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, including plans to hire new accounting personnel and engage external temporary resources. 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 do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, 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.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are contained principally in Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. In some cases, you can identify forward-looking statements by terms such as may, might, will, objective, intend, should, could, would, can. expect, target. design, potential. plan or the negative of these terms, and similar express project, estimate, predict. intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

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

- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the anticipated trends and challenges in our business and the market in which we operate; and
- our use of proceeds from this offering.

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

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

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

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

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

# **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of the common stock that we are offering will be approximately \$11.0 million, assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range listed on the cover page of this prospectus, and after deducting the 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 our net proceeds will be approximately \$12.8 million. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$1.1 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commissions and estimated offering the estimated underwriting discounts and commi

The principal purposes of this offering are to obtain additional capital to support our operations, create a public market for our common stock, facilitate our future access to the public equity markets and increase our visibility in our markets. We intend to use approximately \$5.0 million of the net proceeds of this offering for research and development activities for NS2, including our currently planned clinical trials of NS2 and development of other molecules that may relate to our aldehyde trapping platform, and the remainder for working capital and other general corporate purposes. We believe that our anticipated research and development expenditures will be sufficient to complete the two clinical trials described in this prospectus, and we believe that each clinical trial will require between \$1.0 million to \$2.0 million to complete. 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.

We believe that the expected net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the next two years, although we cannot assure you that this will occur.

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 related 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.

# **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.

# CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2013 as follows:

- on an actual basis;
- on a pro forma basis to reflect (1) the automatic conversion of all outstanding shares of our Series A convertible preferred stock and Series B convertible preferred stock into 3,642,799 shares of our common stock prior to the closing of this offering, (2) assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, the net exercise of our outstanding warrants to purchase Series A convertible preferred stock and Series B convertible preferred stock and the subsequent automatic conversion of such shares of convertible preferred stock into common stock and the related reclassification of liabilities related to convertible preferred stock warrant liability and convertible preferred stock warrant liabilities-related to parties totaling \$3,518,867 to additional paid-in capital, a component of stockholders equity (deficit), and (3) the filing of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 1,200,000 shares of common stock in this offering at an assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section and other financial information contained in this prospectus.

	As of December 31, 2013					
	Actual Pro Forma (unaudited)		Pro Forma As Adjusted(1) (unaudited)			
Balance Sheet Data:						
Cash and cash equivalents	\$	3,262,354	\$	3,262,354	\$	14,256,354
Credit facility (net of discount)		1,187,175		1,187,175		1,187,175
Convertible preferred stock warrant liability		253,247		-		-
Convertible preferred stock warrant						
liabilities related parties		3,265,620		-		-
Redeemable convertible preferred stock:						
Series A Preferred Stock, \$0.001 par value,		29,291,865		-		-
24,000,000 shares authorized; 980,391 shares						
issued and outstanding (Liquidation						

preference of \$36,000,000) actual; no shares			
·			
authorized, no shares issued and outstanding			
pro forma and pro forma as adjusted			
Series B Preferred Stock, \$0.001 par value,			
38,000,000 shares authorized; 1,316,681			
shares issued and outstanding (Liquidation			
preference of \$20,377,506) actual; no shares			
authorized, no shares issued and outstanding			
pro forma and pro forma as adjusted	9,025,433	-	-
Preferred stock, \$0.001 par value, no shares			
authorized, no shares issued and outstanding,			
actual; 15,000,000 shares authorized, no			
shares issued and outstanding, pro forma and			
pro forma as adjusted	_	-	-
Common stock, voting, \$0.001 par value;			
65,000,000 shares authorized, 327,365 issued			
and outstanding, actual; 150,000,000			
authorized, 4,080,811 issued and			
outstanding, pro forma; 150,000,000			
authorized, 5,280,811 issued and			
outstanding, pro forma as adjusted	327	4,080	5,280

	As of December 31, 2013					
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted(1) (unaudited)			
Common stock, non-voting, \$0.001 par value; 65,000,000 shares authorized, no shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	-	_	_			
Additional paid-in capital	1,102,685	42,935,097	53,927,897			
Deficit accumulated during the development stage	(41,324,338)	(41,324,338)	(41,324,338)			
Total stockholders equity (deficit)	(40,221,326)	1,614,839	12,608,839			
Total Capitalization	\$ 2,802,014	\$ 2,802,014	\$ 13,796,014			

(1)Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders equity (deficit) and total capitalization by approximately \$1.1 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, would increase the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders equity and total capitalization by approximately \$10.1 million.

The number of shares of our common stock in the table above excludes:

- 609,842 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013, at a weighted-average exercise price of \$1.4795 per share;
- 14,649 shares of common stock reserved for issuance under our 2010 equity incentive plan as of December 31, 2013;
- 625,000 shares of our common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, which became effective in October 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan;

- 48,000 shares of common stock issuable upon exercise of the warrant to be issued to the representative of the underwriters in connection with this offering, at an exercise price per share equal to 125% of the public offering price; and
- 15,454 shares of common stock issuable upon conversion of a convertible promissory note issued in the original principal amount of \$170,000 at the public offering price per share assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus.

# DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of December 31, 2013, we had a historical net tangible book deficit of \$(40.2) million, or \$(122.86) per share of common stock. Our historical net tangible book value represents total tangible assets less total liabilities divided by the number of shares of common stock outstanding at December 31, 2013.

On a pro forma basis, after giving effect to the automatic conversion of all outstanding shares of our Series A convertible preferred stock and Series B convertible preferred stock into 3,642,799 shares of our common stock immediately prior to the closing of this offering, the net exercise of currently outstanding warrants to purchase shares of our convertible preferred stock and the subsequent automatic conversion of such shares into shares of our common stock, and the reclassification of our convertible preferred stock warrant liabilities to additional paid-in capital, a component of stockholders equity (deficit), our pro forma net tangible book value as of December 31, 2013 would have been approximately \$1.6 million, or approximately \$0.40 per share of our common stock.

After giving further effect to the sale of 1,200,000 shares of common stock that we are offering at an assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2013 would have been approximately \$12.6 million, or approximately \$2.39 per share. This amount represents an immediate increase in pro forma net tangible book value of \$125.25 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$8.61 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Assumed initial public offering price per share		\$11.00
Historical net tangible book value per share as of December 31, 2013	\$(122.86)	
Pro forma increase in historical net tangible book value per share attributable to		
the pro forma transactions described in preceding paragraphs	123.26	
Pro forma as adjusted net tangible book value per share as of December 31,		
2013	0.40	
Increase in pro forma as adjusted net tangible book value per share attributable		
to new investors giving effect to this offering	1.99	
Pro forma as adjusted net tangible book value per share after giving effect to		
this offering		2.39
Dilution in pro forma as adjusted net tangible book value per share to new		
investors		\$ 8.61

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$0.21, and dilution in pro forma net tangible book value per share to new investors by approximately \$0.79, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Each increase of 1.0 million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by approximately \$1.23 per share and decrease the dilution to investors participating in this offering by approximately \$1.23 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts approximately \$1.23 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated underwriting discounts and commissions and the estimated by us.

If the underwriters exercise their over-allotment option to purchase 180,000 additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be \$2.64 per share, the

increase in pro forma net tangible book value per share to existing stockholders would be \$0.25 per share and the dilution per share to new investors would be \$8.36 per share, in each case assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2013, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid. The calculation below is based on the assumed initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of the prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Pu	Shares Purchased		<b>Total Consideration</b>		
	Number	Percent	Amount	Percent	Per	Share
Existing stockholders	4,080,811	77.3%	\$12,571,086	48.8%	\$	3.08
New investors	1,200,000	22.7%	13,200,000	51.2%		
Total	5,280,811	100.0%	\$25,771,086	100.0%		

The foregoing tables and calculations exclude the following:

- 609,842 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013, at a weighted-average exercise price of \$1.4795 per share;
- 14,649 shares of common stock reserved for issuance under our 2010 equity incentive plan as of December 31, 2013;
- 625,000 shares of our common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, which became effective in October 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan;
- 48,000 shares of common stock issuable upon exercise of the warrant to be issued to the representative of the underwriters in connection with this offering, at an exercise price per share equal to 125% of the public offering price; and
- 15,454 shares of common stock issuable upon conversion of a convertible promissory note issued in the original principal amount of \$170,000 at the public offering price per share assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus.

To the extent any of these outstanding options and warrants are exercised and convertible debt converted, there will be further dilution to new investors. If all of such outstanding options and warrants had been exercised and convertible debt converted as of December 31, 2013, the pro forma as adjusted net tangible book value per share after this offering would be \$2.17, and total dilution per share to new investors would be \$8.83.

If the underwriters exercise their over-allotment option to purchase additional 180,000 shares of our common stock in full in this offering:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 74.7% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will increase to 1,380,000, or approximately 25.3% of the total number of shares of our common stock outstanding after this offering.

# SELECTED FINANCIAL DATA

The following tables set forth selected financial data. We derived the selected statement of operations data for the years ended December 31, 2012 and 2013 and the cumulative period from August 13, 2004 (inception) to December 31, 2013, and the selected balance sheet data as of December 31, 2013 from our audited financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected for any future period.

The following selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	Years Ended I	Cumulative for the Period from August 13, 2004 (Inception) to		
	2012	2013	December 31, 2013	
Statements of Operations:				
Operating expenses:				
Research and development (1)	\$ 469,270	\$ 1,541,681	\$ 12,847,149	
General and administrative (1)	644,941	2,134,726	6,359,850	
Loss from operations	(1,114,211)	(3,676,407)	(19,206,999)	
Other income (expenses):				
Change in fair value of preferred stock warrant				
liabilities	(9,000)	720,785	711,785	
Change in fair value of convertible preferred stock			, , , , , , , , , , , , , , , , , , , ,	
rights and rights option liabilities	(125,500)	16,175,386	15,539,486	
Value provided in excess of issuance price of Series	(,)	, _ , _ , _ , _ , _ , _ ,	,,	
B convertible preferred stock	(21,484,762)	-	(21,484,762)	
Other income	871	-	250,756	
Interest income	101	31	188,738	
Other expenses	-	-	(42,566)	
Interest expense	(342,014)	(159,323)	(989,151)	
The second se		(		
Total other income (expenses), net	(21,960,304)	16,736,879	(5,825,714)	
Net income (loss) and comprehensive income (loss)	(23,074,515)	13,060,472	(25,032,713)	
Accretion of issuance costs on preferred stock	(389,487)	(822,550)	(1,936,637)	
Allocation of undistributed earnings to preferred	, , , ,	( , , ,		
stockholders	-	(11,128,012)	(11,128,012)	
Deemed dividend to Series A preferred stockholders	(15,661,898)	-	(15,661,898)	
t	× , · , · /		( ) ) )	
	\$ (39,125,900)	\$ 1,109,910	\$ (53,759,260)	

Net income (loss) attributable to common stockholders			
Net income (loss) per share attributable to common stockholders:			
Basic (2)	\$ (124.44)	\$ 3.49	
Diluted	\$ (124.44)	\$ (17.58)	
Weighted average common shares outstanding:			
Basic (2)	314,419	318,429	
Diluted	314,419	857,183	
Pro forma net income (loss) per share attributable to common stockholders (unaudited):			
Basic		\$ 2.70	
Diluted		\$ (0.71)	
Pro forma weighted average common shares outstanding (unaudited)			
Basic		4,071,875	
Diluted		4,412,887	

Footnotes on page 46.

	As of December 31, 2013					
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)			
Balance Sheet Data:						
Cash and cash equivalents	\$ 3,262,354	\$ 3,262,354	\$ 14,256,354			
Working capital	2,665,755	2,665,755	13,659,755			
Total assets	3,743,233	3,743,233	14,264,766			
Credit facility (net of discount)	1,187,175	1,187,175	1,187,175			
Accrued deferred offering costs	394,368	394,368	-			
Convertible preferred stock warrant liabilities	3,518,867	-	-			
Redeemable convertible preferred stock	38,317,298	-	-			
Total stockholders equity (deficit)	(40,221,326)	1,614,839	12,608,839			

The pro forma column in the balance sheet data table above reflects (1) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,642,799 shares of common stock and (2) the issuance of 110,647 shares of common stock upon the net exercise of outstanding warrants to purchase shares of our Series A convertible preferred stock and Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and the subsequent conversion of such shares of convertible preferred stock warrant liabilities related to convertible preferred stock warrant liability and convertible preferred stock warrant liabilities-related parties totaling \$3,518,867 to additional paid-in capital, a component of stockholders equity (deficit).

The pro forma as adjusted column in the balance sheet data table above reflects (1) the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2013 into an aggregate of 3,642,799 shares of common stock upon completion of this offering, (2) the issuance of 110,647 shares of common stock upon the net exercise of outstanding warrants to purchase shares of our Series A convertible preferred stock and Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and the subsequent conversion of such shares of convertible preferred stock warrant liability and convertible preferred stock warrant liabilities related to convertible preferred stock warrant liability and convertible preferred stock warrant liabilities related parties totaling \$3,518,867 to additional paid-in capital, a component of stockholders equity (deficit), and (3) our sale of 1,200,000 shares of common stock in this offering at an assumed initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by approximately \$1.1 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$11.00 per share would increase each of cash and cash equivalents, working capital, total assets and total stockholders equity by approximately \$10.1 million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

The following shares are excluded from the above calculations:

- 609,842 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013, at a weighted-average exercise price of \$1.4795 per share;
- 14,649 shares of common stock reserved for issuance under our 2010 equity incentive plan as of December 31, 2013;
- 625,000 shares of our common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, which became effective in October 2013 but with respect to which no awards will be granted prior to the effective date of the registration statement of which this prospectus is a part, subject to automatic annual adjustment in accordance with the terms of the plan;

- 48,000 shares of common stock issuable upon exercise of the warrant to be issued to the representative of the underwriters in connection with this offering, at an exercise price per share equal to 125% of the public offering price; and
- 15,454 shares of common stock issuable upon conversion of a convertible promissory note issued in the original principal amount of \$170,000 at the public offering price per share assuming an initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus.

#### Footnotes from page 44:

(1) Includes stock-based compensation expense related to options granted to employees and others as follows:

	Year	Year Ended			
	December 31, 2012	De	cember 31, 2013		
Research and development	\$ 79,415	\$	481,598		
General and administrative	4,986		1,220,115		
Total	\$ 84,401	\$	1,701,713		

(2) Please see Notes 2 and 3 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our actual and pro forma basic and diluted net income (loss) per share attributable to common stockholders, and for the weighted-average number of shares used in the computation of per share amounts.

# MANAGEMENT S DISCUSSION AND ANALYSIS OF

# FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the Summary Financial Data and our financial statements and notes thereto appearing elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those anticipated by these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this prospectus, including those set forth under Risk Factors and Special Note Regarding Forward-Looking Statements.

#### Overview

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

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

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock, common stock, convertible promissory notes and borrowings under our loan and security agreements. We have incurred losses, before non-cash income adjustments, in each year since our inception. Our net loss was approximately \$23.1 million for the year ended December 31, 2012, and net income was \$13.1 million for the year ended December 31, 2013, which includes non-cash income adjustments of \$16.9 million related to the change in fair value of our derivative instrument liabilities. As of December 31, 2013, we had an accumulated deficit of approximately \$41.3 million. Substantially all of our operating losses resulted from expenses incurred in connection with advancing NS2 through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

# **Financial Operations Overview**

# **Research and Development Expenses**

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- non-clinical development, preclinical research, and clinical trial and regulatory-related costs;
- expenses incurred under agreements with sites and consultants that conduct our clinical trials;
- expenses related to generating, filing, and maintaining intellectual property; and

employee-related expenses, including salaries, benefits, travel and stock-based compensation expense. Substantially all of our research and development expenses to date have been incurred in connection with NS2. We expect our research and development expenses to increase for the foreseeable future as we advance NS2 through clinical

development, including the conduct of our planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of NS2. However, we currently estimate the costs to complete our clinical trials and other research and development described in this prospectus will be approximately \$5.0 million. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

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

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of patients;
- · potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and

• the efficacy and safety profile of the product candidate. We do not expect NS2 to be commercially available, if at all, for the next several years.

# General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Our general and administrative expenses consisted primarily of payroll expenses for our full-time

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employees during the two-year period ended December 31, 2013. Other general and administrative expenses include professional fees for auditing, tax, patent costs and legal services.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and Securities and Exchange Commission requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors and officers liability insurance premiums and fees associated with investor relations.

# Total Other Income (Expense)

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts, interest expense incurred on our outstanding debt and changes in the fair value of our derivative liabilities.

# Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

# Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue research and development expenses. This process involves the following:

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

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

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

We base our expense accruals related to non-clinical development, preclinical studies, and clinical trials on our estimates of the services received and efforts expended pursuant to contracts with organizations/consultants that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts may depend on many factors, such as the successful enrollment of patients, site initiation and the completion of clinical study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

# Stock-Based Compensation

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

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

throughout our calculations. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the simplified method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon United States Treasury securities.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of employee stock option grants in 2012 and 2013 were as follows (no employee stock options were granted in 2011):

	December 31, 2012	December 31, 2013
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	\$3.24 - \$14.64	\$10.56 - \$11.03
Exercise price	\$3.24	\$0.552 - \$4.56
Expected life (years)	7.24	5.47 - 7.85
Risk free interest rate	1.24% - 2.23%	1.71% - 2.34%

The following table summarizes by grant date the number of shares of common stock underlying stock options granted from January 1, 2012 through December 31, 2013, as well as the associated per share exercise price and the estimated fair value per share of our common stock on the grant date:

	Number of Common Shares Underlying Options	Exercise Price per Common	Estimated Fair Value per Common	
Grant Dates	Granted	Share	Share	
June 22, 2012	28,695	\$ 3.24	\$ 3.24	
September 8, 2013 (1)	446,568	\$ 0.552	\$ 0.552(2)	
October 30, 2013	96,042	\$ 4.56	\$ 4.56(3)	

- (1) Our board of directors approved the grant of options to purchase 300,147 shares of common stock on June 21, 2013 at an exercise price of \$3.24 per share (the June Options ) which our board of directors for various business reasons subsequently determined not to issue. On September 8, 2013, our board of directors approved the grant of options to purchase an aggregate of 446,568 shares of our common stock at an exercise price of \$0.552 per share (the September Options ), which were subsequently issued. However, under applicable accounting principles, the June Options were deemed to be granted and modified by the grant of the September Options.
- (2) Our board of directors determined the fair market value of our common stock as of the date of the grant of the September Options to be \$0.552 per share. However, in connection with our accounting relative to the stage of our IPO strategy (for the reasons and per the techniques described elsewhere in this section), we utilized for the purpose of our financial statements the fair market value of our common stock on June 21, 2013 of \$16.68 per share and on September 8, 2013 of \$10.56 per share. The fair market value of our common stock declined from June 21, 2013 to September 8, 2013 due to the August 2013 sale of Series B convertible preferred stock that resulted in, among other things, substantial dilution, increased aggregate Series B convertible preferred stock

liquidation preference, and a decrease in the conversion price of Series A convertible preferred stock.

(3) Our board of directors determined the fair market value of our common stock as of the date of the grant of the October options to be \$4.56 per share. However, in connection with our accounting relative to the stage of our IPO strategy (for the reasons and per the techniques described elsewhere in this section), we utilized for the purpose of our financial statements the fair market value of our common stock on October 30, 2013 of \$11.03 per share.

Total stock-based compensation expense related to unvested stock option grants not yet recognized as of December 31, 2013 was approximately \$4.8 million and the weighted-average period over which these grants are expected to vest is approximately 3.4 years.

# Offering Price Range

In consultation with the underwriters, we determined that our initial public offering price range would be \$10.00 to \$12.00 per share. We believe the difference between the fair market value of our common stock for the October 2013 grant, as determined by our compensation committee, and the initial public offering price range of \$10.00 to \$12.00 per share is a result of the following factors:

- the initial public offering price range necessarily assumed that the offering has occurred and a public market for our common stock has been created, and therefore excludes any marketability or illiquidity discount for our common stock, which was appropriately taken into account in our compensation committee s fair value determinations;
- the fact that, if the probability of the IPO scenario (which modeled expected value one-year post IPO) in the probability-weighted expected returns method (PWERM) utilized by our compensation committee to estimate the fair value of our common stock in connection with the October 2013 grant was adjusted to 100% and discounted back to the IPO date at a 25% discount rate (consistent with the discount rate utilized in connection with the September and October 2013 grants), then the PWERM would have calculated a fair market value of our common stock within the initial public offering price range set forth above; and
- differences in the methodologies, assumptions and inputs used in the price range analysis compared to the valuation methodologies, assumptions and inputs used in the valuations considered by the compensation committee.

Based on an assumed initial public offering price of \$11.00 per share, the midpoint of the initial public offering price range reflected on the cover page of this prospectus, the intrinsic value of stock options outstanding as of December 31, 2013 would be approximately \$5.8 million.

#### Determination of the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations. The fair value of the common stock underlying our stock-based awards was determined on each grant date by our board of directors or compensation committee, taking into account input from management and independent third-party valuation analysis. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants.

Our board of directors or compensation committee, as applicable, considers various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

contemporaneous valuations prepared by independent third-party valuation specialists, effective as of December 31, 2012, March 31, 2013, June 30, 2013, August 31, 2013, September 8, 2013, September 30, 2013 and October 29, 2013;

- the prices of our convertible preferred stock and warrants sold to investors in arm s length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preferences and participation rights of our convertible preferred stock;
- our results of operations, financial position and the status of research and development efforts and achievement of enterprise milestones;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the state of the IPO market for similarly situated privately held biotechnology companies.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been significantly different.

# Common Stock Valuation Methodologies

Our valuations were prepared in accordance with several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of future cash flows that are reasonably reflective of our company s future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. The following market approaches were utilized in our various valuations:

- Guideline public company method. The guideline public company market approach estimates the value of a business by comparing a company to similar publicly-traded companies.
- Guideline transaction method. The guideline transaction market approach estimates the value of a business based on valuations from selected mergers and acquisitions transactions for companies with similar characteristics.
- Precedent transaction method. The precedent transaction market approach estimates the value of a business based on the utilization of a company s own relevant stock transactions.

Each valuation methodology was considered in our valuations. We elected not to utilize the cost approach in any of our valuations since our value relates primarily to our intangible assets.

#### Common Stock Valuation Methodologies Employed Prior to September 30, 2013

On October 23, 2008 and on August 31, 2013, common stock valuation reports were issued by independent valuation firms. Together, the reports summarize a multitude of valuation approaches, including, but not limited to, techniques that employ:

- The Option Pricing Method (as described below)
- Book Value
- · Dissolution Value
- · Market Comparables
- Discounted Cash Flow

June 22, 2012 Grant

On June 22, 2012, our board of directors determined that the fair value of our common stock was \$3.24 per share in connection with the grant of stock options. This valuation was based in part on a valuation report from an independent third-party specialist, dated October 23, 2008, that employed the option pricing method to value our common stock. It was determined that the option pricing method was the most reliable given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development and financial position. The calculation of the fair value of our common stock included a discount for lack of marketability, or DLOM, of 15% based on several empirical restricted stock studies and mathematical models for calculating illiquidity discounts. Because the enterprise value was established relative to the sale price of an illiquid security, the DLOM reflected only an incremental discount for lack of marketability attributed to the illiquidity of the common stock relative to that of the Series A convertible preferred stock.

Despite that the October 2008 valuation report was not contemporaneous, the determination was made by our board of directors that, since the date of the report and the issuance of the options on June 22, 2012, the fair value of our common stock had remained the same since the intervening events in the company, when considered in aggregate, had resulted in neither an increase nor a decrease in common stock value. In addition, at the time of the grant, given that the company had significantly curtailed operating expenses due to the requirement of significant funding within six months to maintain

operations, and given that and no financing opportunities were apparent, our board of directors considered that \$3.24 likely represented the upper bound of the fair value of our common stock and thus was a conservative estimate of fair value.

# September 8, 2013 Grant

Subsequent to the June 2012 grant, we sold an aggregate of 1,316,681 shares of Series B convertible preferred stock for \$5.159 per share and warrants to purchase an additional 203,534 shares of our Series B convertible preferred stock. The sale of Series B convertible preferred stock resulted in substantial dilution and the triggering of, among other things, anti-dilution protection for preferred shares, a lower conversion price for our Series A convertible preferred stock, an increased liquidation preference for preferred shares, and full participation rights for preferred shares. On August 31, 2013, a valuation report from an independent third-party valuation specialist was issued that considered a variety of methodologies to value our common stock, including techniques that employed analyses of the inferiority of common shares relative to preferred shares, book value, liquidation value, discounted cash flows, and market comparables. The report concluded that the fair value of our common stock was \$0.552 per share as of August 31, 2013. Based on the results of the report, on September 8, 2013, our board of directors per our 2010 Employee, Director, and Consultant Equity Incentive Plan approved the grant of options to purchase an aggregate of 446,568 shares of our common stock at an exercise price of \$0.552 per share and determined in good faith that the fair value of our common stock was \$0.552 per share base an aggregate of our common stock was \$0.552 per share on such date.<sup>(1)</sup>

In determining fair value of our common stock relative to our preferred stock, the valuation specialist considered minority representation, lack of board of directors and voting control, inferior dividend preferences, inferior liquidation preferences, inferior registration rights, inferior protective provisions, lack of anti-dilution provisions, lack of pre-emptive rights, and inferior information rights. Comparable public companies were selected from twelve biotechnology companies with indications similar to our indications, and both market values and enterprise values were considered. Discounted cash flows were based on a net present value model of our lead drug provided by management; the model was risk-adjusted based on industry drug development success rates, and cash flow was discounted at 25% to account for competition, the need to raise further capital, marketing execution risk, post-marketing litigation, and other risks inherent in commercialization of novel drugs. At the time of the report, the valuation specialist noted, among other things, that we were exploring the possibility of an IPO, but considered an adjustment to the fair value of our common stock not warranted for the following reasons: there were no IPO-related documents in effect; listing on a major stock exchange may require an increase in valuation that the market might not support; the then-contemplated financing size would not be sufficient to effect mandatory conversion of preferred shares to common shares; and the developmental stage of our technology was earlier than that of most companies in our industry that are able to effect an IPO.

#### Common Stock Valuation Methodologies Employed Subsequent to September 30, 2013

Subsequent to September 30, 2013, in connection with our accounting relative to our IPO strategy, we performed various valuations for dates ranging from December 2012 to December 2013. Since inception, we have issued shares of our Series A convertible preferred stock and Series B convertible preferred stock, warrants to purchase shares of our Series A convertible preferred stock and Series B convertible preferred stock, and options to purchase shares of common stock. The investors that purchased our Series A convertible preferred stock and Series B convertible preferred stock, such rights included 25% warrant coverage. As a result of the Series B preferred investment, Series A preferred stockholders gained certain rights that we have valued, including the increased liquidation preference, full participation rights, and so-called full ratchet anti-dilution protection. In order to establish a consistent series of values to account for the issuances of preferred stock, the right to purchase additional

preferred stock, options to purchase common stock, warrant coverage associated with the right to purchase additional preferred stock, warrants to purchase preferred stock, and the benefit that the

(1) Our board of directors approved the grant of options to purchase 300,147 shares of common stock on June 21, 2013 at an exercise price of \$3.24 per share (the June Options ) which our board of directors for various business reasons subsequently determined not to issue. On September 8, 2013, our board of directors approved the grant of options to purchase an aggregate of 446,568 shares of our common stock at an exercise price of \$0.552 per share (the September Options ), which were subsequently issued. However, under applicable accounting principles, the June Options were deemed to be granted and modified by the grant of the September Options. Per our 2010 Employee, Director, and Consultant Equity Incentive Plan, our board of directors determined in good faith the fair market value of our common stock as of the date of the grant of the September Options to be \$0.552 per share. In connection with our accounting relative to the stage of our IPO strategy and for the reasons and per the techniques described elsewhere in this section, we utilized for the purposes of our financial statements the fair market value of our common stock on June 21, 2013 of \$16.68 per share and on September 8, 2013 of \$10.56 per share.

holders of Series A convertible preferred stock derived from the Series B convertible preferred stock financing, we have employed the option pricing method as well as the probability-weighted expected returns method (PWERM) to estimate the fair value of our common and preferred stock, purchase rights, options, and warrants at various dates. Under the option pricing method, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. The enterprise values used for the option pricing method were derived from the discounted cash flow model described above. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

For valuations for dates prior to August of 2013, the option pricing method was exclusively utilized to allocate the enterprise value to our common stock. It was determined that the option pricing method was the most reliable given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development and financial position. Because defined liquidity events were deemed to be more reliably assessable at subsequent dates, we utilized an average of option pricing methodology and PWERM analyses, weighted equally.

Accordingly, as part of our valuation of the fair value of our common stock as of September 30, 2013, for example, we utilized the PWERM with the following probability-weighted liquidity event scenarios:

Scenario	Weighting
IPO using Guideline Public Company Market Approach	55%
Merger or Sale using Guideline Transaction Market Approach	10%
Private Placement using Precedent Transaction Market Approach	25%
No Value to Common	10%

Total 100% As of September 30, 2013, we had begun preparing for an IPO. However, there continued to be a significant likelihood that an IPO would not be achievable due to our stage of development and market conditions. For the IPO liquidity event scenario, we used pre-money IPO valuations of recent initial public offerings of biotechnology companies, under the guideline public company market approach, to determine our enterprise value and then calculated the common stock value on a fully diluted basis. Using three scenarios of technical success based on market comparables, we then discounted the common stock value to present value using a cost of capital of 25%, based on several empirical studies assessing cost of capital for venture-backed pre-IPO companies. The period of discount was based on the expected timing of the next significant technological milestone.

We also considered the potential of a merger or sale. However, in order to prepare for an IPO, we diverted significant time and resources from ongoing merger or sale efforts. Further, the odds a merger or sale are higher for companies with technology more advanced than ours, and as of September 30, 2013, the probability of achieving an IPO was deemed to be considerably higher. For the merger or sale liquidity event scenario, we used the market approach based on a guideline transaction market approach to determine our enterprise value. The guideline transaction market approach to determine our enterprise value. The guideline transaction market approach was based on the enterprise price paid in emerging pharmaceutical and biotechnology acquisitions over approximately the past four years, where the enterprise price paid included any contingent consideration after risk-adjustment for success rates in clinical development. We then discounted the common stock value to present value using a cost of capital of 25%, as described above.

We also utilized the no value to common scenario that contemplated circumstances resulting from technical failure or from our inability to raise additional funding in order to sustain operations. For the no value to common scenario, we used an assumed liquidation for net asset value to determine our enterprise value. This scenario assumes a liquidation of the business, where our preferred stockholders would recover a portion of their original investment through a sale of our assets, but no value would remain available for distribution to holders of our common stock.

Finally, we utilized a precedent transaction market approach to model a private placement, which was then followed by a merger or sale or liquidation, the odds of each were equal, reflecting the relative odds of merger or sale and liquidation in the table above. The private placement was estimated to occur on terms representative of recent discussions as relayed by our

management. The fact that such discussions had occurred suggested to us that the probability of a private placement was higher than either merger or sale or liquidation. The same values for merger or sale or liquidation outcome described above were employed in this model, and we then discounted the common stock value to present value using a cost of capital of 25%, as described above.

To determine the fair value of our common stock, a DLOM of 30% was used in all merger or sale and IPO scenarios based on several empirical restricted stock studies and mathematical models for calculating illiquidity discounts. For all merger or sale and IPO scenarios, we employed varying assumptions in probability modeling that accounted for a portion of lack of marketability, and thus the DLOM reflected an incremental discount for lack of marketability attributed to the illiquidity of the common stock.

### October 30, 2013 Grant

On October 29, 2013, a valuation report from an independent third-party valuation specialist was issued that considered a variety of methodologies to value our common stock, including techniques that employed analyses of the inferiority of common shares relative to preferred shares, book value, liquidation value, discounted cash flows, and market comparables. In addition, the PWERM was employed. The report concluded that the fair value of our common stock was \$4.56 per share as of October 29, 2013. Based on the results of the report, on October 30, 2013, our Compensation Committee per our 2010 Employee, Director, and Consultant Equity Incentive Plan approved the grant of an option to purchase an aggregate of 96,042 shares of our common stock at an exercise price of \$4.56 per share and determined in good faith that the fair value of our common stock was \$4.56 per share on such date.

In determining fair value of our common stock relative to our preferred stock, the valuation specialist considered minority representation, lack of board of directors and voting control, inferior dividend preferences, inferior liquidation preferences, inferior registration rights, inferior protective provisions, lack of anti-dilution provisions, lack of pre-emptive rights, and inferior information rights. Book value was considered with and without liquidation preferences. Comparable public companies were selected from twelve biotechnology companies with indications similar to our indications, and both market values and enterprise values were considered. Discounted cash flows were based on a net present value model of our lead drug provided by management; the model was risk-adjusted based on industry drug development success rates, and cash flow was discounted at 25% to account for competition, the need to raise further capital, marketing execution risk, post-marketing litigation, and other risks inherent in commercialization of novel drugs.

The PWERM was utilized as described above, with the following probability-weighted liquidity event scenarios:

Scenario	Weighting
IPO using Guideline Public Company Market Approach	60%
Merger or Sale using Guideline Transaction Market Approach	5%
Private Placement using Precedent Transaction Market Approach	20%
No Value to Common	15%
Total	100%

Minor changes in the PWERM scenario weightings were made relative to the weightings of the September 30, 2013 PWERM. The probability of an IPO increased from 55% to 60% given the progress made in preparing for the filing of a confidential draft registration statement and in other activities requisite for an IPO. Because of resources diverted from achieving technical milestones and merger and sale-related activities, the probability of a merger or sale decreased from 10% to 5%. Due to an increased IPO weighting, private placement odds were decreased from 25% to

20%. Finally, as the probabilities of merger or sale and private placement decreased, and the dependence on an IPO increased, the odds of liquidation resulting in no value to common increased from 10% to 15%.

*Warrant Liability.* Freestanding warrants for the purchase of convertible preferred stock that is either subject to a put right or redeemable are classified as liabilities on the balance sheet at their estimated fair value. At the end of each reporting period, changes in estimated fair value during the period are recorded as a component of other income (expense). As of December 31, 2012 we had outstanding warrants exercisable to purchase 2,042 shares of our Series A convertible preferred stock and 96,921 shares of our Series B convertible preferred stock and as of December 31, 2013, we had outstanding warrants exercisable to purchase 2,042 shares of our Series A convertible preferred stock and so of December 31, 2013, we had outstanding warrants exercisable to purchase 2,042 shares of our Series A convertible preferred stock and 203,534 shares of our Series B convertible preferred stock. We estimate the fair values of the convertible preferred stock warrants using the Black-Scholes

option pricing model based on inputs as of the valuation measurement dates for the estimated fair value of the underlying convertible preferred stock, the remaining contractual terms of the warrants, risk-free interest rates, expected dividend rates and the estimated volatility of the price of the convertible preferred stock. Since these warrants are subject to liability treatment, they will be re-valued using the Black-Scholes option pricing model as of each future reporting period until they are no longer subject to liability accounting. We have entered into an agreement with the warrant holders whereby such holders have agreed to net exercise the warrants effective and contingent upon the consummation of this offering.

The following assumptions were used in the Black-Scholes option pricing model to determine the fair value of the preferred stock warrant liability for warrants to purchase shares of Series A convertible preferred stock, which expire 7 years from the date of grant and were issued on April 12, 2012 (there were no warrants to purchase shares of Series A convertible preferred stock outstanding in 2011):

		Year Ended December 31,	
	2012	2013	
Assumed Risk-Free Interest Rate	1.0%	1.75%	
Assumed Volatility	89%	89%	
Remaining Contractual Term in Years	6.3	5.3	
Expected Dividend Yield	0.0%	0.0%	
Current Price	\$48.48	\$45.20	
Exercise Price	\$12.24	\$12.24	
The following assumptions were used in the Pleak Scholes ontion	priving model to determine the fair vel	up of the	

The following assumptions were used in the Black-Scholes option pricing model to determine the fair value of the preferred stock warrant liability for warrants to purchase shares of Series B convertible preferred stock, which expire 5 to 7 years from the date of grant and were issued on December 20, 2012, August 14, 2013 and November 20, 2013:

	Year Ended December 31,	
	2012	2013
Assumed Risk-Free Interest Rate	0.7%	0.78% - 2.45%
Assumed Volatility	89%	89%
Remaining Contractual Term in Years	5.0	4.0 - 6.9
Expected Dividend Yield	0.0%	0.0%
Current Price	\$25.56	\$19.92
Exercise Price	\$5.16	\$5.16

*Series A and Series B Preferred Stock Purchase Rights.* As part of both Series A convertible preferred stock and Series B convertible preferred stock financings, investors were granted rights to invest further capital at the same price as the initial investment within finite periods of time. These rights were valued using Black-Scholes methodology, as described above.

The first tranche of our Series A convertible preferred stock financing was invested on June 23, 2008, and at that time investors were given the rights to invest a second tranche of capital: 248,311 shares of Series A convertible preferred stock at \$12.24 per share, the same price as the first tranche. The second investment tranche was to be triggered at a financial milestone that, at the time of the grant of the right, was thought to be met in approximately two years. The

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milestone was met sooner than anticipated at the time of the grant of the right, and the second tranche was triggered on February 1, 2010.

The first tranche of our Series B convertible preferred stock financing was invested on December 20, 2012, and at that time investors were given the right to invest a second tranche of capital: 928,995 shares of Series B convertible preferred stock at \$5.16 per share, the same price as the first tranche. In addition, 25% warrant coverage was granted for share purchases in the first and second tranches. A second tranche of capital was invested on August 14, 2013, at which time investors elected to purchase 387,686 shares of Series B convertible preferred stock at \$5.16 per share. The right to purchase the remaining 541,308 shares of Series B convertible stock subject to the right expired on October 1, 2013. The following

assumptions were used in the Black-Scholes option pricing model to determine the fair value of the Series B convertible preferred stock purchase right (as described above, there were no such Series B convertible preferred purchase rights outstanding in 2011 or as of December 31, 2013):

	Year Ended December 31, 2012
Assumed Risk-Free Interest Rate	0.1%
Assumed Volatility	89%
Remaining Contractual Term in Years	0.8
Expected Dividend Yield	0.0%
Current Price	\$25.56
Exercise Price	\$5.16
The Black-Scholes option pricing model was also utilized to value the warrant coverage o	n the Series B convertible

preferred stock purchase rights. For the Black-Scholes calculations, the current share price was the result of the Black-Scholes option pricing model warrant valuations described above, and the exercise price was zero. The following assumptions were used in the Black-Scholes option pricing model to determine the fair value of the warrant coverage on the Series B convertible preferred stock purchase rights (as described above, there were no such Series B purchase rights outstanding in 2011 or as of December 31, 2013):

	Year Ended December 31,
	2012
Assumed Risk-Free Interest Rate	0.1%
Assumed Volatility	89%
Remaining Contractual Term in Years	0.8
Expected Dividend Yield	0.0%
Current Price	\$22.44
Exercise Price	\$0.00
Valuation of Benefit to Series A Convertible Preferred Stockholders as a	Result of the Series B Preferred Financing

Valuation of Benefit to Series A Convertible Preferred Stockholders as a Result of the Series B Preferred Financing. When the second tranche of the Series B convertible preferred stock financing was completed on December 20, 2012, the rights of the Series A convertible preferred stock were modified as follows: broad-based weighted-average anti-dilution protection was increased to full-ratchet anti-dilution protection; 1x liquidation preference was increased to 3x liquidation preference; and capped (3x purchase price, including liquidation preference) participation rights were increased to full participation rights.

We employed the option pricing method to calculate the fair value of a share of Series A convertible preferred stock on December 20, 2012 before and after the above modifications. The difference between the two values represents the benefit to the Series A convertible preferred stock on a per share basis as a result of the above modifications. It was determined that the option pricing method was the most reliable valuation technique for this purpose given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development and financial position. We then discounted the results by a 15% DLOM for preferred shares based on several empirical restricted stock studies and mathematical models for calculating illiquidity discounts. Since some degree of lack of marketability was inherent in our assumptions for the option pricing method, the DLOM reflected an incremental discount for lack of marketability attributed to the illiquidity of the Series A convertible preferred stock.

## **Other Information**

### Net Operating Loss Carryforwards

As of December 31, 2013 we have Federal and State income tax net operating loss ( NOL ) carryovers of approximately \$10.9 million and \$9.8 million, respectively, which will expire at various dates through 2033. As of

December 31, 2013 we have Federal and State tax carryovers of credits for increasing research activities (R&D tax credits) of approximately \$233,000 and \$25,000, respectively, which will expire at various dates through 2033.

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

### JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period 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.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board (PCAOB) regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (c) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

### **Results of Operations**

### Comparison of Years Ended December 31, 2012 and 2013

The following table summarizes the results of our operations for the years ended December 31, 2012 and 2013:

	Year Ended December 31,		Increase/	
		2012	2013	(Decrease)
Research and development	\$	469,270	\$ 1,541,681	\$ 1,072,411
General and administrative		644,941	2,134,726	1,489,785
Other income (expense):				
Other income (expenses)		871	-	(871)

Interest income	101	31	(70)
Interest expense	(342,014)	(159,323)	182,691
Change in fair value of warrant liability	(9,000)	720,785	729,785
Change in fair value of convertible preferred			
stock rights and rights option liabilities	(125,500)	16,175,386	16,300,886
Value provided in excess of issuance price of			
Series B convertible preferred stock	(21,484,762)	-	21,484,762
_			

Total other income (expense)\$ (21,960,304)\$ 16,736,879\$ 38,697,183Research and Development Expenses.Research and development expenses were \$469,270 for the year endedDecember 31, 2012 compared to \$1.5 million for the year ended December 31, 2013. The increase of \$1.1 million isprimarily related to the increase in our external research and development expenditures and stock-basedcompensation.

Specifically, during the year ended December 31, 2013, we expanded our testing of NS2 and our other product candidates in a variety of preclinical models in an effort to more broadly characterize the effects of aldehyde trapping. In addition, we awarded options to purchase common stock to an employee involved in research and development activities.

*General and Administrative Expenses.* General and administrative expenses were \$644,941 for the year ended December 31, 2012, compared to \$2.1 million for the year ended December 31, 2013. The increase of \$1.5 million is primarily related to legal, consulting and stock-based compensation for employee expenses incurred during the year ended December 31, 2013. Specifically, we incurred internal costs associated with the Series B convertible preferred stock financing and stock-based compensation associated with the financing.

*Other Income (Expense).* Total other income (expense) was \$(22.0) million for the year ended December 31, 2012 and primarily consisted of the expense associated with the excess fair value over purchase price provided to the purchasers of our Series B convertible preferred stock in the December 20, 2012 tranche to the holders of our Series A convertible preferred stock. Total other income (expense) was \$16.7 million for the year ended December 31, 2013 and primarily consisted of the change in fair market value of our derivative liabilities. Convertible preferred stock rights and rights option liabilities, described elsewhere in this prospectus, are non-recurring liabilities associated with our preferred stock financings. Such liabilities were recorded through October 1, 2013, at which time the rights expired. If future preferred stock financings occur, and we decide to offer purchase rights, similar liabilities may be recorded.

## Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and convertible equity securities and borrowings under our loan and security agreement. Through December 31, 2013, we have received approximately \$12.0 million in net proceeds from the sale of our Series A convertible preferred stock and approximately \$6.8 million in net proceeds from the sale of our Series B convertible preferred stock, including proceeds from debt which were converted into Series A and Series B preferred stock, respectively. We have incurred losses since inception and negative cash flows from operating activities. As of December 31, 2013, we had approximately \$3.3 million in cash and cash equivalents, working capital of \$2.7 million and an accumulated deficit of \$41.3 million.

In October 2013, we issued a convertible promissory note to Domain Partners VI, L.P., in the principal amount of \$170,000, which was amended in February 2014 to extend its maturity date. The note accrues interest at a rate of 6% per annum, and will convert into shares of Series B convertible preferred stock in June 2014 unless it is converted into shares of our capital stock prior to such time pursuant to its terms. The terms of the convertible promissory note provide that it shall convert into shares of our common stock, immediately prior to the closing of this offering at a price per share equal to the initial offering price per share for our common stock listed on the cover page of this prospectus.

In April 2012, we entered into a \$500,000 loan and security agreement with Square 1 Bank which is collateralized by all of our assets. Interest on advances under the agreement is equal to the greater of (A) 2.75% above the prime rate then in effect or (B) 6.50%. The interest rate since inception of the loan has been in accordance with (B), 6.50%. In November 2013, we amended this loan and security agreement to provide for up to an additional \$1.0 million to be available for drawdown. As of September 30, 2013, we had drawn down \$500,000 under the agreement to fund working capital. We subsequently drew an additional amount of \$1.0 million in connection with the amendment to the loan and security agreement executed in November 2013 and have no credit available for future borrowings. In connection with the loan and security agreement entered into in April 2012, we issued a warrant to Square 1 Bank which was immediately exercisable for an aggregate of 2,042 shares of our Series A convertible preferred stock, at an

exercise price of \$12.24 per share. The warrant will automatically be adjusted to provide for the purchase of an aggregate of 4,844 shares of our common stock immediately prior to the closing of this offering. In addition, in connection with the amendment to the loan and security agreement executed in November 2013, we issued an additional warrant to Square 1 Bank which was immediately exercisable for an aggregate of 9,692 shares of our Series B convertible preferred stock, at an exercise price of \$5.1588 per share. The warrant will automatically be adjusted to provide for the purchase of an aggregate of 9,692 shares of our common stock immediately prior to the closing of this offering.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. In the near-term, we anticipate that our expenses will increase substantially as we:

- initiate significant clinical trials associated with NS2 and our other product candidates, including the NS2 clinical trials that we currently plan to initiate in 2014;
- hire additional staff, including a chief financial officer and additional administrative, financial and accounting, clinical and scientific personnel; and

· maintain, expand and protect our intellectual property portfolio.

To fund further operations we will need to raise additional capital. The expected net proceeds from this offering will not be sufficient for us to complete clinical development for any potential product or any substantial, additional development requirements requested by the FDA. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued clinical development of NS2. However, we currently estimate the costs to complete our clinical trials currently expected to be initiated in 2014 will be approximately \$5.0 million. Subsequent trials initiated at a later date will cost considerably more, depending on the results of our prior clinical trials, and feedback from the FDA or other third parties. Accordingly, we will continue to require substantial additional capital beyond the expected proceeds from this offering to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant additional liens on certain of our assets that may limit our flexibility. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

The following table summarizes of our cash flows for the years ended December 31, 2012 and 2013:

	Years Ended December 31,	
	2012	2013
Net cash used in operating activities	\$ (778,046)	\$(1,706,601)
Net cash provided by financing activities	1,750,729	3,745,317
Net increase in cash and cash equivalents	\$ 972,683	\$ 2,038,716

*Operating Activities.* Net cash used in operating activities was \$778,046 for the year ended December 31, 2012 compared to net cash used in operating activities of \$1.7 million for the year ended December 31, 2013. The primary use of cash was to fund our operations.

*Financing Activities.* Net cash provided by financing activities was \$1.8 million for the year ended December 31, 2012 compared to net cash provided by financing activities of \$3.7 million for the year ended December 31, 2013. Net cash provided by financing activities for the year ended December 31, 2012 was the result of proceeds from the Square 1 Bank loan that closed in April 2012 and proceeds from the sale of our Series B convertible preferred stock. Net cash provided by financing activities for the year ended December 31, 2013 was the result of proceeds from our Series B convertible preferred stock financing, proceeds from the issuance of a convertible note to a related party and an increase in the credit facility with Square 1 Bank.

We believe that our existing cash and cash equivalents as of December 31, 2013, together with interest thereon, and the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through 2015 based on our current business plans. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and

uncertainties, and actual results could vary materially.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the initiation, progress, costs, results of and timing of our clinical development program for NS2 and our other product candidates, including our planned clinical trials expected to be initiated in 2014 to assess NS2 when administered topically to patients with SLS and acute anterior uveitis;
- the need for, and the progress, costs and results of, any additional clinical trials of NS2 we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of NS2;

- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing NS2 for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development and scientific personnel;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the timing and costs associated with establishing sales and marketing capabilities;
- market acceptance of NS2;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- our need to remediate any material weaknesses and implement additional internal systems and infrastructure, including financial and reporting systems.

### **Off-Balance Sheet Arrangements**

Through December 31, 2013, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

## **Contractual Obligations**

Our long-term debt obligation consists of amounts we are obligated to repay under our loan and security agreement with Square 1 Bank, of which we have drawn the amount of \$1.5 million with an outstanding balance of \$1.4 million as of December 31, 2013. Unless principal is paid in advance, the loan requires interest only payments of approximately \$7,500 a month until December 2014 when principal and interest payments become due of approximately \$58,160 through November 2016.

As of December 31, 2013, we had no operating lease commitments.

## BUSINESS

### Overview

Aldeyra was formed as a Delaware corporation in 2004, and from inception until December 20, 2012, we operated as Neuron Systems, Inc. and from December 2012 until March 2014 we operated as Aldexa Therapeutics, Inc. Since our incorporation, we have devoted substantially all of our resources to the preclinical and clinical development of our product candidates. Our ability to generate additional revenues largely depends upon our ability, alone or with others, to complete the development of our product candidates to obtain the regulatory approvals for and to manufacture, market and sell our products and product candidates. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business and industry, risks relating to intellectual property and other legal matters, risks related to our common stock, and other risks that are detailed in the section of this 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 species known as free aldehydes. We have developed a series of product candidates that are designed specifically to trap and allow for the disposal of free aldehydes. In 2014, we plan to begin clinical testing of one of our product candidates 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 test are rare, we intend to request orphan drug designation from the United States Food and Drug Administration (FDA).

We intend to test our most advanced product candidate, NS2, for the treatment of a disease called Sjögren-Larsson Syndrome (SLS), a rare condition that we believe afflicts approximately 2,000 patients in the United States and Europe, collectively. The disease is caused by mutations in an enzyme that metabolizes fatty (generally 16-18 carbon) free aldehydes, resulting in high levels of toxic fatty aldehydes that are the suspected cause of severe skin disease, mental delay, spasticity, and, in some patients, retinal dysfunction. NS2 has demonstrated fatty aldehyde trapping in human skin cells in preclinical studies. In order to attempt to improve the dermatologic symptoms of SLS, we plan to initiate Phase II/III clinical testing of NS2 applied topically to the skin of SLS patients beginning in 2014. We are not aware of any therapy for SLS that has been approved by the FDA.

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

We believe that diseases of the eye may also be mediated in part by free aldehyde toxicity. We have developed an eye drop formulation of NS2 that has completed Phase I clinical testing for safety and tolerability in healthy volunteers. In 2014, we plan to initiate Phase II clinical trials of the NS2 eye drop formulation in a severe and, we believe, poorly treated ocular disease called acute anterior uveitis. In acute anterior uveitis, aldehydes may mediate, at least in part, inflammation, fibrotic changes, and lipid destruction leading to dryness and surface irritation. Patients with acute 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 severe cases, lead to blindness).

### **Business Strategy**

We intend to develop NS2 and other novel aldehyde traps for the diseases described above as well as potentially other diseases where aldehydes may mediate pathology. We believe that aldehyde trapping is a novel approach with broad therapeutic potential across immune-mediated, inflammatory, orphan and other diseases. Accordingly, we have attempted and will continue to attempt to patent novel drug compositions, formulations, and methods that relate to aldehyde trapping. While we may continue to develop and eventually attempt to market aldehyde traps for certain diseases following regulatory approval, if any, we may also partner with larger companies to develop and commercialize products for other diseases where aldehyde toxicity is implicated, particularly diseases that afflict large populations worldwide.

Specifically, our business strategy is to:

- *Continue the development of and pursue regulatory approval for NS2.* We are currently preparing to initiate clinical trials of NS2 in several diseases. If sufficient safety and efficacy is demonstrated, we intend to apply to the FDA and comparable foreign agencies for marketing approval of NS2.
- Aggressively develop new intellectual property and consider partnerships to accelerate and maximize the potential for other product candidates that are aldehyde traps. We have discovered and synthesized a variety of aldehyde traps that we intend to develop and patent for new indications. For some indications, especially those that afflict large populations worldwide, we will consider development and commercialization licensing opportunities with strategic partners that have more financial resources, commercialization experience, and global infrastructures that could realize the commercial potential of NS2 to a greater extent than we could achieve operating without such partnerships.
  - *Explore building in-house capabilities to commercialize NS2 in the United States and other geographies.* As, and if, NS2 progresses through clinical programs, in addition to partnering opportunities that we may consider, we also intend to evaluate the development of our own specialty sales force and marketing capabilities to allow us to directly market NS2 for rare diseases in the United States or in other geographies, if approved by FDA or analogous regulatory agencies outside the United States.

### The Market for Aldehyde Traps

Occurring generally as a result of a large number of metabolic processes, free aldehydes are naturally occurring endogenous chemical species that, among other things, promote inflammation. At high levels, free aldehydes are toxic and are implicated as mediators of many immune-mediated and inflammatory diseases. A variety of diseases are thought to be related to free aldehydes, at least in part, including autoimmune diseases (e.g., systemic lupus erythematosis), inflammatory diseases (e.g., uveitis), neurological disease (e.g., multiple sclerosis), cardiovascular disease (e.g., atherosclerosis) and endocrinologic disease (e.g., diabetic nephropathy). We believe that the medical needs of these patients are not currently well addressed and that there is a large market potential for therapies that can lower free aldehyde levels.

We intend to test our lead aldehyde trap product candidate, NS2, in diseases that we believe are likely to be mediated at least in part by free aldehydes and that we view as poorly treated, if treated at all, by currently available medications. SLS, for which we intend to initiate Phase II/III testing in 2014 with NS2, is a rare condition that we believe affects approximately 2,000 patients collectively in the United States and Europe. We also intend to initiate a Phase II clinical trial of NS2 in 2014 to test for efficacy in acute anterior uveitis, also a rare disease. While the patient populations for rare diseases are limited, we believe that reimbursement and pricing have the potential to be sufficient to generate significant revenues for approved therapies that offer significant advantages over standard of care.

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

### Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome (SLS) is caused by a variety of mutations of an enzyme called Fatty Aldehyde Dehydrogenase (FALDH), leading to the accumulation of fatty aldehydes or precursor molecules that are generally 16 to 18 carbons in length. The aldehyde accumulation is thought to result in the pathology of the disease, which includes a severe skin disorder called ichthyosis, mental delay, spasticity, and, in some patients, retinal dysfunction. While FALDH dysfunction also leads to diminished levels of certain fatty acids, therapy with these fatty acids has been ineffective in SLS patients. SLS patients are generally diagnosed as neonates given the severe ichthyosis that presents at birth. The disease persists lifelong, and SLS patients have a shortened lifespan, often expiring in the sixth decade of life. Some SLS patients are believed to inherit the disease, though most SLS appears to be due to sporadic mutations. The disease occurs worldwide. To our knowledge, Sweden is currently the only country to have estimated the prevalence of the disease, at 1 per 250,000 people. Extrapolating from the Swedish estimate, it is generally assumed that there are approximately 1,000 or fewer SLS patients in the United States and a larger number in Europe. We believe that some older SLS patients may be undiagnosed, potentially due to the lack of available dermatologic and genetic medicine expertise. There is no currently approved treatment that specifically addresses SLS.

The primary day-to-day complaint of SLS patients and their caregivers is ichthyosis, a severe skin disease characterized in SLS patients by thick, scaly, wrinkled, pigmented, pruritic (itchy), inflamed skin. SLS patients are consistently disturbed by pruritus and often excoriate skin by scratching. The ichthyosis in SLS affects most of the body, and is worse in flexure areas and the nape of the neck. There is currently no specific therapy approved for the dermatologic disease in SLS, though some patients and their caregivers apply non-specific topical creams, including keratinolytics (acids that soften skin) and moisturizers. We believe that the effects of keratinolytic and moisturizing creams are minimal or non-existent in treating severe ichthyosis.

The dermatologic disease in SLS is thought to be caused by aldehyde-mediated modification of lipids (fats) that are generated in the epidermis (the most superficial layer of skin) to form a moisture barrier that holds water in the skin. Moisture barrier compromise leads to water loss, which in turn leads to dermal thickening characteristic of ichthyosis. We believe that by lowering levels of aldehydes and thereby preventing lipid modification and the ensuing moisture barrier dysfunction, NS2, when applied topically to the skin, has the potential to ameliorate the dermatologic symptoms of SLS, deter disease progression, and potentially cure the ichthyosis that occurs in SLS.

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

#### Acute Anterior Uveitis

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

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

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

### Free Aldehyde Toxicity

Free aldehydes are generated through a variety of metabolic processes and are pro-inflammatory. At high levels, free aldehydes are toxic, binding proteins, lipids, carbohydrates, and DNA, and may mediate inflammation in, and the progression of, many serious diseases through the activation of intracellular inflammatory factors, including NF-kB, an important protein in the inflammatory response. In many cases, aldehyde binding to cellular constituents leads to the formation of indigestible adducts and aggregates that are pro-inflammatory and may lead to cellular dysfunction. Because of the inherent toxicity of aldehydes, most, if not all, living organisms contain enzymes, called aldehyde dehydrogenases, that detoxify aldehydes. The toxicity of aldehydes is evidenced by human studies showing an increased rate of cognitive decline, cancer, and cardiovascular disease in populations with diminished aldehyde dehydrogenase capacity. Additionally, most inflammatory diseases, including autoimmune disease, neurodegenerative disease, and cardiovascular diseases, manifest elevated free aldehyde levels that apparently overwhelm endogenous aldehyde levels. Thus, we believe that trapping aldehydes represents a novel platform for the treatment of inflammatory conditions and other diseases where aldehydes are implicated in pathogenesis.

### NS2 - Efficacy

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

To our knowledge, we have been the first to demonstrate the positive effects of lowering aldehyde levels with an aldehyde trap in a variety of animal models relating to inflammation, suggesting that aldehyde traps may have potent anti-inflammatory effects that persist hours after NS2 administration at a variety of different doses relevant to clinical testing.

In mice injected with a pro-inflammatory agent known as endotoxin, a single intra-peritoneal (gut) injection of NS2, administered 30 minutes prior to endotoxin, statistically reduced a variety of inflammatory cytokines (protein inflammatory mediators), including IL-5, Il-1b, IL-17, and TNF-a, while up-regulating the primary anti-inflammatory cytokine, IL-10, measured two hours after endotoxin exposure.

- In models of murine contact (induced by phorbol myristate acetate) and allergic (induced by sensitivity to oxazolone) dermatitis, a single intra-peritoneal injection of NS2 statistically reduced swelling when measured 6.5 and 24.5 hours, respectively, after NS2 administration.
- · In a model of radiation mucositis (oral inflammation) in hamsters, chronic subcutaneous administration of NS2 reduced healing time and decreased fibrosis (scarring).

- In human skin cells and in cells lacking FALDH, NS2 was at low doses able to fully protect a lipid (fat) critical to the moisture barrier in skin and ocular tear lubrication and moisturizing effectiveness.
- In dry eye and dry skin models where human ocular and skin tissues were exposed to abnormally dry conditions for 72 hours, NS2 was able to quench elevated levels of a known toxic aldehyde (malondialdehyde).

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

## NS2 Safety and Therapeutic Index

Aside from increasing levels of inflammation, there is no generally accepted role of free aldehydes. Some physiologic molecules have aldehyde forms, including retinaldehyde (a form of Vitamin A) and pyridoxal and pyridoxal phosphate (forms of Vitamin B6), but these molecules are not free aldehydes in that they are tightly chaperoned and protected by special proteins. As such, retinaldehyde and pyridoxal are likely not exposed to the cellular milieu, thereby precluding the non-specific binding that is characteristic of free aldehydes. Thus, aldehyde trapping is expected *a priori* only to dampen inflammatory response and we believe would be predicted not to lead to overt toxicity.

We have completed a number of non-clinical and preclinical toxicity studies of NS2, which appears to be generally well tolerated and safe. Based on the evidence collected by us to date, NS2 is an aldehyde trap that has minimal pharmacological activity per se, in that there are no known direct interactions with cellular components that appear to have significant effects in animals. After systemic exposure to NS2, no signs of retinaldehyde deficiency on retinal function have

been observed, nor have we observed any effects in animals that would suggest pyridoxal deficiencies. No toxicity has been observed by us in an animal model when NS2 was administered as a 0.5% eye drop daily for up to nine months. No toxicity has been observed in animals when NS2 was systemically administered in special cardiovascular, neurobehavioral and pulmonary safety studies. We currently have an IND that is active and in good standing relating to the clinical testing of NS2 as an eye drop for the treatment of aldehyde-mediated retinal disease. At high doses of NS2, we have observed toxicity in *ex vivo* human skin tissue and have formulated NS2 in a dermatologic topical preparation at a dose where toxicity is not observed. Based in part on these findings, we intend to submit an IND for NS2 in a dermatologic topical in early 2014 following our targeted finalization of our dermatologic formulation and completion of dermatological toxicity studies in animals.

To our knowledge, the highest published level of aldehydes in tissue is approximately 10µM. However, based on cell toxicity studies after exposure to free aldehydes, 10µM concentrations lead to significant cell death. In skin cell culture from patients with SLS, over 80% cell death has been observed at 60µM concentrations of aldehydes; however, biopsies of SLS patients do not indicate cell death, suggesting that the actual aldehyde concentrations in the skin of SLS patients is far lower than 60µM. In the tears of patients with dry eye, aldehyde concentrations are estimated at 1µM. Based on the totality of these results, we believe that the levels of aldehydes in SLS or other human diseases are likely significantly lower than 10µM on a sustained basis. Relative to aldehyde levels, concentrations. Eye drops containing 0.5% NS2 are greater than 20mM (20,000-fold greater than reported aldehyde load in tears of dry eye patients), and a single drop results in anterior ocular tissue concentrations of greater than 5µM. Likewise, NS2 concentrations in 0.05% dermatologic topical preparations are greater than 2mM. Given the potential to be able to administer NS2 topically in concentrations that far exceed predicted free aldehyde concentrations, we believe that NS2 will significantly lower free aldehyde loads in diseases where topical administration of NS2 is applicable.

## NS2 - Phase I Clinical Trial

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

# NS2 - Proposed Clinical Trials

In 2014, pending successful IND submissions, we intend to initiate clinical trials in SLS and acute anterior uveitis. Table 1 summarizes the proposed key characteristics of these clinical trials, which are subject to change depending on input from regulatory agencies, advisors and other entities. We can provide no assurances that the clinical designs below will be utilized.

### **Table 1. Anticipated Clinical Trial Designs**

Indication	SLS Dermatologic Topical	Acute Anterior Uveitis
Drug Product	NS2 0.05%	NS2 0.5% eye drop
Patients	12	40-45
Control	1:1 Placebo	1:1 Active Control (topical corticosteroid)
Treatment Time	8 weeks	8 weeks
Endpoints	Visual Ichthyosis Scale	Anterior chamber cell score, pain and visual acuity

Our currently anticipated timing of the initiation and completion of our clinical trials is 2014 and the second half of 2015, respectively, although trial timing may change depending on input from regulatory agencies, advisors and other entities. Assuming that the first trial in patients with SLS is positive, we intend to initiate a second clinical trial as early as 2015. The nature of the second trial in patients with SLS will depend on results from the first trial as well as guidance from the FDA and other regulatory bodies, authorities and advisors.

### Novel Aldehyde Trap Development

In addition to the development of NS2, we intend to continue the discovery and development of other novel aldehyde traps and we intend to continue to develop intellectual property around such molecules. We have identified, synthesized, and tested *in vitro* numerous molecules that may be more potent than NS2 in trapping free aldehydes. We are currently screening for product candidates to address diseases where oral and topical administration are applicable to reduce free aldehyde-mediated toxicity. We expect to nominate new oral and topical product candidates in 2014; however, given the unpredictable nature of medicinal chemistry and early stage molecular screening, the timing of product candidate selection is difficult to ascertain.

### **Intellectual Property and Proprietary Rights**

#### Overview

We are building an intellectual property portfolio for NS2 and other aldehyde traps in the United States and abroad. We currently seek, and intend to continue to seek, patent protection in the United States and internationally for our product candidates, methods of use, and processes for manufacture, and for other technologies, where appropriate. Our current policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad relating to proprietary technologies that are important to the development of our business. We also rely on, and will continue to rely on, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

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

### Patent Portfolio

Our patent portfolio currently includes patents and patent applications covering the composition, formulation, and uses of NS2, and the compositions and uses of other novel aldehyde trapping compounds. As of January 9, 2014, we owned one United States patent, four United States non-provisional patent applications, and five provisional patent applications, as well as numerous foreign counterparts to these patents and patent applications. We expect the issued NS2 composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2028. It is possible that the term of the composition of matter patent in the United States under the provisions of the Hatch-Waxman Act. We expect the foreign NS2 composition of matter patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2026. We expect other patent applications in the portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2026 to 2034. NS2 composition of matter patents have been issued in Australia, China, the European Patent Office, Hong Kong, Indonesia, Japan, Mexico, and Russia. NS2 composition of matter patent claims have been allowed in Canada and South Korea, and are pending

### **Other Intellectual Property Rights**

We are currently in the process of registering a trademark for ALDEYRA THERAPEUTICS and registering a trademark for our logo in the United States. We can provide no assurances that these registrations will be successful.

In February 2010, we entered into a License and Supply Agreement with CyDex Pharmaceuticals, Inc., which was subsequently acquired by Ligand Pharmaceuticals Incorporated. The agreement grants us an exclusive license in the field of retinal degeneration (with certain exclusions) to certain excipient-related composition of matter and method of use patents to produce, use or sell our products that contain a certain solubilizing excipient, and allows for us to purchase at a defined cost an excipient used in our eye drop formulation of NS2. We will also be obligated to make milestone payments of up to an aggregate of \$2.15 million upon reaching certain development and regulatory milestones in the development of our product. In the event of commercialization of a product containing the excipient,

the agreement stipulates royalties at a low single digit percentage of applicable net sales, with an annual cap. The agreement continues in effect until the 7th anniversary of the expiration of all patents licensed under the agreement, which we currently estimate to be April 2036 unless earlier terminated by the parties. CyDex has the right to terminate the agreement if we are in default under the agreement and should fail to cure such default within thirty (30) days (or ten (10) days with respect to any payment obligation). Default includes, among other things, the failure to fulfill certain obligations and meet certain deadlines in connection with the commercialization of our product. We have the right to terminate the agreement at any time by 90 days written notice, or 45 days written notice in the event of a material breach by CyDex.

### Confidential Information and Inventions Assignment Agreements

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

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

#### Sales and Marketing

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

### Manufacturing

We do not own or operate manufacturing facilities for the production of NS2 or our other product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished drug product for our preclinical research and clinical trials. We have no immediate plans to purchase, erect or otherwise create any manufacturing facilities to be owned by us for any of these purposes, and intend to continue to depend on third-party contract manufacturers for the foreseeable future. We do not have any current contractual relationships for the manufacture of commercial supplies of NS2 or our other product candidates. If NS2 or our other product candidates are approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturing contractors. We believe that NS2 and other materials needed for the formulation of NS2 are relatively easy to manufacture, and that multiple suppliers and formulators could be employed for this purpose. Further, the raw materials needed for manufacture of NS2 and other ingredients in NS2 formulations are generally readily available from multiple sources.

#### Competition

### Aldehyde Traps

Various academic groups have published on the idea of reducing aldehyde levels, primarily by using compounds with primary amines (certain nitrogen-containing compounds) that react with aldehydes through a well-known chemical process known as the Schiff base reaction. The Schiff base reaction is reversible, and generally the substrates (precursors) and products of the reaction exist in equilibrium such that at any point in time, the aldehyde substrate may be bound or unbound. In this way, Schiff base reactions alone represent reversible and temporary aldehyde binding. Various amines have been described, particularly carnosine (a naturally occurring dipeptide), which has a variety of additional potential mechanisms of action unrelated to aldehyde binding. At least one group has published on the use of certain nitrogen-containing marketed products to temporarily, in a reversible manner, bind retinaldehyde as a potential therapy for retinal disease. We believe that NS2 and other novel aldehyde traps that we have discovered are differentiated from the above approaches in that the chemical structures are novel and the reaction with free aldehyde is essentially irreversible *in vivo*, which we believe may result in a more effective means of diminishing aldehyde levels.

### Other Pharmacotherapies

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

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for products and achieving widespread market acceptance. Our

competitors products may be more effective, or more effectively marketed and sold, than any product that we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. In addition, the development of new treatment methods for the diseases we are targeting could render our products non-competitive or obsolete.

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

### Table 2. Competitive Pharmaceuticals by Indication

**Competitive Products** 

Indication Sjögren-Larsson Syndrome

### Prescription and over-the-counter keratinolytics and moisturizers Topical corticosteroids

### **Acute Anterior Uveitis**

We believe that there is significant unmet medical need for the diseases that we intend to study. If NS2 is proven to be safe and effective, we believe that NS2 could be used in place of or in addition to current therapies, especially in instances where current therapies are toxic and reducing exposure to such therapies would be desirable. There is no approved therapy for SLS. We believe that the current non-specific creams and medications for SLS are poorly effective, if effective at all. Topical corticosteroids for ocular inflammatory diseases are often associated with toxicity, including corneal ulceration, cataracts, and glaucoma. While NS2 and other novel aldehyde traps may manifest efficacy and safety advantages over currently available therapies, many such therapies are generic or may be priced considerably lower than the NS2 pricing that we anticipate. Pricing factors may discourage the initial or prolonged use of NS2.

We believe that there are no drugs in development specifically for SLS. Novartis (ESBA105) and EyeGate Pharmaceuticals, Inc. (EGP-437) have conducted or are conducting clinical trials in anterior uveitis. For the diseases we intend to study, there may be other developmental therapies of which we are not aware.

A myriad of new treatments have been or are being developed to treat inflammatory diseases, and in theory could be used for the treatment of the diseases our products are intended to target. Immune-modulating products include cytokine inhibitors, immune cell receptor inhibitors, and Janus kinase inhibitors. Companies that currently market such therapies include Abbvie, Inc., Johnson & Johnson, UCB Inc. and UCB S.A., Amgen, Inc., Bristol-Myers Squibb Co., and Pfizer, Inc. As these products become used more commonly, they may begin to be used in the diseases that we intend to target, and such products may manifest efficacy and safety advantages over NS2 or our other product candidates.

### **Government Regulation**

### FDA Approval Process

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

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

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulation;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each site where a clinical trial will be performed before the trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed product candidate for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA s cGMP regulations;
- submission to the FDA of a new drug application, or NDA, which must be accepted for filing by the FDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- · payment of user fees, if applicable; and

• FDA review and approval of the NDA.

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

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

If a Phase II clinical trial is the subject of discussion at an end-of-Phase II meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the design of the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA and may not be changed unless the sponsor fails to follow the agreed-upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. Even if an SPA is agreed to, approval of the NDA is not guaranteed because a final determination that an agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data in the NDA.

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

- *Phase I:* The product is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase II:* The product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.
- *Phase III:* These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the product and to provide adequate information for the labeling of the product.
- *Phase IV:* In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor s agreement to conduct additional clinical trials to further assess the product s safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase IV studies.

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

# **Orphan Drug Designation**

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

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it was designed, the product will be entitled to seven years of product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. If a competitor obtains approval of the same drug, as defined by the FDA, or if our product candidate is determined to be contained within the competitor s product for the same indication or disease, the competitor s exclusivity could block the approval of our product candidate in the designated orphan indication for seven years.

For some products, the FDA may require a risk evaluation and mitigation strategy, or REMS, which could include measures imposed by the FDA such as prescribing restrictions, requirements for post-marketing studies or certain restrictions on distribution and use. Under federal law, the submission of most NDAs is additionally subject to a substantial application

user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing.

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

It is likely that our product candidates will be granted a Standard Review. The review process may be extended by the FDA for three additional months to consider certain information or obtain clarification regarding information already provided in the submission. The FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. In addition, for combination products, the FDA s review may include the participation of both the FDA s Center for Drug Evaluation and Research and the FDA s Center for Devices and Radiological Health, which may complicate or prolong the review.

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

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

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase IV studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Products may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms, such as a Black Box Warning, which highlights a specific warning (typically life-threatening), or a REMS program. Further, if there are any modifications to the product, including changes in indications, labeling, or manufacturing processes or facilities, a company may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the company to develop additional data or conduct

additional preclinical studies and clinical trials.

### **Post-Approval Requirements**

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also

require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. While physicians may prescribe for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability, both at the federal and state levels.

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

# Patent Term Restoration and Marketing Exclusivity

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

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not

previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

# Manufacturing Requirements

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

# Other Regulatory Requirements

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

# **Research and Development Expenses**

Substantially all of our research and development expenses incurred to date have been related to the development of NS2. Our research and development expenses totaled \$469,270 for the year ended December 31, 2012 and \$1.5 million for the year ended December 31, 2013. We anticipate that we will incur additional expenses of approximately \$2.5 million and \$2.5 million in 2014 and 2015, respectively, to complete the currently planned clinical trials of NS2 and other research and development activities.

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

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

- salaries and related expenses for personnel;
- fees paid to consultants and contract research organizations in conjunction with independently monitoring clinical trials and acquiring and evaluating data in conjunction with clinical trials, including all related fees such as investigator grants, patient screening, lab work and data compilation and statistical analysis;
- costs incurred with third parties related to the establishment of a commercially viable manufacturing process for our product candidates;
- · costs related to production of clinical materials, including fees paid to contract manufacturers;
- · costs related to upfront and milestone payments under in-licensing agreements;
- costs related to compliance with FDA regulatory requirements;
- consulting fees paid to third-parties involved in research and development activities; and
- costs related to stock options or other stock-based compensation granted to personnel in development functions.

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

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

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

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit

price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of

clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

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

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

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

### **Employees**

As of April 15, 2014, we had two full time senior employees and had engaged a number of key consultants. We intend to increase our employee base upon the closing of this offering and in connection with the commencement of our clinical trials for NS2. We expect that a number of consultants previously engaged in development of NS2 will participate in ongoing clinical and manufacturing activities.

# Facilities

We currently have no facilities other than our principal executive offices located at 15 New England Executive Park, Burlington Massachusetts, and conduct our operations using third-party manufacturing facilities and trial sites.

# **Legal Proceedings**

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

# MANAGEMENT

#### **Executive Officers and Directors**

Our executive officers and directors, and their ages and positions as of April 15, 2014, are set forth below:

Name	Age	Position	Served as Officer or Director Since
Executive Officers			
Todd C. Brady, M.D., Ph.D.	42	Chief Executive Officer, President and Director	January 2012
Scott L. Young	52	Chief Operating Officer	December 2011
Directors			
C. Boyd Clarke (2)	65	Chairman of the Board of Directors	October 2013
Martin J. Joyce (1)(3)	60	Director	October 2013
Gary Phillips, M.D. (1)(3)	47	Director	May 2009
Ben Bronstein, M.D.	64	Director	June 2010
Neal Walker, D.O. (3)	44	Director	June 2013
Jesse Treu, Ph.D. (2)	67	Director	June 2013

(1) Member of Compensation Committee.

(2) Member of Nominating and Corporate Governance Committee.

(3) Member of Audit Committee.

**Executive Officers** 

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

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

## **Non-Employee Directors**

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

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

*Gary Phillips, M.D.* has served as Senior Vice President and Chief Strategy Officer at Mallinckrodt Pharmaceuticals plc since October 2013 and has been a member of our Board of Directors since May 2009. Before joining our company, he was President of Reckitt Benckiser Pharmaceuticals, Inc. from 2011 to 2012. He served as President of U.S. Surgical and Pharmaceuticals at Bausch & Lomb Incorporated from 2002 to 2008. Dr. Phillips has also held executive roles at Merck Serono SA (a division of Merck KGaA) from 2008 to 2011, Novartis Corporation from 2000 to 2002, and Wyeth Pharmaceuticals, Inc. (now Pfizer, Inc.) from 1999 to 2000. He was most recently Head of Global Health & Healthcare Industries at the World Economic Forum in Geneva from January 2012 to September 2013. Dr. Phillips was also healthcare strategy managing consultant at Towers Perrin Forster & Crosby, Inc. (now Towers

Watson & Co) from 1997 to 1999, and practiced as a general medicine clinician/officer in the US Navy, from which he was honorably discharged as a lieutenant commander. Dr. Phillips was educated at the University of Pennsylvania, where he received an M.D. (Alpha Omega Alpha) from the School of Medicine in 1992, an MBA from the Wharton School in 1991, and B.A. (summa cum laude, Phi Beta Kappa) in biochemistry from the College of Arts and Sciences in 1987. He completed postgraduate medical education at Naval Medical Center San Diego and maintains an active medical license. Dr. Phillip s extensive knowledge of our business and history, and his experience in pharmaceutical strategy at multiple multinational companies, contributed to our conclusion that he should serve as a director of our company.

*Ben Bronstein, M.D.* has served as a member of our board of directors since 2010, and from 2010 to 2011 served as Chief Executive Officer of Aldeyra Therapeutics, then known as Neuron Systems. Dr. Bronstein is a Visiting Scholar at the Wyss Institute of Biologically Inspired Engineering at Harvard Medical School and an active advisor to life science

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

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

*Jesse I. Treu, Ph.D.* has served on our board of directors since June 2013. Dr. Treu has been a Managing Member of Domain Associates, L.L.C. since its inception in 1986. He has been a director of over 35 early-stage healthcare companies. Dr. Treu currently serves as a member of the boards of directors of Afferent Pharmaceuticals, Inc., CoLucid Pharmaceuticals, Inc., Regado Biosciences, Inc., Tandem Diabetes Care, Inc., RightCare Solutions, Inc. and Veracyte, Inc. He has also served as a founder, president and chairman of numerous venture-stage companies. Prior to the formation of Domain Associates, Dr. Treu had twelve years of experience in the healthcare industry. He was Vice President of the predecessor organization to The Wilkerson Group and its venture capital arm, CW Ventures. While at CW Ventures, he served as President and CEO of Microsonics, Inc., a pioneer in computer image processing for cardiology. From 1977 through 1982, Dr. Treu led new product development and marketing planning for immunoassay and histopathology products at Technicon Corporation, which is now part of Siemens Diagnostics. Dr. Treu began his career with General Electric Company in 1973, initially as a research scientist developing thin film optical sensors for immunoassay testing, and later serving on the corporate staff with responsibility for technology assessment and strategic planning. Dr. Treu received his B.S. in Physics from Rensselaer Polytechnic Institute and his M.A. and Ph.D. in physics from Princeton University. Dr. Treu s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies and expertise in developing

and financing contributed to our conclusion that he should serve as a director of our company.

#### **Board of Directors**

Members of our board of directors are elected at our annual meeting of stockholders.

#### **Independent Directors**

Our board of directors is currently composed of seven (7) members. Drs. Walker, Treu and Phillips, and Mr. Clarke and Mr. Joyce qualify as independent directors in accordance with the published listing requirements of NASDAQ. The independent members of our board of directors also will hold separate regularly scheduled executive session meetings at which only independent directors are present.

# **Classified Board**

Immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Drs. Treu and Bronstein, and their terms will expire at the annual meeting of stockholders to be held in 2015;
- The Class II directors will be Drs. Walker and Phillips, and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- The Class III directors will be Dr. Brady, Mr. Joyce and Mr. Clarke, and their terms will expire at the annual meeting of stockholders to be held in 2017.

The authorized number of directors may be changed only by resolution of the board of directors. This classification of the board of directors into three classes with staggered three-year terms may have the effect of delaying or preventing changes in our control or management.

#### **Board Leadership Structure**

Our board of directors is currently led by its chairman, Mr. Clarke. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for the company and the day-to-day leadership and performance of the company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

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

# **Role of Board in Risk Oversight Process**

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

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

#### **Corporate Governance**

We believe our corporate governance initiatives comply with the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) and the rules and regulations of the SEC adopted thereunder. In addition, we believe our corporate governance initiatives comply with the rules of The NASDAQ Capital Market. After this offering, our board of directors will continue to evaluate our corporate governance principles and policies.

Our board of directors adopted a code of business conduct that applies to each of our directors, officers and employees. The code addresses various topics, including:

- compliance with applicable laws, rules and regulations;
- · conflicts of interest;
- public disclosure of information;
- insider trading;
- · corporate opportunities;
- competition and fair dealing;
- · gifts;
- · discrimination, harassment and retaliation;
- health and safety;
- · record-keeping;
- · confidentiality;
- protection and proper use of company assets;

- · payments to government personnel; and
  - reporting illegal and unethical behavior.

The code of business conduct is posted on our website. Any waiver of the code of business conduct for an executive officer or director may be granted only by our board of directors or a committee thereof and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish format protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to the audit committee.

## **Board Committees**

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

### Audit Committee

In October 2013, our board of directors established an audit committee of the board, which is currently comprised of Martin J. Joyce, Gary Phillips, M.D. and Neal Walker, D.O., each of whom is a non-employee member of the board of directors. Mr. Joyce serves as the chair of the audit committee. The audit committee s main function is to oversee our

accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. Pursuant to the audit committee charter, the functions of the committee include, among other things:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting and our disclosure controls and procedures;
- meeting independently with our registered public accounting firm and management;
- preparing the audit committee report required by SEC rules;
- · reviewing and approving or ratifying any related person transactions; and
- overseeing our risk assessment and risk management policies.

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

#### **Compensation Committee**

In October 2013, our board of directors established a compensation committee of the board, which is currently comprised of Gary Phillips, M.D. and Martin J. Joyce. Dr. Phillips serves as the chair of the compensation committee. Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. Pursuant to the compensation committee charter, the functions of this committee include:

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

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

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

### Nominating and Corporate Governance Committee

In October 2013, our board of directors established a nominating and corporate governance committee of the board, which is currently comprised of Jesse Treu, Ph.D. and Mr. Clarke. Dr. Treu serves as the chair of the nominating and corporate governance committee. Pursuant to the nominating and corporate governance committee charter, the functions of this committee include, among other things:

- identifying, evaluating, and making recommendations to our board of directors and our stockholders concerning nominees for election to our board, to each of the board s committees and as committee chairs;
- annually reviewing the performance and effectiveness of our board and developing and overseeing a performance evaluation process;
- annually evaluating the performance of management, the board and each board committee against their duties and responsibilities relating to corporate governance;
- annually evaluating adequacy of our corporate governance structure, policies, and procedures; and
- providing reports to our board regarding the committee s nominations for election to the board and its committees.

#### Compensation Committee Interlocks and Insider Participation

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

# Limitations on Liability and Indemnification Matters

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### 2013 Director Compensation Table

During our fiscal year ended December 31, 2013, we did not pay any cash fees, make any non-equity awards, or pay any other non-equity compensation, to the non-employee members of our board directors. Dr. Brady, our president and chief executive officer, receives no compensation for his service as a director and is not included in the table below.

The table below shows the value of option awards granted to our non-employee director during our fiscal year ended December 31, 2013:

Name	Option Awards (\$)(4)(5)(6)
Ben Bronstein, M.D.	99,107
Martin J. Joyce (1)	-
Boyd Clarke (1)	-
Gary Phillips, M.D.	56,110
Jesse Treu, Ph.D. (2)	-
Neal Walker, D.O. (2)	99,027
Asish Xavier (3)	-

(1)Messrs. Joyce and Clarke joined our board of directors effective October 2013.

(2)Drs. Treu and Walker joined our board of directors effective June 2013.

(3)Mr. Xavier resigned from our board of directors effective October 2013.

- (4) The amounts in this column represent the aggregate grant date fair value of option awards granted to the director during our fiscal year ended December 31, 2013, computed in accordance with FASB ASC Topic 718. See Note 2 to our financial statements included elsewhere in this prospectus for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards.
- (5)As of December 31, 2013, Drs. Bronstein, Phillips and Walker each held outstanding options to purchase 9,604 shares of our common stock and Messrs. Joyce, Clarke and Xavier, and Dr. Treu held no outstanding options to purchase shares of our common stock.
- (6) On September 8, 2013, each of Drs. Bronstein and Walker received an option to purchase 9,604 shares of our common stock, and Dr. Phillips received an option to purchase 5,437 shares of our common stock, at an exercise price per share of \$0.552. These options vest in equal monthly installments over 48 months of service following January 1, 2012, with respect to Drs. Bronstein and Phillips and following June 24, 2013, with respect to Dr. Walker. In addition, all of the options shares will immediately vest if we experience a change of control. *Non-Employee Director Compensation*

Prior to this offering, we generally have not provided any cash compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. Although we granted an option to each of Drs. Bronstein, Phillips and Walker, as reflected in the table above, we have not had any established policy with

regard to equity-based compensation of members of our board of directors.

On the effective date of the registration statement of which this prospectus is a part, each of our non-employee directors will be granted an option to purchase 12,166 shares of our common stock (other than the chairman of the board of directors, who will be granted an option to purchase 18,250 shares of common stock) with an exercise price per share equal to the initial public offering price listed on the cover of this prospectus. Each of these options will vest in three equal annual installments following the date of the grant, and each shall provide for full acceleration in the event of a change of control.

Following the effectiveness of this offering, each member of our board of directors who is not our employee will receive the following cash compensation for board services, as applicable:

- \$17,500 per year for service as a board of directors member;
- \$17,500 per year for service as chairman of the board of directors.
- \$7,500 per year for service as chairman of the Audit Committee;
- \$5,000 per year for service as chairman of the Compensation Committee;
- \$3,500 per year for service as chairman of the Nominating and Corporate Governance Committee;
- \$3,750 per year for service as non-chairman member of the Audit Committee;
- \$2,500 per year for service as non-chairman member of the Compensation Committee; and
- \$1,750 per year for service as non-chairman member of the Nominating and Corporate Governance Committee.

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

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

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

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

# **EXECUTIVE COMPENSATION**

This section discusses the material components of the compensation paid to certain of our executive officers, which we refer to as our named executive officers. For our fiscal years ended December 31, 2012 and December 31, 2013, our named executive officers and their positions were:

- Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer
- · Scott L. Young, Chief Operating Officer

### **Summary Compensation Table**

The following table sets forth information concerning the compensation of Mr. Young during our fiscal years ended December 31, 2012 and December 31, 2013 and the compensation of Dr. Brady during our fiscal year ended December 31, 2013. Dr. Brady received no compensation from us in fiscal year 2012.

Name and Principal Position	Year	Salary (\$)	Stock Awards (\$)(3)		All Other Compensation (\$)(5)	Total (\$)
Todd C. Brady, M.D., Ph. D.						
President and Chief Executive						
Officer	2013	70,833	136,732	3,480,256(4	-) -	3,687,821
Scott L. Young						
5						
Chief Operating Officer	2012	326,078(1	.) -	72,168	18,774	417,020
	2013	300,000(2	2) -	1,240,727(4	) 30,410	1,571,137

(1)Represents amounts paid to Mr. Young pursuant to his consulting agreement with us.

(2)Includes \$267,910 paid to Mr. Young pursuant to his consulting agreement with us.

(3) The amounts in this column represent the aggregate grant date fair value of option awards or stock awards granted to the officer in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. See Note 2 to our consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. In accordance with SEC rules, the grant date fair value of an award subject to performance conditions is based on the probable outcome of the conditions.

Amount reflects the probable achievement of performance conditions applicable to 48,021 of the option shares granted to each of Mr. Young and Dr. Brady. The maximum grant date fair value of these awards, assuming all of the performance conditions were to be achieved, was \$1,483,317 for Mr. Young and \$3,722,846 for Dr. Brady.

(5)Represents \$34,429 to reimburse Mr. Young for medical and dental insurance premiums he paid and \$14,755 to reimburse Mr. Young with respect to taxes incurred (by way of a gross-up) with respect to such payments.Narrative Disclosure to Compensation Tables

### **Employment Letters**

In November 2013, we entered into a letter agreement with Dr. Brady that will become effective on the effective date of this registration statement. We and Dr. Brady amended such letter agreement in February 2014. Pursuant to such letter, Dr. Brady s annual base salary will increase from \$340,000 to \$400,000 and his cash bonus opportunity for each of our fiscal years will increase from 30% to 45% of his base salary. Such letter agreement supersedes in its entirety our offer letter with Dr. Brady that became effective on August 1, 2013.

In November 2013, we entered into a letter agreement with Mr. Young that will become effective on the effective date of this registration statement. We and Mr. Young amended such letter agreement in February 2014. Pursuant to such letter, Mr. Young s annual base salary will increase from \$300,000 to \$315,000 and his cash bonus opportunity for each of our fiscal years will increase from 25% to 35% of his base salary. Such letter agreement supersedes in its entirety our offer letter with Mr. Young that became effective on July 15, 2013.

The cash bonus for each of Dr. Brady and Mr. Young is determined solely at the discretion of our Board of Directors based on the executive s job performance and our overall financial performance. Any bonus earned will be paid within  $2\frac{1}{2}$  months after the end of our fiscal year. Except as described below under Severance and Change in Control Benefits, each of Dr. Brady and Mr. Young must remain employed with us through the date of payment to receive a bonus.

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

### **Equity Compensation**

We offer stock options and restricted shares to our named executive officers as the long-term incentive component of our compensation program. We typically grant equity awards to new hires upon their commencing employment with us. Stock options allow employees to purchase shares of our common stock at a price per share equal to the fair market value of our common stock on the date of grant and may or may not be intended to qualify as incentive stock options for United States federal income tax purposes. In the past, our board of directors has determined the fair market value of our common stock based upon inputs including valuation reports prepared by third-party valuation firms. Generally, the equity awards we grant vest in equal monthly installments over 48 months, subject to the employee s continued employment with us on the vesting date. We also generally offer our employees the opportunity to early exercise their unvested stock options by purchasing shares underlying the unvested portion of an option subject to our right to repurchase any unvested shares for the lesser of the exercise price paid for the shares and the fair market value of the shares on the date of the holder s termination of service if the employee s service with us terminates prior to the date on which the options are fully vested.

In September 2013, our board of directors, and in October 2013, our compensation committee, granted or approved stock options to each of our named executive officers, as well as to a number of our other employees. The grants to our named executive officers were intended to strengthen the long-term component of each such officer s compensation, provide further retention incentive for these officers. Except as noted below, such options were granted under our 2010 Employee, Director and Consultant Equity Incentive Plan (our 2010 Plan):

		Number of Shares Underlying	Exercise Price
Name	<b>Grant Date</b>	Option Grants	(\$)
Todd C. Brady, M.D., Ph.D.	9/8/2013	192,084 (1)	0.552
	9/8/2013	48,021 (2)	0.552
	9/8/2013	32,953 (3)	0.552
	10/30/2013	96,042 (4)	4.56
	Effective date of		
	this offering	76,068 (5)	Offering price

Scott L. Young	9/8/2013	96,042 (6)	0.552
-	9/8/2013	48,021(2)	0.552
(1) Option vests over four years of service	e from April 15, 2013, wit	h 25% vesting upon completion of	f 12 months of

service and in 36 equal monthly installments thereafter.

(2) As amended by our compensation committee in October 2013, 16,007 of the shares vest upon each of the effective date of this offering, the date on which our closing market capitalization equals at least \$55.0 million for 10 consecutive trading days and the date on which our closing market capitalization equals at least \$70.0 million for 10 consecutive trading days, provided that the officer remains in continuous service with us through each such date.

(3) Option vested in equal monthly installments over six months of service following April 1, 2013.

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

(5) Option vests in equal quarterly installments over four years of service following the effective date of this offering. The option will be granted under our 2013 Equity Incentive Plan.

(6) Option vests over four years of service from April 15, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.

In addition, on September 8, 2013 our board of directors granted 12,948 fully vested shares of stock to Dr. Brady under our 2010 Plan. This grant was made in recognition of Dr. Brady services previously provided to the Company during 2012. Dr. Brady subsequently transferred 10,358 of such shares to Domain Associates LLC, which had previously employed Dr. Brady for a period of time while Dr. Brady provided services to us an executive officer.

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

#### Outstanding Equity Awards at 2013 Fiscal Year-End

The following tables shows certain information regarding outstanding equity awards held by our named executive officers as of December 31, 2013.

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

		<b>Option Awards</b>						
		Number of						
		Securities						
		Underlying		<b>Equity Incentive Plan</b>				
		Unexercised	Number of Securities Underlying	Awards: Number of Securities Underlying				
		<b>Options</b> (#)	• 0	Unexercised Unearned	<b>Option Exercise</b>	<b>Option Expiration</b>		
	Grant		<b>Options</b> (#)		-			
Name	Grant Date	Vested	Options (#) Unvested	<b>Options</b> (#)	Price (\$)	Date		
<b>Name</b> Todd C.		Vested	L ()	<b>Options</b> (#)	Price (\$)	Date		
Todd		Vested	L ()	Options (#)	<b>Price (\$)</b> 0.552	<b>Date</b> 9/7/2023		
Todd C.	Date		Unvested	<b>Options</b> (#) -				
Todd C.	<b>Date</b> 9/8/2013	-(1)	<b>Unvested</b> 192,084	-	0.552	9/7/2023		
Todd C.	Date 9/8/2013 9/8/2013	-(1) 32,953(2)	<b>Unvested</b> 192,084	-	0.552 0.552	9/7/2023 9/7/2023		

				ia morapoati		
Scott						
L.						
Young						
	9/8/2013	-(1)	96,042	-	0.552	9/7/2023
	9/8/2013	-	-	48.021(5)	0.552	9/7/2023

- (1) Option vests over four years of service following April 15, 2013, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.
- (2) Option vested in equal monthly installments over six months of service following April 1, 2013.
- (3) Option vests in equal quarterly installments over four years of service following October 30, 2013.
- (4) Option vests over four years of service following January 1, 2012, with 25% vesting upon completion of 12 months of service and in 36 equal monthly installments thereafter.
- (5) 16,007 of the shares vest upon each of the effective date of this offering, the date on which our closing market capitalization equals at least \$55.0 million for 10 consecutive trading days and the date on which our closing market capitalization equals at least \$70.0 million for 10 consecutive trading days, provided that the officer remains in continuous service with us through each such date.

#### Severance and Change in Control Benefits

Pursuant to their November 2013 letter agreements, as amended in February 2014, if we terminate the employment of Dr. Brady or Mr. Young without cause or if such executive resigns for good reason, then he will be eligible to receive:

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

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

Cause means an officer s:

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

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

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

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

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

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

## **Employee Benefits and Perquisites**

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

## **Equity Plans**

## 2013 Equity Incentive Plan

Our board of directors adopted our 2013 Equity Incentive Plan (the 2013 Plan) in October 2013, and we expect our stockholders to approve the 2013 Plan prior to the completion of this offering. The 2013 Plan became effective immediately on adoption although no awards may be made under it until the effective date of the registration statement of which this prospectus is a part. Our 2013 Plan will replace our 2010 Plan (described below), and no further grants will be made under such plan following this offering. However, options outstanding under the 2010 Plan and our 2004 Plan (as described below) will continue to be governed by their existing terms.

*Share Reserve.* The number of shares of our common stock available for issuance under our 2013 Plan will equal 625,000 shares. The number of shares reserved for issuance under the 2013 Plan will be increased automatically on January 1 of each year during the term of the plan, starting with 2015, by a number equal to the smallest of:

- · 333,333 shares;
- 4.00% of the shares of common stock outstanding on December 31 of the prior year ; or
- the number of shares determined by our board of directors.

In general, if awards under the 2013 Plan are forfeited, terminate, expire or lapse without the issuance of shares, if we repurchase shares issued under the 2013 Plan, if shares are applied to pay the exercise or purchase price of an award or are withheld to satisfy tax obligations with respect to any award, then such shares will again become available for awards. All share numbers described in this summary of the 2013 Plan will automatically adjust in the event of a stock split, a stock dividend, or a reverse stock split.

*Administration*. Our compensation committee administers the 2013 Plan. The committee has complete discretion to make all decisions relating to the 2013 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards.

Eligibility. Employees, non-employee directors and consultants are eligible to participate in our 2013 Plan.

Types of Award. Our 2013 Plan provides for the following types of awards:

incentive and nonstatutory stock options;

- stock appreciation rights;
- · direct award or sale of shares of our common stock;
- stock units; and
- performance cash awards.

*Options and Stock Appreciation Rights.* The exercise price for options granted under the 2013 Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or, with the consent of the compensation committee and as set forth in the applicable agreement:

- with shares of common stock that are already owned;
- by an immediate sale of the shares acquired through a broker approved by us;

- through a net exercise procedure;
- through tender of a promissory note; or
- by other methods permitted by applicable law.

A participant who exercises a stock appreciation right receives the increase in value of our common stock over the base price. The base price for stock appreciation rights may not be less than 100% of the fair market value of our common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash or shares of common stock or a combination of both.

Options and stock appreciation rights vest at the time or times determined by the compensation committee. In most cases, they will vest over a four-year period following the date of grant. Options and stock appreciation rights also expire at the time determined by the compensation committee but in no event more than 10 years after they are granted. These awards generally expire earlier if the participant s service terminates earlier. No participant may be granted stock options and stock appreciation rights covering more than 250,000 shares during any single fiscal year, other than to a new employee in the fiscal year in which service commences.

*Restricted Shares and Stock Units*. Restricted shares and stock units may be awarded under the 2013 Plan in return for any lawful consideration (and as set forth in the applicable award agreement), and participants who receive restricted shares or stock units generally are not required to pay for their awards in cash. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones, or a combination of both, as determined by the compensation committee. No participant may be granted awards of restricted shares and stock units covering more than 250,000 shares during any single fiscal year, other than to a new employee in the fiscal year in which service commences. This annual limit is in addition to any stock options and stock appreciation rights the participant may receive during a fiscal year. Settlement of vested stock units may be made in the form of cash, shares of common stock, or a combination of both.

*Performance Cash Awards*. Performance cash awards may be granted under the 2013 Plan that qualify as performance-based compensation that is not subject to the income tax deductibility limitations imposed by Section 162(m) of the Code, if the award is approved by our compensation committee and the grant or vesting of the award is tied solely to the attainment of performance goals during a designated performance period. No participant may be paid more than \$6.0 million in cash in any fiscal year pursuant to a performance cash award granted under the 2013 Plan.

Performance goals for the grant or vesting of awards under the 2013 Plan include earnings (before or after taxes); earnings per share; earnings before interest, taxes, depreciation and amortization; total stockholder return; stockholders equity or return on equity or average stockholders equity; return on assets, investment or capital employed; operating income; gross margin; operating margin; net operating income (before or after taxes); return on operating revenue; specified levels or changes in sales or revenue; expense or cost reduction; working capital; economic value added; market share; cash flow; operating cash flow; cash flow per share; share price; debt reduction; customer satisfaction; contract awards or backlog; or other objective corporate or individual strategic or individual performance goals. To the extent a performance award is not intended to comply with Section 162(m) of the Code, the compensation committee may select other measures of performance.

*Corporate Transactions.* In the event we are a party to a merger, consolidation or a change in control transaction, outstanding awards granted under the 2013 Plan, and all shares acquired under the plan, will be subject to the terms of

the definitive transaction agreement (or, if there is no such agreement, as determined by our compensation committee. Unless an award agreement provides otherwise, such treatment shall include (without limitation) any of the following with respect to each outstanding award:

- the continuation, assumption or substitution of an award by us or the surviving entity or its parent;
- the cancellation of options and stock appreciation rights without payment of any consideration;
- the cancellation of the awards in exchange for a payment equal to the product of the number of shares subject to the award multiplied by the excess, if any, of the per stock value of property that a holder of our

common stock receives in the transaction over (if applicable) the exercise price of such award. Such payments may be subject to vesting based on a participant s continued service; or

the assignment of any repurchase, forfeiture or reacquisition rights in favor of us to the surviving entity or its parent.

The compensation committee has the discretion to provide that an award granted under the 2013 Plan will vest on an accelerated basis if a change in control of our company occurs or if the participant is subject to an involuntary termination, either at the time such award is granted or afterward.

A change in control includes:

- our merger or consolidation with or into another entity after which our stockholders own 50% or less of the voting power of the stock of the surviving entity or its parent;
- a sale or other disposition of all or substantially all of our assets; or

an acquisition of more than 50% of our outstanding voting stock by any person or group. The compensation committee is not required to treat all awards, or portions thereof, in the same manner.

*Changes in Capitalization.* In the event that there is a change in the capital structure of our common stock, such as a stock split, reverse stock split, or dividend paid in common stock, proportionate adjustments will automatically be made to the kind and maximum number of shares:

- reserved for issuance under the 2013 Plan;
- by which the share reserve may increase automatically each year;
- subject to stock awards that can be granted to a participant in a year (as established under the 2013 Plan pursuant to Section 162(m) of the Code);
- that may be issued upon the exercise of incentive stock options; and
- covered by each outstanding option, stock appreciation right and stock unit, the exercise price applicable to each outstanding option and stock appreciation right, and the repurchase price, if any, applicable to restricted shares.

In the event that there is a declaration of an extraordinary dividend payable in a form other than our common stock in an amount that has a material effect on the price of our common stock, a recapitalization, a spin-off or a similar

occurrence, the compensation committee may make such adjustments as it deems appropriate, in its sole discretion, to one or more of the foregoing.

*Amendments or Termination*. Our board of directors may amend or terminate the 2013 Plan at any time and for any or no reason. If our board of directors amends the 2013 Plan, it does not need to ask for stockholder approval of the amendment unless required by applicable law or exchange listing requirements. The 2013 Plan will continue in effect for 10 years, unless our board of directors decides to terminate the plan earlier or unless our board of directors and stockholders later approve an extension of this term.

# 2010 Employee, Director and Consultant Equity Incentive Plan

Our board of directors adopted our 2010 Employee, Director and Consultant Equity Incentive Plan, or 2010 Plan, in September 2010, and it has been approved by our stockholders. The 2010 Plan became effective on adoption and replaced our 2004 Plan (described below). No further awards will be made under our 2010 Plan following the completion of this offering; however, awards outstanding under our 2010 Plan will continue to be governed by their existing terms.

*Share Reserve*. Up to 681,788 shares of our common stock have been reserved for issuance under the 2010 Plan, including 194,726 shares subject to awards under our 2004 Plan (described below) that are forfeited, expire or are cancelled or

which result in the forfeiture of shares back to the Company. As of December 31, 2013, options to purchase 585,888 shares of common stock at exercise prices ranging from \$0.552 to \$4.56 per share, or a weighted average exercise price of \$1.408 per share, remained outstanding under the 2010 Plan, and 14,649 shares of common stock remained available for future issuance under the 2010 Plan. Shares subject to awards that cease to be outstanding, or shares that the Company reacquires at not more than the original issuance price, generally again become available for issuance under the 2010 Plan.

*Administration*. Our board of directors administers the 2010 Plan. The board of directors has complete discretion to make all decisions relating to the plan and outstanding awards, including repricing outstanding options and modifying outstanding awards.

*Eligibility*. Employees, non-employee members of our board of directors and consultants are eligible to participate in our 2010 Plan.

Types of Awards. Our 2010 Plan provides for the following types of awards:

- incentive and nonstatutory stock options;
- · direct award or sale of shares of our common stock; and
- other stock-based awards.

Terms of Awards. Subject to the terms of the 2010 Plan, the plan administrator determines the terms of all awards.

The exercise price for options granted under the 2010 Plan may not be less than 100% of the fair market value of our common stock on the grant date; however, the exercise price for an incentive stock option granted to a holder of more than 10% of our stock may not be less than 110% of such fair market value on the grant date. Options are generally transferable only by beneficiary designation, a will or the laws of descent and distribution; however, the board of directors may permit the transfer of stock options other than for value. The term of options granted under the 2010 Plan may not exceed ten years and will generally expire sooner if the optione s service terminates. Options vest at the times determined by the board of directors, which has generally been four years following the date of grant.

Shares may be awarded under the 2010 Plan in consideration for services rendered to us or sold under the 2010 Plan. Shares awarded or sold under the 2010 Plan may be fully vested at grant or subject to special forfeiture conditions or rights of repurchase, as determined by our board of directors.

Participants may pay the exercise price for options, or the purchase price for shares (if applicable) in cash or check, or at the discretion of the plan administrator, by tendering shares of common stock already owned; through a net exercise procedure; by tender of a promissory note; or any combination of the above.

*Corporate Transactions.* In the event that we are a party to a merger, consolidation, or sale of all or substantially all of our assets, all outstanding options and share awards shall be subject to one of the following actions:

- the substitution of an award by the surviving entity or its parent;
- the cancellation of any portion of an option not exercised without payment of any consideration; or
- the cancellation of the vested portion of outstanding options or share awards in exchange for a payment per share equal to the excess, if any, of (a) the consideration payable in such transaction to a holder of shares of common stock over (b) the per share exercise or purchase price of the award.

Our board of directors may, in its discretion, accelerate the vesting of any or all portions of outstanding awards. Our board of directors is not obligated to treat all awards in the same manner.

*Stock Dividends and Stock Splits.* All share numbers described in this summary of the 2010 Plan will automatically adjust in the event of a stock split, a stock dividend, or a reverse stock split. In addition, the number of shares subject to awards, and the exercise or purchase price applicable to such awards, will be appropriately adjusted in the event of such change in capitalization.

*Amendments or Termination.* Our board of directors may, at any time and for any reason, amend the 2010 Plan. If our board of directors amends the plan, it does not need to ask for stockholder approval of the amendment unless our board of directors determines such approval is necessary. The 2010 Plan will terminate automatically on September 28, 2020 unless terminated earlier by either our stockholders or our board of directors.

## 2004 Employee, Director and Consultant Stock Plan

Our board of directors adopted our 2004 Employee, Director and Consultant Stock Plan, or 2004 Plan, in August 2004 and it has been approved by our stockholders. The 2004 Plan became effective on adoption and terminated automatically on August 13, 2010; however, awards outstanding under our 2004 Plan continue to be governed by their existing terms.

*Share Reserve*. As of December 31, 2013, options to purchase 23,954 shares of common stock at an average weighted exercise price of \$3.24 per share, remained outstanding under the 2004 Plan.

*Administration*. The board of directors administers the 2004 Stock Plan. The board of directors has complete discretion to make all decisions relating to the plan and outstanding awards, including repricing outstanding options and modifying outstanding awards.

*Eligibility*. Employees, non-employee members of our board of directors and consultants are eligible to participate in our 2004 Plan.

Types of Awards. Our 2004 Plan provides for the following types of awards:

- incentive and nonstatutory stock options; and
- direct award or sale of shares of our common stock.

*Terms of Awards*. Subject to the terms of the 2004 Plan, the plan administrator determines the terms of all awards. The exercise price for incentive stock options granted under the 2004 Plan may not be less than 100% of the fair market value of our common stock on the grant date; The exercise price for nonstatutory stock options granted under the 2004 Plan may not be less than the par value of our common stock. Options are generally transferable only by beneficiary designation, a will or the laws of descent and distribution; however, the board of directors may permit the transfer of stock options other than for value. The term of options granted under the 2004 Plan may not exceed seven years and will generally expire sooner if the optione service terminates. Options vest at the times determined by the board of directors, which has generally been four years following the date of grant.

Shares may be awarded under the 2004 Plan in consideration for services rendered to us or sold under the 2004 Plan. Shares awarded or sold under the 2004 Plan may be fully vested at grant or subject to special forfeiture conditions or rights of repurchase, as determined by our board of directors.

Participants may pay the exercise price for options, or the purchase price for shares (if applicable) in cash or check, or at the discretion of the plan administrator, by tendering shares of common stock already owned; by tender of a promissory note; through a cashless exercise program established with a securities brokerage firm; or through any combination of the above.

*Corporate Transactions*. In the event that we are a party to a merger, consolidation, or sale of all or substantially all of our assets, all outstanding options and share awards shall be subject to one of the following actions:

- the substitution of an award by the surviving entity or its parent;
- the cancellation of any portion of an option not exercised (or, with respect to a share award, cancellation of any portion of such award not accepted) without payment of any consideration; or
- the cancellation of the vested portion of outstanding options or share awards in exchange for a payment per share equal to the excess, if any, of (a) the consideration payable in such transaction to a holder of shares of common stock over (b) the per share exercise or purchase price (if any) of the award.

Our board of directors may, in its discretion, accelerate the vesting of any or all portions of outstanding awards. Our board of directors is not obligated to treat all awards in the same manner.

*Changes in Capitalization.* All share numbers described in this summary of the 2004 Plan will automatically adjust in the event of a stock split, a stock dividend, or a reverse stock split. In addition, the number of shares subject to awards, and the exercise or purchase price applicable to such awards, will be appropriately adjusted in the event of such change in capitalization.

*Amendments or Termination.* Our board of directors may, at any time and for any reason, amend the 2004 Plan. If our board of directors amends the plan, it does not need to ask for stockholder approval of the amendment unless our board of directors determines such approval is necessary. The 2004 Plan terminated automatically on August 13, 2010.

### Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director s duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or

any transaction from which the director derived an improper personal benefit. Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors and officers liability insurance.

Prior to the consummation of this offering, we expect to enter into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, will provide for indemnification of our directors and executive officers for certain expenses, judgments, fines and settlement amounts,

among others, incurred by such person in any action or proceeding arising out of such person s services as a director or executive officer in any capacity with respect to any employee benefit plan or as a director, partner, trustee or agent of another entity at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is incorporated by reference as an exhibit to this registration statement.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay

the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

## **RELATED PARTY TRANSACTIONS**

The following is a description of transactions since January 1, 2011 to which we have been a party, in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our convertible preferred stock or common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under Executive Compensation. We also describe below certain other transactions with our directors, executive officers and stockholders.

All of the transactions set forth below were approved by a majority of our board of directors, including a majority of the independent and disinterested members of our board of directors. We believe that we have executed all of the transactions set forth below on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by the audit committee and a majority of the members of our board of directors, including a majority of the independent and disinterested members of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

### **Preferred Stock Financings**

In sales occurring in December of 2012 and August of 2013, we issued and sold to investors affiliated with Domain Associates, L.L.C. and Johnson & Johnson Development Corporation an aggregate of 1,316,681 shares of our Series B convertible preferred stock at a purchase price of \$5.1588 per share and issued such investors warrants to purchase an aggregate of 193,842 shares of our Series B convertible preferred stock at an exercise price of \$5.1588 per share, for aggregate consideration of approximately \$6.8 million. We have entered into an agreement with the warrant holders whereby such holders have agreed to net exercise the warrants effective and contingent upon the consummation of this offering.

The following table summarizes the purchases of Series B convertible preferred stock by the beneficial holders of more than 5% of our capital stock or entities affiliated with them:

		Number of Voting	Number of Non-Voting
Stockholder	<b>Aldeyra Director</b>	Series B Shares	Series B Shares
Entities affiliated with Domain Associates, LLC	Jesse Treu Ph.D.	755,263	
Johnson & Johnson Development Corporation	(1)	427,591	133,827

(1) Asish Xavier, Ph.D., an affiliate of Johnson & Johnson Development Corporation, resigned as a director of the company in October 2013.

Some of our directors have previously been or are currently associated with our principal stockholders as indicated in the table below:

**Director** Todd C. Brady, M.D., Ph.D. Principal Stockholder Previously affiliated with Domain Associates, L.L.C. and its affiliates Jesse Treu, Ph.D.

Currently affiliated with Domain Associates, L.L.C. and its affiliates

# Investors Rights Agreement

In connection with the initial closing of the Series B convertible preferred stock financing described above, we entered into an amended and restated investors rights agreement with the holders of all of our outstanding shares of convertible preferred stock, including entities affiliated with Domain Associates, L.L.C and Johnson & Johnson Development Corporation. Pursuant to this agreement, we granted such stockholders certain registration rights with respect to shares of our common stock and a right of first offer with respect to future issuances of the Company s securities. This agreement will terminate pursuant to its terms upon the consummation of this offering. For more information regarding this agreement, see Description of Capital Stock Registration Rights.

# **Voting Agreement**

In connection with the initial closing of the Series B convertible preferred stock financing, along with certain holders of our common stock and certain holders of our convertible preferred stock, we entered into an amended and restated

voting agreement, which was amended in June 2013 and again in October 2013. Under the terms of the voting agreement, the parties have agreed, subject to certain conditions, to vote their shares so as to elect as directors the nominees designated by certain of our investors, including Domain Partners VI, L.P., which designated Jesse Treu, Ph.D. following the amendment to the voting agreement in June 2013 and Johnson & Johnson Development Corporation, which currently has not designated a director. In addition, the parties to the voting agreement have agreed, pursuant to the amendment executed in June 2013, to vote their shares so as to elect to our board of directors our Chief Executive Officer, who is currently Todd C. Brady, M.D., Ph.D., and additional at-large directors nominated by the holders of our common stock and the holders of our convertible preferred stock, voting together, who are currently Ben Bronstein, M.D., Neal Walker, D.O., Gary Phillips, M.D., Martin J. Joyce and C. Boyd Clarke. The voting agreement will terminate immediately prior to the completion of this offering.

# **Right of First Refusal and Co-sale Agreement**

In connection with the initial closing of the Series A convertible preferred stock financing with certain holders of our common stock and certain holders of our convertible preferred stock, we entered into a right of first refusal and co-sale agreement. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock and common stock issuable upon conversion of the shares of convertible preferred stock held by the parties thereto. The right of first refusal and co-sale agreement will terminate immediately prior to the completion of this offering.

# **Convertible Promissory Note**

In October 2013, we issued a convertible promissory note to Domain Partners VI, L.P., in a principal amount of \$170,000, which was amended in February 2014 to extend its maturity date. The note accrues interest at a rate of 6% per annum, and will be converted into shares of Series B convertible preferred stock in June 2014 unless it is converted into shares of our capital stock prior to such time pursuant to its terms. The note provides that it shall convert in connection with a public offering of our securities and therefore immediately prior to the closing of this offering, the principal and accrued but unpaid interest on the note shall convert into shares of our common stock at a price per share equal to the initial public offering price per share for common stock listed on the cover page of this prospectus.

# **Employment Agreements**

We have entered into offer letters with the following executive officers: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; and Scott L. Young, our Chief Operating Officer. For more information regarding these agreements, see the section of this prospectus entitled Executive Compensation Narrative Disclosure to Compensation Tables.

# **Indemnification Agreements**

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

as directors and executive officers.

## Stock Option Grants to Executive Officers and Directors

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

## **Restricted Stock Sales to Executive Officers**

On September 8, 2013, the board of directors approved the sale to Dr. Brady 12,948 shares of our common stock at a price of \$0.552 per share pursuant to the 2010 Plan. The stock was fully vested at the time of grant and subject to certain restriction regarding transfer of the shares, including a right of first refusal for the benefit of the Company. On September 10, 2013, Dr. Brady transferred 10,358 of such shares to Domain Associates L.L.C., an entity affiliated with certain of the Company s stockholders. All of the rights and restrictions that applied to the common stock granted to Dr. Brady continue to apply to the shares following the transfer to Domain Associates L.L.C.

### PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of April 15, 2014, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each of our named executive officers;
- each of our directors;
- · all of our directors and current executive officers as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 3,970,164 shares of common stock outstanding on April 15, 2014, which gives effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of April 15, 2014 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Aldeyra Therapeutics, Inc., 15 New England Executive Park, Burlington, MA 01803. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
Name of Beneficial Owner	Number	Percentage	Number	Percentage
5% or Greater Stockholders				
Funds affiliated with Domain				
Associates, L.L.C . One Palmer Square Princeton, NJ 08542	2,049,831(1)	50.1%	2,049,831(1)	38.7%
Johnson & Johnson Development	1,797,169(2)	44.5%	1,797,169(2)	34.3%
Corporation				

### 410 George Street

New Brunswick, NJ 08901

Executive Officers and Directors				
Todd Brady, M.D., Ph.D.	99,568(3)	2.4%	115,575(4)	2.2%
Scott Young	43,347(5)	1.1%	59,354(6)	1.1%
Ben Bronstein, M.D.	5,800(7)	*	5,800(7)	*
Gary Phillips, M.D.	7,443(8)	*	7,443(8)	*
Jesse Treu, Ph.D .	2,049,831(9)	50.1%	2,049,831(9)	38.7%
Neal Walker, D.O.	4,600(10)	*	4,600(10)	*
Martin Joyce	-	*	-	*
C. Boyd Clarke	-	*	-	*
Asish Xavier, Ph.D.	1,797,169(11)	44.5%	1,797,169(11)	34.3%
All current executive officers and directors				
as a group				
(8 persons)	2,210,589(12)	52.0%	2,242,603(13)	40.9%

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

(1) Consists of 10,358 shares of common stock held by Domain Associates LLC, 1,909,113 shares of common stock held by Domain Partners VI, L.P., 9,208 shares of common stock held by DP VI Associates, L.P., and currently exercisable

warrants to purchase up to 121,152 shares of common stock held by Domain Partners VI, L.P. The managing members of One Palmer Square Associates VI, L.L.C., the general partner of Domain Partners VI, L.P. and DP VI Associates, L.P., share voting and investment power with respect to these shares. The managing members of Domain Associates LLC are James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak and Kim Kamdar. Each of James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak and Kim Kamdar share voting and investment power with respect to the securities held by Domain Associates LLC. Each of James Blair, Kathleen Schoemaker, Jesse Treu, Brian Dovey, Nicole Vitullo, Brian Halak, and Kim Kamdar disclaims beneficial ownership of the securities held by Domain Associates LLC except to the extent of his or her pecuniary interest therein, if any.

- (2) Consists of 1,724,478 shares of common stock, held by the Johnson & Johnson Development Corporation (JJDC) and currently exercisable warrants to purchase up to 72,691 shares of common stock held by JJDC. Linda Vogel, Investment Portfolio Manager, of 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) Includes options to purchase 96,979 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (4) Includes options to purchase 96,979 shares of common stock that may be exercised within 60 days of April 15, 2014 and 16,007 shares of common stock that may be exercised as of the effective date of this offering.
- (5) Consists of options to purchase 43,347 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (6) Consists of options to purchase 43,347 shares of common stock that may be exercised within 60 days of April 15, 2014 and 16,007 shares of common stock that may be exercised as of the effective date of this offering.
- (7) Consists of options to purchase 5,800 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (8) Consists of options to purchase 7,443 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (9) Consists of securities beneficially owned by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC as set forth in footnote 1 above, for which Dr. Treu may be deemed to share voting and investment power. Dr. Treu disclaims beneficial ownership of the securities held by Domain Partners VI, DP VI Associates, L.P. and Domain Associates LLC except to the extent of his pecuniary interest therein, if any.
- (10)Consists of options to purchase 4,600 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (11)Consists of securities beneficially owned by JJDC as set forth in footnote 2 above, for which Mr. Xavier, a former director of our company, may be deemed to share voting and investment power. Mr. Xavier disclaims beneficial ownership of the securities held by JJDC except to the extent of his pecuniary interest therein, if any. Mr. Xavier resigned from our board of directors in October 2013.
- (12)Includes currently exercisable warrants to purchase up to 193,843 shares of common stock and options to purchase an aggregate of 158,169 shares of common stock that may be exercised within 60 days of April 15, 2014.
- (13)Includes currently exercisable warrants to purchase up to 193,843 shares of common stock and options to purchase an aggregate of 158,169 shares of common stock that may be exercised within 60 days of April 15, 2014 and 32,014 shares of common stock that may be exercised as of the effective date of this offering.

# **DESCRIPTION OF CAPITAL STOCK**

## General

Following the closing of this offering, our authorized capital stock will consist of 150,000,000 shares of common stock, par value \$0.001 per share, and 15,000,000 shares of preferred stock, par value \$0.001 per share. The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws does not purport to be complete and is qualified in its entirety by the provisions of our restated certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

# **Common Stock**

*Outstanding Shares.* Based on 3,970,164 shares of common stock outstanding as of December 31, 2013, assuming conversion of all outstanding shares of our Series A convertible preferred stock and Series B convertible preferred stock into shares of common stock immediately prior to the closing of this offering and the issuance of 1,200,000 shares of common stock in this offering, and no exercise of outstanding options or warrants, there will be 5,170,164 shares of common stock outstanding upon the closing of this offering. As of December 31, 2013, assuming the conversion of all outstanding shares of our Series A convertible preferred stock and Series B convertible preferred stock into common stock upon the closing of this offering, we had eleven (11) record holders of our common stock.

As of December 31, 2013, there were 609,842 shares of common stock subject to outstanding options.

*Voting Rights.* Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Except as otherwise provided by law or our restated certificate of incorporation or bylaws, all matters other than the election of directors submitted to the stockholders at any meeting shall be decided by the affirmative vote of a majority of the outstanding shares of common stock present in person or represented by proxy at the meeting and entitled to vote thereon. Directors are elected by a plurality of the votes cast at the meeting. Our restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. At present, we have no plans to issue dividends. See the section titled Dividend Policy .

*Liquidation.* In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

*Other Rights and Preferences.* Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

*Fully Paid and Nonassessable.* All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

# **Preferred Stock**

Upon the closing of this offering, we will have no shares of our preferred stock outstanding. Outstanding shares of voting Series A convertible preferred stock will be converted into 2,078,424 shares of common stock, outstanding shares of non-voting Series A convertible preferred stock will be converted into 247,694 shares of common stock, outstanding shares of voting Series B convertible preferred stock will be converted into 1,182,854 shares of common stock, and outstanding shares of non-voting Series B convertible preferred stock will be converted into 1,182,854 shares of common stock, and outstanding shares of non-voting Series B convertible preferred stock will be converted into 133,827 shares of common stock.

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Our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any preferred stock.

# Options

As of December 31, 2013, options to purchase 609,842 shares of our common stock were outstanding under our 2004 equity incentive plan and 2010 equity incentive plan, collectively, of which 96,949 were vested and 512,893 of which were unvested as of that date.

# **Convertible Promissory Note**

In October 2013, we issued a convertible promissory note to Domain Partners VI, L.P., in a principal amount of \$170,000, which was amended in February 2014 to extend its maturity date. The note accrues interest at a rate of 6% per annum, and will convert into shares of Series B preferred convertible stock in June 2014 unless it is converted into shares of our capital stock prior to such time pursuant to its terms. The note provides that it shall convert in connection with a public offering of our securities and therefore immediately prior to the closing of this offering, the principal and accrued but unpaid interest on the note shall convert into shares of our common stock at a price per share equal to the initial public offering price for common stock listed on the cover page of this prospectus. Assuming an initial public offering price of \$11.00 per share, the midpoint or the range set forth on the cover page of this offering.

# Warrants

In April 2012, in connection with the closing of a debt facility, we issued a warrant to Square 1 Bank, which warrant was immediately exercisable for an aggregate of 2,042 shares of our Series A convertible preferred stock, at an exercise price of \$12.24 per share. Upon the closing of this offering, this warrant will become exercisable for 4,844 shares of common stock at an exercise price of \$5.1588 per share. This warrant will expire three years from the effective date of the registration statement of which this prospectus is a part. In November 2013, in connection with the amendment to our loan and security agreement with Square 1 Bank, we issued Square 1 Bank a warrant that is immediately exercisable for an aggregate of 9,692 shares of our Series B convertible preferred stock, at an exercise price of \$5.1588 per share. Upon the closing of this offering, this warrant will become exercisable for 9,692 shares of common stock at an exercise price of \$5.1588 per share of our Series B convertible preferred stock, at an exercise price of \$5.1588 per share. Upon the closing of this offering, this warrant will become exercisable for 9,692 shares of common stock at an exercise price of \$5.1588 per share assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant will expire three years from the effective date of the registration statement of which this prospectus is a part. We have entered into an agreement with the warrant holder whereby the holder has agreed to net exercise the warrants effective and contingent upon the consummation of this offering.

In December 2012 and August 2013, in connection with our Series B convertible preferred stock financing, we issued warrants to the investors in such financing, which warrants are immediately exercisable for an aggregate of 193,842 shares of our Series B convertible preferred stock, at an exercise price of \$5.1588 per share. Immediately prior to the closing of this offering, this warrant will become exercisable for 193,842 shares of common stock at an exercise price of \$5.1588 per share assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant will expire three years from the effective date of the registration statement of which this prospectus is a part. We have entered into an agreement with the warrant holders whereby such holders have agreed to net exercise the warrants

effective and contingent upon the consummation of this offering.

## **Representative s Warrants**

We have agreed to issue to the representative of the underwriters in this offering warrants to purchase up to 48,000 shares of our common stock, with a per share exercise price equal to 125% of the initial public offering price per share of common stock. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). See Underwriting Representative s Warrants section of this prospectus for a description of these warrants.

## **Registration Rights**

After the completion of this offering, holders of 3,642,799 shares of our common stock will be entitled to rights with respect to the registration of those shares under the Securities Act. Under the terms of the investors rights agreement between us and the holders of these registrable securities, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders exercising registration rights, these holders are entitled to notice of registration and are entitled to include their shares of common stock in the registration. The holders of these registrable securities are also entitled to specified demand registration rights under which they may require us to file a registration statement under the Securities Act at our expense with respect to our shares of common stock, and we are required to use our commercially reasonable efforts to effect this registration. Further, the holders of these registrable securities may require us to file additional registration statements on Form S-3. All of these registration rights are subject to conditions and limitations, among them the right of the underwriters of an offering to limit the number of shares included in the registration and our right not to effect a requested registration within six months following the initial offering of our securities, including this offering. This is not a complete description of this investors rights agreement and is qualified by the full text of the investors rights agreement which has been filed as an exhibit to the registration statement of which this prospectus is a part.

In addition, the Representative s Warrants and the warrants listed in the section entitled Description of Capital Stock Warrants provide for certain registration rights to the holders thereof. Each of the warrants provide that upon its exercise the holder shall have certain rights to participate in registrations of our common stock that we may decide to do, from time to time.

## Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

# Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 15,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

### Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board or president, or by a resolution adopted by a majority of our board of directors.

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## Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

## Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

### Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see Management Board Composition and Election of Directors. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

### Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than  $66^{2}/_{3}\%$  of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

#### Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

#### Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be interested stockholders from engaging in a business combination with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

#### Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least  $66^{2}/_{3}\%$  of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

### **Transfer Agent and Registrar**

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The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC.

# NASDAQ Capital Market

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol ALDX.

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on The NASDAQ Capital Market, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of December 31, 2013 and assuming (1) the issuance of shares in this offering, and (2) the conversion of all outstanding shares of our convertible preferred stock into 3,642,799 shares of our common stock, which we expect to automatically occur immediately prior to the closing of the offering, (3) no exercise of the underwriters over-allotment option to purchase additional shares of common stock, (4) no exercise of outstanding options and (5) the net exercise of outstanding warrants to purchase shares of our convertible preferred stock and the subsequent automatic conversion of such shares into shares of common stock, we will have outstanding an aggregate of 5,280,811 shares of common stock upon the effectiveness of the public offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 4,080,811 shares of common stock will be restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, of the 609,842 shares of our common stock that were subject to stock options outstanding as of December 31, 2013, options to purchase 96,949 of such shares of common stock were vested as of such date and, upon exercise, these shares will be eligible for sale subject to the lock up agreements described below and Rules 144 and 701 under the Securities Act.

# Lock-Up Agreements

We, each of our directors and executive officers and holders of all of our outstanding shares of common stock have agreed that, without the prior written consent of Aegis Capital Corp. on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, subject to extension in specified circumstances:

- offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock or any securities convertible into or

exchangeable or exercisable for shares of our common stock, whether such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise;

 make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock; or

• publicly announce an intention to do any of the foregoing. The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under Underwriting.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

## Rule 144

## Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in broker s transactions or certain riskless principal transactions or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 52,809 shares immediately after this offering; or
- the average weekly trading volume in 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 such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and The NASDAQ Capital Market concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

### Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date 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 requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Equity Plan**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plan. We expect to file the registration statement covering shares offered pursuant to our stock plan shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

# **Registration Rights**

Based on the number of shares of our convertible preferred stock outstanding as of December 31, 2013 and assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 3,642,799 shares of our common stock immediately prior to the closing of the offering, the holders of 3,642,799 shares of common stock or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the

closing of this offering. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. In addition, the Representative s Warrants and the warrants listed in the section entitled Description of Capital Stock Warrants provide for certain registration rights to the holders thereof. See Description of Capital Stock Registration Rights for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

## MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material United States federal income tax consequences of the purchase, ownership and disposition of our common stock as of the date hereof.

This discussion is based on the provisions of the Internal Revenue Code of 1986, as amended, or the Code, and regulations, rulings and judicial decisions as of the date hereof. Those authorities may be changed, possibly with retroactive effect, or subject to different interpretations. This discussion is limited to persons who hold shares of our common stock as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). Moreover, this discussion does not address all the United States federal income tax consequences and does not address foreign, state, local or other tax considerations that may be relevant to you in light of your personal circumstances. This discussion does not address special situations, including, without limitation, those of: brokers or dealers in securities; regulated investment companies; real estate investment trusts; persons holding common stock as a part of a hedging, integrated, conversion or constructive sale transaction or a straddle; traders in securities that elect to use a mark-to-market method of accounting for their securities holdings; persons liable for alternative minimum tax; United States Holders (as defined below) whose functional currency is not the United States dollar; investors in pass-through entities; persons who acquired our common stock through the exercise of employee stock options or otherwise as compensation; United States expatriates, controlled foreign corporations, passive foreign investment companies, financial institutions, insurance companies, tax-exempt organizations, or entities or arrangements treated as partnerships or other pass-through entities for United States federal income tax purposes.

If you are a partnership holding our common stock, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. If you are a partner in a partnership holding our common stock, you should consult your tax advisor.

EACH PROSPECTIVE PURCHASER IS ADVISED TO CONSULT A TAX ADVISOR REGARDING THE UNITED STATES FEDERAL, STATE, LOCAL AND FOREIGN INCOME, ESTATE AND OTHER TAX CONSEQUENCES OF PURCHASING, OWNING AND DISPOSING OF OUR COMMON STOCK.

### **Consequences to United States Holders**

The following is a summary of the material United States federal income tax consequences that will apply to you if you are a United States Holder of shares of our common stock. A United States Holder of common stock means a beneficial owner of common stock that is for United States federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or

a trust if it is subject to the primary supervision of a court within the United States and one or more United States persons have the authority to control all substantial decisions of the trust or has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person.

# Distributions on Common Stock

In general, if you receive a distribution with respect to our common stock, such distributions will be treated as a dividend to the extent of our current and accumulated earnings and profits as determined for United States federal income tax purposes. Any portion of a distribution that exceeds our current and accumulated earnings and profits will first be applied to reduce your tax basis in our common stock and, to the extent such portion exceeds your tax basis, the excess will be treated as gain from the disposition of the common stock, the tax treatment of which is discussed below under Sale, Exchange, or Other Disposition of Common Stock.

Under current legislation, dividend income may be taxed to an individual at rates applicable to long term capital gains, provided that a minimum holding period and other limitations and requirements are satisfied. Any dividends that we pay to a

United States Holder that is a United States corporation will qualify for a deduction allowed to United States corporations in respect of dividends received from other United States corporations equal to a portion of any dividends received, subject to generally applicable limitations on that deduction. In general, a dividend distribution to a corporate United States Holder may qualify for the 70% dividends received deduction if the United States Holder owns less than 20% of the voting power and value of our stock. You should consult your tax advisor regarding the holding period and other requirements that must be satisfied in order to qualify for the dividends-received deduction and the reduced maximum tax rate on dividends.

## Sale, Exchange, or Other Disposition of Common Stock

You will generally recognize capital gain or loss on a sale, exchange or certain other dispositions of our common stock. Your gain or loss will equal the difference between your amount realized and your tax basis in the stock. Your amount realized will include the amount of any cash and the fair market value of any other property received for the stock. The gain or loss recognized on a sale or exchange of stock will be long-term capital gain or loss if you have held the stock for more than one year. Long-term capital gains of non-corporate taxpayers are generally taxed at lower rates than those applicable to ordinary income. The deductibility of capital losses is subject to certain limitations.

# Medicare Contribution Tax

Recently enacted legislation requires certain United States Holders who are individuals, estates or certain trusts to pay a 3.8% tax on the lesser of (1) the United States person s net investment income for the relevant taxable year and (2) the excess of the United States person s modified gross income for the taxable year over a certain threshold (which in the case of individuals will be between \$125,000 and \$250,000 depending on the individual s circumstances). Net investment income generally includes, among other things, dividends and capital gains from the sale or other dispositions of stock, unless such dividend income or gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). A United States Holder that is an individual, estate or trust should consult its tax advisor regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our common stock.

# American Taxpayer Relief Act of 2012

The American Taxpayer Relief Act of 2012 (ATRA) was signed into law by President Obama on January 2, 2013. Certain provisions of United States federal income tax law relating to capital gain taxation and the applicability of capital gain rates to dividends designated as qualified dividend income were scheduled to sunset and revert to provisions of prior law for taxable years beginning after December 31, 2012. ATRA has modified those rules. For taxable years beginning after 2012, for noncorporate taxpayers, both the maximum capital gain tax rate (for gain other than unrecaptured section 1250 gain ) and the maximum rate applicable to qualified dividend income generally is 20%.

# Information Reporting and Backup Withholding

Under certain circumstances, United States Treasury regulations require information reporting and backup withholding on certain payments on common stock or on the sale thereof. When required, we will report to the Internal Revenue Service and to each United States Holder the amounts paid on or with respect to our common stock and the United States federal withholding tax, if any, withheld from such payments. A United States Holder will be subject to backup withholding on the dividends paid on the common stock and proceeds from the sale of the common stock at the applicable rate if the United States Holder (a) fails to provide us or our paying agent with a correct taxpayer identification number or certification of exempt status (such as a certification of corporate status), (b) has been notified by the Internal Revenue Service that it is subject to backup withholding as a result of the failure to

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properly report payments of interest or dividends, or (c) in certain circumstances, has failed to certify under penalty of perjury that it is not subject to backup withholding. A United States Holder may be eligible for an exemption from backup withholding by providing a properly completed Internal Revenue Service Form W-9 to us or our paying agent.

Backup withholding does not represent an additional United States federal income tax. Any amounts withheld from a payment to a United States Holder under the backup withholding rules will be allowed as a credit against such holder s United States federal income tax liability and may entitle the holder to a refund, provided that the required information or returns are timely furnished by the holder to the Internal Revenue Service.

# **Consequences to Non-United States Holders**

The following is a summary of the material United States federal income tax consequences that will apply to you if you are a Non-United States Holder of shares of our common stock. A Non-United States Holder is a beneficial owner of common stock (other than an entity or arrangement treated as a partnership for United States federal income tax purposes) that is not a United States Holder.

# **Distributions on Common Stock**

If you receive a distribution in respect of shares of our common stock and such distribution is treated as a dividend (see Consequences to United States Holders Distributions on Common Stock ), as a Non-United States Holder, you will generally be subject to withholding of United States federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To claim the benefit of a lower rate under an income tax treaty, you must properly file with the payor an Internal Revenue Service Form W-8BEN, or successor form, certifying under penalty of perjury that you are not a United States person (as defined under the Code) and claiming an exemption from or reduction in withholding under the applicable tax treaty. Special certification and other requirements apply to you if you are a pass-through entity rather than a corporation or individual or if our common stock is held through certain foreign intermediaries.

If dividends are considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, are attributable to a United States permanent establishment of yours, those dividends will not be subject to withholding tax, but instead will be subject to United States federal income tax on a net basis at applicable graduated individual or corporate rates as if you were a United States person (as defined under the Code), unless an applicable income tax treaty provides otherwise, provided an Internal Revenue Service Form W-8ECI, or successor form, is filed with the payor. In addition, if you are required to provide an Internal Revenue Service Form W-8ECI or successor form, as discussed above, you must also provide your tax identification number. If you are a foreign corporation, any effectively connected dividends may, under certain circumstances, be subject to an additional branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If you do not timely provide the relevant paying agent with the required certification but are eligible for a reduced rate of United States withholding tax pursuant to an income tax treaty, you may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the Internal Revenue Service.

#### Gain on Disposition of Common Stock

Subject to the discussion below under Foreign Account Legislation, as a Non-United States Holder, you generally will not be subject to United States federal income tax on any gain realized on the sale or other disposition of our common stock (including a distribution with respect to our common stock that is treated as a sale or exchange) unless:

• the gain is considered effectively connected with the conduct of a trade or business by you within the United States and, where a tax treaty applies, is attributable to a United States permanent establishment of yours, in which case, you will generally be subject to tax on the net gain derived from the sale under regular graduated United States federal income tax rates as if you were a United States person (as defined in the Code) and, if you are a corporation, you may be subject to an additional branch profits tax equal to 30% or such lower rate as may be specified by an applicable income tax treaty;

- you are an individual who is present in the United States for 183 or more days in the taxable year of the sale or other disposition and certain other conditions are met, in which case, you will be subject to a 30% (or such lower rate as may be specified by an applicable income tax treaty) tax on the gain derived from the sale, which may be offset by United States source capital losses; or
- we are or have been a United States real property holding corporation for United States federal income tax purposes at any time within the shorter of the five-year period ending on the date of disposition or the period you held our common stock. As long as our common stock is regularly traded on an established securities market, within the meaning of section 897(c)(3) of the Code, these rules will apply only if you actually or constructively hold more than 5% of our common stock at any time during the applicable period that is specified in the Code. We believe that we are not currently, and are not likely to become, a United States real property holding corporation.

#### Information Reporting and Backup Withholding Tax

We must report annually to the Internal Revenue Service and to each of you the amount of dividends paid to you and the tax withheld with respect to those dividends, regardless of whether withholding was required. Copies of the information returns reporting those dividends and withholding may also be made available by the Internal Revenue Service to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty or other applicable agreements.

Backup withholding tax may also apply to dividend payments made to you on or with respect to our common stock unless you certify under penalty of perjury that you are a Non-United States Holder (and we do not have actual knowledge or reason to know that you are a United States person (as defined under the Code)) or you otherwise establish an exemption.

Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through United States-related financial intermediaries unless the beneficial owner certifies under penalty of perjury that it is a Non-United States Holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person (as defined under the Code)) or the holder otherwise establishes an exemption.

Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against your United States federal income tax liability provided that the required procedures are followed.

You should consult your tax advisor regarding the application of the information reporting and backup withholding rules to you.

#### **Foreign Account Legislation**

Recently enacted legislation generally will impose a withholding tax of 30% on any dividends on our common stock paid to a foreign financial institution, unless such institution enters into an agreement with the United States government to, among other things, collect and provide to the United States tax authorities substantial information regarding United States account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with United States owners). Institutions in certain jurisdictions that have entered into agreements with the United States may have their compliance determined by such agreements. The legislation will also generally impose a withholding tax of 30% on any dividends on our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either certification that such entity does not have any substantial United States owners or identification of the direct and indirect substantial United States owners of the entity. Finally, withholding of 30% also generally will apply to the gross proceeds of a disposition of our common stock paid to a foreign financial institution or to a non-financial foreign entity unless the reporting and certification requirements described above have been met. Under certain circumstances, a Non-United States Holder of our common stock may be eligible for refunds or credits of such taxes. You are encouraged to consult with your own tax advisor regarding the possible implications of this legislation on your investment in our common stock. Although this legislation currently applies to amounts paid after December 31, 2012, the IRS has issued guidance providing that the withholding provisions described above will generally apply to payments of dividends on our common stock made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of such stock on or after January 1, 2017.

You are encouraged to consult with your own tax advisor regarding the possible implications of this legislation on your investment in our common stock.

# UNDERWRITING

Aegis Capital Corp. is acting as the sole manager of the offering and as representative of the underwriters. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the representative of the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of shares of common stock listed next to its name in the following table.

Underwriters	Number of Shares
Aegis Capital Corp.	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of nondefaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters over-allotment option described below. 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 contained in the underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Certain of our directors, officers, employees and business associates or their affiliates or related parties have indicated that they may have an interest in purchasing shares in this offering, which would reduce the number of shares sold to the general public. However, because indications of interest are not binding agreements or commitments to purchase, these persons or entities may determine not to purchase any shares in this offering.

#### **Discounts and Commissions**

Total

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise of the over-allotment option we granted to the representative of the underwriters.

Total WithoutTotal WithOver-AllotmentOver-AllotmentOptionOption

1,200,000

Per Share

Public offering price	\$ \$	\$
Underwriting discounts and commissions		
Non-accountable expense allowance		

Proceeds, before expenses, to us

We have agreed to pay a non-accountable expense allowance to the representative of the underwriters equal to 1% of the gross proceeds received in the offering; provided, however, that an allowance shall not be paid in connection with the over-allotment option if the over-allotment option is exercised. We have paid an expense deposit of \$25,000 to the representative of the underwriters, which will be applied against accountable expenses that will be paid by us to the representative in connection with this offering, which advance will be refunded to us to the extent not actually incurred by the representative in the event this offering is terminated.

We have also agreed to pay the representative s expenses relating to the offering, including (a) all actual filing fees incurred in connection with the review of this offering by the Financial Industry Regulatory Authority, or FINRA, and all fees and expenses relating to the listing of our shares of common stock on The NASDAQ Capital Market; (b) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$5,000 per individual, or a maximum aggregate of \$40,000; (c) all actual fees, expenses and disbursements relating to the registration or

qualification of securities offered under state securities laws, or blue sky laws, or under the securities laws of foreign jurisdictions designated by the representative in an amount not to exceed \$10,000 in the aggregate; (d) all actual fees, expenses and disbursements relating to the registration, qualification or exemption of our shares of common stock under the securities laws of such foreign jurisdictions as the representative may reasonably designate; (e) the costs of all mailing and printing of the underwriting documents as the representative may reasonably deem necessary; (f) the fees and expenses of our accountant; (g) the fees and expenses of our legal counsel and other agents and representatives, (h) \$21,775 for the underwriters use of Ipreo s book-building, prospectus tracking and compliance software for this offering; (i) the costs associated with bound volumes of the public offering materials as well as commerative mementos and lucite tombstones, in such quantities as the representative may reasonably request in an amount not to exceed \$1,000 and (j) up to \$20,000 of the representative s actual accountable road show expenses for the offering.

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$1.2 million and are payable by us.

#### **Over-Allotment Option**

We have granted to the underwriters an option to purchase up to 180,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 45 days from the date of this prospectus solely to cover sales of shares of common stock by underwriters in excess of the total number of shares set forth in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

#### **Representative** s Warrants

We have agreed to issue to the representative of the underwriters warrants to purchase up to 48,000 shares of common stock, which is 4% of the shares sold in this offering, excluding the over-allotment option, as additional compensation. The shares issuable upon exercise of these warrants are identical to those offered by this prospectus. We are registering hereby the warrants and the shares of common stock issuable upon exercise of the warrants. The warrants are exercisable for cash or on a cashless basis at a per share exercise price equal to 125% of the public offering price per share in this offering commencing on a date which is one year from the date of effectiveness and expiring on a date which is no more than five years from the date of effectiveness in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants and the shares of common stock underlying the warrants 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 representative (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate these warrants or the securities underlying these warrants, 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. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the date of effectiveness in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants, other than underwriting commissions incurred and payable by the holders. 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.

# **Determination of Offering Price**

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be negotiated between us and the representative. Among the factors to be considered in these negotiations are:

- the prospects for our company and the industry in which we operate;
- our past and present financial and operating performance;
- financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;

- the prevailing conditions of United States securities markets at the time of this offering; and
- other factors deemed relevant.

#### Lock-Up Agreements

We, our officers and directors and holders of all of our outstanding stock have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock or securities convertible into, or exchangeable or exercisable for, common stock, during a period ending 180 days after the date of this prospectus, without first obtaining the written consent of representative of the underwriters.

Specifically, we and these other individuals have agreed not to:

- offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or other securities, in cash or otherwise; make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock; or

• publicly announce an intention to do any of the foregoing. The restrictions described above do not apply to:

- the sale of shares of common stock to the underwriters pursuant to the underwriting agreement;
- the issuance by us of shares of common stock upon the exercise of an option or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing or that is described in this prospectus;
- the grant by us of stock options or other stock-based awards, or the issuance of shares of common stock upon exercise thereof, to eligible participants pursuant to employee benefit or equity incentive plans described in this prospectus, provided that, prior to the grant of any such stock options or other stock-based awards that vest within the restricted period, each recipient of such grant shall sign and deliver a lock-up agreement agreeing to be subject to the restrictions on transfer described above;

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- the establishment of a Rule 10b5-1 trading plan under the Exchange Act by a security holder for the sale of shares of common stock, provided that such plan does not provide for the transfer of common stock during the restricted period;
- transfers by security holders of shares of common stock or other securities as a bona fide gift or by will or intestacy;
- transfers by distribution by security holders of shares of common stock or other securities to partners, members, or shareholders of the security holder; or
- transfers by security holders of shares of common stock or other securities to any trust for the direct or indirect benefit of the security holder or the immediate family of the security holder;

provided that in the case of each of the preceding three types of transactions, the transfer does not involve a disposition for value and each transferee or distributee signs and delivers a lock-up agreement agreeing to be subject to the restrictions on transfer described above.

## **Right of First Refusal**

Subject to certain conditions, we granted the representative of the underwriters in this offering, for a period of eight months after the date of effectiveness, a right of first refusal to act as sole book-running manager for each and every future public and private equity and public debt offering.

## Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

# **NASDAQ** Listing

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol ALDX.

# Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering.

Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising the over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales 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 result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the representative of the underwriters purchases common stock in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once

commenced, will not be discontinued without notice.

# **Electronic Offer, Sale and Distribution of Shares**

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters and selling group members that may make Internet

distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

#### Notice to Non-United States Investors

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, each of which we refer to as a relevant member state, with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state, or the relevant implementation date, an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to legal entities that 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;
- to any legal entity that has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than 43,000,000 and (iii) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of representative for any such offer; or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of shares to the public in relation to any shares of common stock 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 shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the same may be varied in that member state by any measure implementing the Prospectus Directive in that member state and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

#### **Other Relationships**

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

#### **Offer Restrictions Outside the United States**

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Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction is unlawful.

## Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities

under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

# China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People s Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to qualified domestic institutional investors.

# European Economic Area Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ( Prospectus Directive ), as implemented in Member States of the European Economic Area (each, a Relevant Member State ), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

(a) to legal entities that 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;

(b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than 43,000,000 (as shown on its last annual financial statements) and (iii) an annual net turnover of more than 50,000,000 (as shown on its last annual financial statements);

(c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

#### France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ( AMF ). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to

the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.764-1 of the French Monetary and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

# Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the Prospectus Regulations ). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

# Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

#### Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societ \$\$ Aga e la Borsa, CONSOB ) pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (Decree No. 58), other than:

- qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ( Regulation no. 11971 ) as amended ( Qualified Investors ); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

 made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

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in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws. Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

# Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the FIEL) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than

Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

# Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are qualified investors (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

# Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are qualified investors (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

# Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

# United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other

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governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

# **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of

the Financial Services and Markets Act 2000, as amended (FSMA) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to qualified investors (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (FPO), (ii) who fall within the categories of persons referred to in Article 49 (2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together relevant persons). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

#### 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 Waltham, 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 New York, New York. Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C. owns an aggregate of 28,655 shares of our common stock.

#### EXPERTS

BDO, USA, LLP, an independent registered public accounting firm, has audited our financial statements at December 31, 2012 and December 31, 2013, and for each of the two years in the period ended December 31, 2013, and for the cumulative period from August 13, 2004 (inception) through December 31, 2013, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on BDO USA, LLP s report, given on their authority as experts in accounting and auditing.

# WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock we are offering. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits and the financial statements and notes filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

A copy of the registration statement, including the exhibits and the financial statements and notes filed as a part of the registration statement, may be inspected without charge at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the SEC upon the payment of fees prescribed by it. You may call the SEC at 1-800-SEC-0330 for more information on the operation of the public reference facilities. The SEC maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies, such as Aldeyra, that file electronically with it.

Upon the completion of this offering, we will be subject to the information reporting requirements of the Securities Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at 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.

# ALDEYRA THERAPEUTICS, INC.

# (A Development Stage Company)

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The accompanying financial statements give effect to a 1-for-12 reverse split for the common stock and each series of preferred stock of Aldeyra Therapeutics, Inc. (the Company ) which will take place prior to the effective date of the registration statement. The following report is in the form which will be furnished by BDO USA, LLP an independent registered public accounting firm, upon completion of the 1-for-12 reverse split of the common stock and each series of preferred stock of the Company described in the first paragraph of Note 2 to the financial statements and assuming that from March 17, 2014 to the date of such completion no other material events have occurred that would affect the accompanying financial statements and disclosure therein.

# /s/ BDO USA, LLP

Boston, Massachusetts

March 17, 2014

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of

Aldeyra Therapeutics, Inc.

# Burlington, Massachusetts

We have audited the accompanying balance sheets of Aldeyra Therapeutics, Inc. (formerly known as Aldexa Therapeutics, Inc.) (the Company ) as of December 31, 2012 and 2013 and the related statements of operations and comprehensive income (loss), redeemable convertible preferred stock and stockholders equity (deficit), and cash flows for each of the two years in the period ended December 31, 2013, and for the period from August 13, 2004 (inception) through December 31, 2013. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Aldeyra Therapeutics, Inc. as of December 31, 2012 and 2013, and the results of its operations and its cash flows for the years then ended, and for the period from August 13, 2004 (inception) through December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Boston, Massachusetts

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March 17, 2014

(except for the first paragraph of Note 2, as to which the date is April , 2014)

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# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

# **Balance Sheets**

	ASSETS						
		Decen	nber 3	1,	Pro forma		
		2012		2013		ecember 31, 2013 (Note 2)	
Comment					(1	unaudited)	
Current assets:							
Cash and cash equivalents	\$	1,223,638	\$	3,262,354	\$	3,262,354	
Preferred stock issuance receivable related party		750,436		-		-	
Prepaid expenses and other current assets		2,950		8,412		8,412	
* *							
Total current assets		1,977,024		3,270,766		3,270,766	
Deferred offering costs		-		472,467		472,467	
Total assets	\$	1,977,024	\$	3,743,233	\$	3,743,233	

# LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

Current liabilities:			
Accounts payable	\$ 72,538	\$ 341,853	\$ 341,853
Convertible notes payable related parties (Note 6)	-	85,000	85,000
Accrued interest on convertible notes payable related parties	-	2,125	2,125
Accrued expenses	124,228	117,873	117,873
Current portion of credit facility	166,667	58,160	58,160
Total current liabilities	363,433	605,011	605,011
Credit facility, net of current portion and debt discount (Note			
7)	266,253	1,129,015	1,129,015
Accrued deferred offering costs	-	394,368	394,368
Convertible preferred stock rights and rights option liabilities			
related parties (Notes 12 and 13)	24,233,900	-	-
Convertible preferred stock warrant liability (Notes 7 and			
12)	87,600	253,247	-
Convertible preferred stock warrant liabilities related parties			
(Notes 11 and 12)	2,180,500	3,265,620	-
Total liabilities	27,131,686	5,647,261	2,128,394

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Commitments and contingencies (Note 15)

Redeemable convertible preferred stock (Note 11):			
Series A Preferred Stock, \$0.001 par value, 23,572,432, and			
24,000,000 shares authorized as of December 31, 2012 and			
2013; 980,391 shares issued and outstanding. (Liquidation		20 201 075	
preference of \$36,000,000)	29,063,167	29,291,865	-
Series B Preferred Stock, \$0.001 par value, 36,205,634 and			
38,000,000 shares authorized as of December 31, 2012 and 2013; 928,995 shares issued and outstanding as of December			
31, 2012; 1,316,681 shares issued and outstanding as of			
December 31, 2013. (Liquidation preference of \$20,377,506)	166,667	9,025,433	_
December 51, 2015. (Exquidution preference of \$20,577,500)	100,007	7,025,155	
Total redeemable convertible preferred stock	29,229,834	38,317,298	-
F		, ,	
Stockholders equity (deficit):			
Common stock, voting, \$0.001 par value; 40,000,000 and			
65,000,000 shares authorized as of December 31, 2012 and			
2013; 314,419, and 327,365 issued and outstanding	314	327	4,080
Common stock, non-voting, \$0.001 par value; 40,000,000,			
and 65,000,000 shares authorized as of December 31, 2012			
and 2013; none issued and outstanding	-	-	-
Additional paid-in capital	-	1,102,685	42,935,097
Deficit accumulated during the development stage	(54,384,810)	(41,324,338)	(41,324,338)
	(54 284 40()	(40.001.00()	1 (14 020
Total stockholders equity (deficit)	(54,384,496)	(40,221,326)	1,614,839
Total liabilities, redeemable convertible preferred stock and			
stockholders equity (deficit)	\$ 1,977,024	\$ 3,743,233	\$ 3,743,233
stockholders equity (deficit)	$\Psi^{-1,777,024}$	$\psi = 5,7 \pm 5,255$	$\Psi = 3,7 \pm 3,233$

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# ALDEYRA THERAPEUTICS, INC.

# (A Development Stage Company)

# Statements of Operations and Comprehensive Income (Loss)

		Years Ended I	Dece	mber 31,	Cumulative for the Period from August 13, 2004 (Inception) to December 31,		
		2012		2013	D	2013	
OPERATING EXPENSES:		2012		2015		2015	
Research and development	\$	469,270	\$	1,541,681	\$	12,847,149	
General and administrative	Ŷ	644,941	Ŷ	2,134,726	Ŷ	6,359,850	
		011,911		2,10 1,720		0,000,000	
Loss from operations		(1,114,211)		(3,676,407)		(19,206,999)	
OTHER INCOME (EXPENSES):							
Change in fair value of preferred stock warrant							
liabilities (Note 4 and 12)		(9,000)		720,785		711,785	
Change in fair value of convertible preferred stock		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		120,100		/11,/00	
rights and rights option liabilities (Note 4 and 13)		(125,500)		16,175,386		15,539,486	
Value provided in excess of issuance price of Series B		(, c c c)				,,	
Preferred Stock (Note 11)	C	21,484,762)		-		(21,484,762)	
Other income	(-	871		-		250,756	
Interest income		101		31		188,738	
Other expenses		-		-		(42,566)	
Interest expense		(342,014)		(159,323)		(989,151)	
I I I I I I I I I I I I I I I I I I I		(- )- )					
Total other expenses, net	C	21,960,304)		16,736,879		(5,825,714)	
····· · · · · · · · · · · · · · · · ·	(	, <u>/</u>		-,,		(-))- )	
Net income (loss) and comprehensive income (loss)	(2	23,074,515)		13,060,472		(25,032,713)	
Accretion on preferred stock (Note 11)	,	(389,487)		(822,550)		(1,936,637)	
Allocation of undistributed earnings to preferred							
stockholders		-	(	(11,128,012)		(11,128,012)	
Deemed dividend to Series A Preferred stockholders						,	
(Note 11)	()	15,661,898)		-		(15,661,898)	
Net income (loss) attributable to common stockholders	\$(3	39,125,900)	\$	1,109,910	\$	(53,759,260)	
Net income (loss) per share attributable to common stockholders:							
Basic	\$	(124.44)	\$	3.49			
Diluted	\$	(124.44)	\$	(17.58)			

Weighted average common shares outstanding:			
Basic	314,419	318,429	
Diluted	314,419	857,183	
Pro forma net income (loss) per share attributable to			
common stockholders (unaudited) (Note 3):			
Basic		\$ 2.70	
Diluted		\$ (0.71)	
Pro forma weighted average common shares outstanding (unaudited) (Note 3):			
Basic		4,071,875	
Diluted		4,412,887	

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# ALDEYRA THERAPEUTICS, INC.

# (A Development Stage Company)

# Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

	Rede Series A Pre			vertible Preferred Stock Series B Preferred Total				Stoc	Equity (Deficit)		
	Stock Preferred S		Preferred Shares	ck	Co	edeemable onvertible Preferred Stock Total	Commor Voti Shares	ng	Additiona Paid-in Capital	Accumulated Deficit 1 During the Development Stage	Tota Stockho Equit (Defic
ce, st 13,											
tion)	- \$	-	-	\$ -	\$	-	-	\$ -	\$ -	\$-	\$
ce of											
on stock	-	-	-	-		-	250,000	250	2,750	-	3
based											
ensation	-	-	-	-		-	-	-	269	-	
SS	-	-	-	-		-	-	-	-	(2,322)	(2
ce, nber 31,	-	-	_	-		-	250,000	250	3,019	(2,322)	
-based ensation	-	-	-	-		_	-	-	294		
SS	-	-	-	-		-	-	-	-	(386,454)	(386
ce, nber 31,										<i></i>	( - 0 -
1 1	-	-	-	-		-	250,000	250	3,313	(388,776)	(385
-based ensation	-	-	-	-		-	-	-	50		(020
ss ce, nber 31,	-	-	-	-		-	-	-	-	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(939
-based	-	-	-	-		-	250,000	250	3,363	(1,327,802)	(1,324
ensation	-	-	-	-		-	-	-	50	-	
SS	-	-	-	-		-	-	-	-	(523,032)	(523

ce, nber 31,										
1	-	-	-	-	-	250,000	250	3,413	(1,850,834)	(1,847
-based ensation	-	-	-	-	-	-	-	15,437	-	15
ise of on stock is	-	-	-	-	-	5,416	5	6,495	-	6
ce of A red net of ce costs vestor										
ersion of	490,197	4,526,900	-	-	4,526,900	-	-	-	-	
rtible payable lated vd st to A red										
C.	241,883	2,960,649	-	-	2,960,649	-	-	-	-	
ce of on stock lated ensation se	_	_	_	_	_	27,941	28	90,836	_	90
30						27,941	20	70,050		70
tion of ints and ce costs ferred	_	99,210	_	_	99,210	_	_	(99,210)	_	(99
SS	-	- ,	-	-	-	-	-	-	(2,224,375)	(2,224
ce, nber 31,	732,080	7,586,759	_	_	7,586,759	283,357	283	16,971	(4,075,209)	(4,057
-based	152,000	1,500,157	_	_	1,300,137	205,557	203		(1,075,207)	
ensation tion of ints and ce costs ferred	-	-	-	-	-	-	-	23,638	-	23
iciicu	-	201,050	-	-	201,050	-	-	(40,609)	(160,441)	(201
SS	-	-	-	-	-	-	-	-	(4,975,228)	(4,975

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# ALDEYRA THERAPEUTICS, INC.

# (A Development Stage Company)

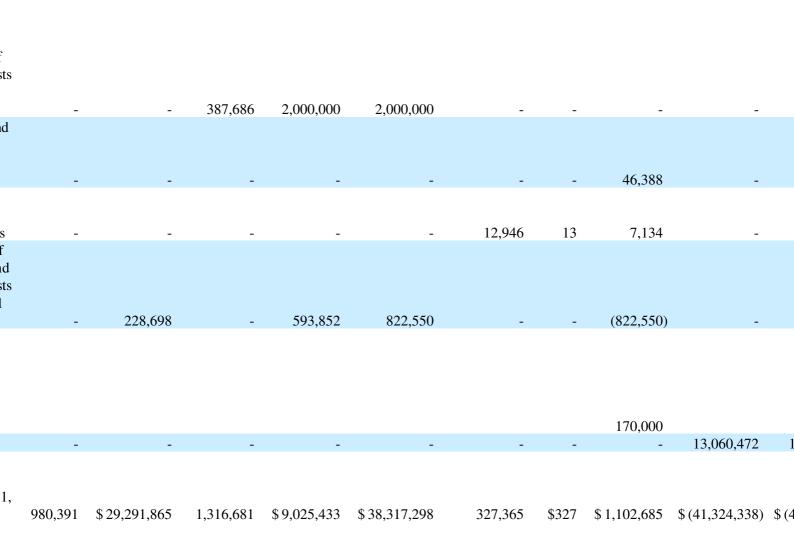
# Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)...continued

	Redeemable Series A Preferred Stock Preferred Stock		Convertible P Series B Pret Preferre	ferred Stock	Total Redeemable Convertible	Commor Voti	1 Stock	Additional	Equity (Deficit) Accumulated Deficit During the	Sto
	Shares	Amount	Shares	Amount	Preferred Stock	Shares	Amount	Paid-in Capital	Development Stage	(
1,	732,080	7,787,809		-	7,787,809	283,357	283	-	(9,210,878)	
on			_	-		- 203,557	- 205	40,206		
r,										
sts of	248,311	2,982,800	-	-	2,982,800	-	-	-	-	
nt										
	-	1,983,500	-	-	1,983,500	-	-	-	-	
f Id sts										
	-	209,304	-	-	209,304	-	-	(40,548)	(168,756)	
ck	-	-	-	-	-	31,062	31	342	-	
	-	-	-	-	-	-	-	-	(3,590,169)	(
1,	980,391	12,963,413	_		12,963,413	314,419	314		(12,969,803)	(1
on	200,321	12,705,715			12,703,713	517,717		49,592	(12,707,003)	(1
f Id	-	215,036	-	-	215,036	-	-	(49,592)	(165,444)	

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sts										
	-	-	-	-	-	-	-	-	(2,378,064)	(
1,	980,391	13,178,449	-	-	13,178,449	314,419	314	-	(15,513,311)	(1
on	-	-	-	-	-	-	-	84,401	-	
sts			287 400							
ts of	-	-	387,499	-	-	-	-	-	-	
le	_	_	541,496	_	_	_	_	-	_	
ıd			511,190							
	-	-	-	-	-	-	-	170,000	-	
f id sts l										
	-	222,820	-	166,667	389,487	-	-	(254,401)	(135,086)	
5	-	15,661,898	-	-	15,661,898	-	-	-	(15,661,898) (23,074,515)	(1
	-	-	-	-		-	-	-	(23,074,313)	(2
1,	980,391	29,063,167	928,995	166,667	29,229,834	314,419	314	-	(54,384,810)	(5
on	-	-	-	-	-	-	-	1,701,713	-	
of :	-	-	-	6,264,914	6,264,914	-	-	-	-	
nt										

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# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

# **Statements of Cash Flows**

	Years Decem		Cumulative for the Period from August 13, 2004 (Inception) to December 31,
	2012	2013	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$ (23,074,515)	\$ 13,060,472	\$ (25,032,713)
Adjustments to reconcile net income (loss) to net cash used			
in operating activities:			
Stock-based compensation	84,401	1,701,713	2,006,179
Interest converted to preferred stock	306,308	-	593,473
President and CEO contributed services	170,000	46,388	216,388
Amortization of debt discount non-cash interest expense	21,020	121,374	142,394
Change in fair value of warrant liability, purchase rights			
and warrant purchase rights	134,500	(16,896,171)	(16,251,271)
Value provided in excess of issuance price of Series B			
redeemable convertible preferred Stock (Note 11)	21,484,762	-	21,484,762
Depreciation	3,737	-	7,942
Change in assets and liabilities:			
(Increase) decrease			
Prepaid expenses and other current assets	1,262	(5,462)	(8,412)
Accounts payable	47,240	269,315	341,853
Accrued interest on convertible notes payable-related			
parties	-	2,125	2,125
Accrued expenses	43,239	(6,355)	117,873
Net cash used in operating activities	(778,046)	(1,706,601)	(16,379,407)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisitions of property and equipment	-	-	(7,942)
Net cash used in investing activities	-	-	(7,942)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from convertible notes payable related parties	-	170,000	5,130,000
Proceeds from issuance of common stock	-	-	3,773
Proceeds from issuance of restricted common stock	-	7,147	7,147
Proceeds from exercise of stock options	-	-	6,435
Borrowings under credit facility, net	500,000	1,000,000	1,500,000

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	1	,				
Repayments of credit facility		-		(104,167)		(104,167)
Cash paid for deferred offering costs		-		(78,099)		(78,099)
Net proceeds from issuance of Series A redeemable						
convertible preferred stock		-		-		9,183,449
Net proceeds from issuance of Series B redeemable						
convertible preferred stock		1,250,729		2,750,436		4,001,165
Net cash provided by financing activities		1,750,729		3,745,317		19,649,703
NET INCREASE (DECREASE) IN CASH		972,683		2,038,716		3,262,354
CASH AND CASH EQUIVALENTS, BEGINNING OF						
PERIOD		250,955		1,223,638		-
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	1,223,638	\$	3,262,354	\$	3,262,254
SUPPLEMENTAL DISCLOSURES OF CASH FLOW						
INFORMATION:						
Cash paid during the period for:	¢	25 506	<b>b</b>	24.025	<b>b</b>	071 100
Interest	\$	35,706	\$	34,825	\$	271,180
T d	¢		¢		¢	
Income taxes	\$	-	\$	-	\$	-
SUPPLEMENTAL DISCLOSURES OF NONCASH						
INVESTING AND FINANCING ACTIVITIES:						
Accretion of redeemable convertible preferred stock	\$	389,487	\$	822,550	\$	1,936,637
Accretion of redeemable convertible preferred stock	φ	309,407	φ	822,330	φ	1,930,037
Redeemable convertible preferred stock issuance receivable	\$	750,436	\$	-	\$	_
Redeemable convertible preferred stock issuance receivable	Ψ	750,450	Ψ	_	Ψ	_
Fair value of warrants issued in connection with credit						
facility	\$	88,100	\$	177,952	\$	266,052
licility	Ψ	00,100	Ψ	111,502	Ψ	200,002
Fair value of warrants, purchase rights and warrant						
purchase rights issued in connection with redeemable						
convertible preferred stock	\$	26,279,400	\$	-	\$	26,279,400
1		, ,				, ,
Allocation of fair value of investor purchase rights to						
redeemable convertible preferred stock	\$	-	\$	6,264,914	\$	9,047,714
-						
Offeratory costs in connection with Series B redeemable						
convertible preferred stock issuance included in accrued						
expenses	\$	45,750	\$	17,200	\$	62,950
Conversion of notes payable related parties and accrued						
interest related parties into Series B redeemable						
convertible preferred stock	\$	2,793,474	\$	-	\$	2,793,474
Conversion of bridge loans into Series A redeemable						
convertible preferred stock	\$	-	\$	-	\$	2,960,649
Deferred offering costs not yet paid	\$	-	\$	394,368	\$	394,368

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Exercise of Series B warrant purchase rights into warrants	\$	- \$ 1,793,600	\$ 1,793,600

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements

#### 1. NATURE OF BUSINESS

Aldeyra Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on August 13, 2004 as Neuron Systems, Inc. On December 20, 2012, the Company changed its name to Aldexa Therapeutics, Inc. and on March 17, 2014 the Company changed its name to Aldeyra Therapeutics, Inc. The Company is developing a treatment for diseases related to high levels of free aldehydes, naturally occurring pro-inflammatory toxins. The ongoing research and development activities will be subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any drug developed by the Company must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process implemented by the United States Food and Drug Administration (FDA) under the Food, Drug and Cosmetic Act. The Company has limited experience in conducting and managing the preclinical and clinical testing necessary to obtain regulatory approval. There can be no assurance that the Company will not encounter problems in the clinical trials that will cause the Company or the FDA to delay or suspend clinical trials.

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

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

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

On January 23, 2014 the Company s board of directors and stockholders approved an amendment to the restated certificate of incorporation to effect a one-for-twelve reverse stock split of the Company s common stock, options for common stock, convertible preferred stock, and warrants for convertible preferred stock to take effect immediately prior to the effectiveness of the Registration Statement on Form S-1 for the Company s initial public offering (the Reverse Stock Split). The par value and the authorized shares of the common and convertible preferred stock will not be adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, options for common stock, convertible preferred stock, and rights and warrants for convertible preferred stock, as well as the exercise price of each option for common stock, each right and each warrant for convertible preferred stock, and each right for warrants for convertible preferred stock and the conversion price for convertible preferred stock, have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. All of the share and per share amounts have been adjusted, on a retroactive basis, to reflect this planned one-for-twelve reverse stock split.

**Development Stage Operations** The Company s executive personnel have devoted substantially all of their time to date to the planning and organization of the Company, the process of initiating research and development programs, and securing adequate capital for anticipated growth and operations. The Company is subject to a number of risks, including, but not limited to, the need to raise capital through equity and/or debt financings; the uncertainty of whether the Company s research and development efforts will result in successful commercial products; competition from larger organizations; dependence on key personnel and uncertain patent protection. The Company is in its development stage as defined by the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 915, *Development Stage Entities*.

*Liquidity* At December 31, 2013, the Company had an accumulated deficit of approximately \$41.3 million and cash and cash equivalents of approximately \$3.3 million. As discussed in Note 11, the Company raised \$2.0 million in gross proceeds from the issuance of Series B redeemable convertible preferred stock (Series B Preferred Stock) in August 2013 as well as collecting the cash in January 2013 from the preferred stock receivable outstanding at December 31, 2012 in the amount of \$750,436. In addition, in November 2013, the Company amended its credit facility to provide for

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued

and an additional \$1.0 million of available funding and subsequently in November 2013 borrowed \$1.0 million in the form of a term loan. The terms of the amended credit facility also extended the payment terms of the existing notes under the credit facility for an additional one year period.

The Company s management believes that its currently available resources, including funds obtained from the preferred stock transaction and amended credit facility, will provide sufficient funds to enable the Company to meet its obligations through at least the first quarter of 2015. The Company will need to raise additional capital to implement its near-term business plan. Additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to secure additional capital, or meet financial covenants that could be implemented under the Company s term loans in certain circumstances, it will be required to significantly decrease the amount of planned expenditures, and may be required to cease operations.

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

**Unaudited Pro Forma Presentation** On October 2, 2013, the Company's board of directors authorized management of the Company to file a registration statement with the Securities and Exchange Commission for the Company to sell shares of common stock to the public. The unaudited proforma balance sheet information as of December 31, 2013 assumes (1) the automatic conversion of all outstanding shares of the Company's Series A convertible preferred stock and Series B convertible preferred stock into 3,642,799 shares of common stock prior to the closing of this offering, (2) the issuance of 110,647 shares of common stock upon the net exercise of the Company's outstanding warrants to purchase Series A convertible preferred stock and Series B convertible preferred stock assuming an initial public offering price of \$11.00 per share, the mid-point of the initial public offering price range reflected on the cover page of this prospectus and the subsequent automatic conversion of such shares of convertible preferred stock into common stock and the related reclassification of liabilities related to convertible preferred stock warrant liability and convertible preferred stock warrant liabilities-related parties totaling \$3,518,867 to additional paid-in capital, a component of stockholders' equity (deficit), and (3) the filing of the Company's amended and restated certificate of incorporation immediately prior to the closing of the offering.

The pro forma presentation does not give effect to the conversion of the convertible promissory note issued in the original principal amount of \$170,000.

The unaudited pro forma net loss per share for the year ended December 31, 2013 gives effect to the adjustments arising upon the completion of the Company s planned initial public offering as of the beginning of the period presented, which primarily includes assuming that amortization of preferred stock discounts, allocation of undistributed earnings to preferred stock under the two-class method and changes in fair value of the Company s warrants, purchase rights and warrant purchase rights, excluding those that expired during the year, did not occur since

the warrants, purchase rights and warrant purchase rights were exercised and converted as of the beginning of the period. It is computed using the weighted-average number of common shares outstanding and gives effect to (i) the automatic conversion of all outstanding shares of the Company s convertible preferred stock into an aggregate of 3,642,799 shares of common stock; and (ii) the net exercise of warrants to purchase 208,378 shares of redeemable, convertible preferred stock immediately prior to the completion of the Company s planned initial public offering that will subsequently be automatically converted into 110,647 shares of common stock.

*Use of Estimates* The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company s financial statements relate to accruals, including research and development costs, accounting for income

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued

taxes and the related valuation allowance, estimating the fair value of the Company s common and preferred stock, preferred stock warrants, purchase rights and warrant purchase rights, and accounting for stock based compensation and the related fair value. Although these estimates are based on the Company s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

*Segment Information* Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of a treatment for diseases related to high levels of free aldehydes.

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

*Fair Value of Financial Instruments* Financial instruments including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value based on the short maturities of those instruments. The carrying amount of the Company s term loans under its credit facility approximates market rates currently available to the Company. The fair value of our derivative instruments, including warrants and forms of preferred stock purchase rights, are more fully described in Note 4.

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

**Deferred Offering Costs** Deferred offering costs, which primarily consist of legal and accounting fees relating to the Company s initial public offering (IPO), are capitalized. The deferred offering costs will be offset against proceeds from the IPO upon the consummation of the offering. In the event the offering is terminated or significantly delayed, deferred offering costs will be expensed. Deferred offering costs were \$472,467 at December 31, 2013, of which \$394,368 were accrued at December 31, 2013. No amounts were incurred or deferred as of December 31, 2012.

*Intellectual Property* The legal and professional costs incurred by the Company to acquire its patent rights have been expensed as part of operating expenses since inception. At December 31, 2012 and 2013, the Company has determined that these expenses have not met the criteria to be capitalized. Intellectual property related expenses for the years ended December 31, 2012 and 2013 and inception to date from August 13, 2004 through December 31, 2013

were \$159,293, \$189,965, and \$935,358, respectively.

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

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

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued

*Research and Development Costs* Research and development costs are charged to expense as incurred. Research and development expenses include consulting expenses, preclinical studies, clinical trials, clinical trial materials, regulatory and clinical consultants, lab supplies, lab services, lab equipment maintenance and small equipment purchased to support the research laboratory. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred.

*Stock-Based Compensation* Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation Stock Compensation*. For options, the fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes option pricing model. For restricted stock, fair value is based on the fair value of the stock on the date of grant. The resulting fair value for restricted stock and options is recognized ratably over the requisite service period, which is generally the vesting period of the applicable restricted stock or option.

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

A discussion of management s methodology for developing some of the assumptions used in the Black-Scholes option pricing model follows:

*Fair Value of Common Stock* Given the lack of an active public market for the Company s common stock, the Company has from time to time engaged an independent third party valuation firm to calculate and provide recommendations to the Company with respect to the fair value of the common stock. In the absence of a public trading market, and as a development stage company with no significant revenues, the Company believes that it is appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. In determining the fair value of its common stock, the Company uses methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants (AICPA) Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation* (the AICPA Practice Guide). In addition, the Company considered various objective and subjective factors, along with input from an independent third-party valuation firm. The factors included (1) the achievement of technical and operational milestones by the Company s stage of development; (4) capital market conditions for life science companies, particularly similarly situated, privately held, early-stage life science companies; (5) the Company s available cash, financial condition, and results of operations; (6) the most recent sales of the Company s preferred stock to the extent they were with outside parties; and (7) the preferential rights of the outstanding preferred stock.

*Expected Dividend Yield* The Company has never declared or paid cash dividends and has no plans to do so in the foreseeable future.

*Expected Volatility* Volatility is a measure of the amount by which a financial variable such as share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company does not maintain an internal market for its shares, and its shares are not traded publicly. The Company has been able to identify several public entities of similar size, complexity, and stage of development; accordingly, historical volatility has been calculated using the volatility of these companies.

*Risk-Free Interest Rate* This is the United States Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

*Expected Term* This is a period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company uses a simplified method to calculate the average expected term. For non-employee grants the contractual term is used.

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued

*Expected Forfeiture Rate* The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were granted. To date, forfeitures have not been material.

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

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

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

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

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

*Recent Accounting Pronouncements* In February 2013, the FASB issued ASU 2013-02, Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02)*,

which finalizes the requirements of ASU 2011-05 that were deferred by ASU 2011-12. ASU 2013-02 clarifies how to report the effect of significant reclassifications out of accumulated other comprehensive income. ASU 2013-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2012 and early adoption is permitted. The adoption of ASU 2013-02 did not have a material impact on the Company s financial statements.

On September 13, 2013, Treasury and the Internal Revenue Service issued final regulations regarding the deduction and capitalization of expenditures related to tangible property. The final regulations under Internal Revenue Code Sections 162, 167 and 263(a) apply to amounts paid to acquire, produce, or improve tangible property as well as dispositions of such property and are generally effective for tax years beginning on or after January 1, 2014. We have evaluated these regulations and determined they will not have a material impact on our consolidated results of operations, cash flows or financial position.

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

# 3. NET INCOME (LOSS) AND PRO FORMA NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS

Net income (loss) attributable to common stockholders

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

	Year Ended December 31,		
	2012	2013	
Numerator:			
Basic			
Net income (loss) and comprehensive income (loss)	\$ (23,074,515)	\$ 13,060,472	
Accretion of preferred stock to redemption value	(389,487)	(822,550)	
Allocation of undistributed earnings to preferred stockholders	-	(11,128,012)	
Deemed dividends	(15,661,898)	-	
Net income (loss) attributable to common stockholders basic	\$ (39,125,900)	\$ 1,109,910	
Diluted			
Net income (loss) attributable to common stockholders basic	\$ (39,125,900)	\$ 1,109,910	
Less: change in fair value of derivative liabilities	-	(16,175,386)	
Net income (loss) available to common stockholders diluted	\$ (39,125,900)	\$(15,065,476)	
Denominator:			
Basic			
Weighted-average number of common shares basic	314,419	318,429	
Diluted			
Weighted-average number of common shares basic	314,419	318,429	
Rights (treasury stock)	-	429,663	
Stock options (treasury stock)	-	1,675	
Warrant purchase rights (treasury stock)	-	107,416	
Total weighted average number of common shares diluted	314,419	857,183	
Net income (loss) per share:			

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Basic		\$	(124.44)	\$ 3.49
Diluted		\$	(124.44)	\$ (17.58)

Because the Company reported a net loss for the year ended December 31, 2012, diluted net loss per common share is the same as basic net loss per common share for that period.

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

# 3. NET INCOME (LOSS) AND PRO FORMA NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS continued

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

	Year ended D	ecember 31,
	2012	2013
Options to purchase stock	67,237	-
Warrants to purchase Preferred Stock	98,964	60,065
Preferred Stock	1,909,387	995,880
Convertible note payable-related parties	-	7,083
Rights to receive warrants for Preferred Stock	232,248	-
Investor rights to purchase Preferred Stock	928,995	-
Total of common equivalent shares	3,236,831	1,063,028

The Convertible Notes (as defined in Note 6) were convertible into convertible preferred equity securities. The quantity to be converted into would be determined based upon the occurrence and terms of a qualified equity financing, as defined in the applicable agreement, or in the case of a liquidating transaction, as defined in the applicable agreement, it would be converted into Series A preferred stock at a \$12.24 conversion rate. The Convertible Notes converted into Series B preferred stock during December 2012.

#### Pro Forma net income (loss) attributable to common stockholders (unaudited)

	Year ended December 31, 2013
Numerator for pro forma calculation:	
Basic	
Net income (loss) attributable to common stockholders basic and diluted	\$ 13,060,472
Change in fair value of warrants, purchase rights and warrant purchase rights	(2,055,233)

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Pro forma net income attributable to common stockholders basic	\$	11,005,239
Diluted		
Pro forma net income attributable to common stockholders basic	\$	11,005,239
Change in fair value of derivatives	(	14,120,153)
Pro forma net Loss attributable to common shareholders-diluted	\$	(3,114,914)
Denominator for pro forma calculation:		
Basic		
Weighted-average number of shares outstanding basic		318,429
Pro forma adjustments to reflect automatic conversion of outstanding redeemable, convertible preferred		3,642,799
Pro forma adjustments to reflect net exercise of warrants and warrant purchase rights and immediate conversion into common stock consideration		110,647
Weighted-average number of pro forma shares outstanding basic		4,071,875
Pro forma net loss per share attributable to common stockholders basic	\$	2.70
Diluted		
Weighted-average number of shares basic		4,071,875
Stock options		4,941
Warrant purchase rights		67,216
Rights		268,855
Weighted-average number of pro forma shares outstanding diluted		4,412,887
Pro forma net loss per share attributable to common stockholders diluted	\$	(0.71)

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 4. FAIR VALUE MEASUREMENTS

As of December 31, 2012 and 2013, the carrying amounts of cash and cash equivalents, prepaid expenses and other current assets, credit facility, and accounts payable approximated their estimated fair values because of the short term nature of these financial instruments. The carrying value of the Company s credit facility and convertible notes related parties in current and long-term liabilities approximates fair value because the Company s interest rate yield is near current market rates available to the Company.

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

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

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

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

Liabilities measured at fair value on a recurring basis as of December 31, 2012 and December 31, 2013 are as follows.

Level 1	Level 2	Level 3	Total
\$ -	\$ -	\$ 2,180,500	\$ 2,180,500
-	-	87,600	87,600
-	-	24,233,900	24,233,900
	\$ -	\$ - \$ -	\$ - \$ - \$ 2,180,500 87,600

Convertible preferred stock rights a option liabilities related parties	and rights					
Balance at end of period		\$ -	\$	-	26,502,000	26,502,000
December 31, 2013:						
Liabilities:						
Preferred Stock Warrant Liability Preferred Stock	Series B	\$ -	\$	-	\$ 3,439,059	\$ 3,439,059
Preferred Stock Warrant Liability Preferred Stock	Series A	-		-	79,808	79,808
Balance at end of period		\$ -	\$	-	\$ 3,518,867	\$ 3,518,867

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 4. FAIR VALUE MEASUREMENTS continued

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

#### **Preferred stock warrant liability** Series A Preferred Stock:

	Year Ended D 2012	ecembe	r 31, 2013
Balance at beginning of period	\$ -	\$	87,600
Warrant liability Series A	88,100		-
Change in fair value	(500)		(7,792)
Balance at end of period	\$ 87,600	\$	79,808
Preferred stock warrant liability Series B Preferred Stock:			

Balance at beginning of period	\$		\$	2,180,500
Exercise of warrants purchase rights into Series B Warrants	φ	-	φ	1,793,600
Warrant liability Series B		2,171,000		177,952
Change in fair value		9,500		(712,993)
Balance at end of period	\$	2,180,500	\$	3,439,059

**Convertible preferred stock rights liability** Series B Preferred Stock:

Year Ended December 31,

Year Ended December 31,

2013

2012

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	20	12		2013
Balance at beginning of period	\$	-	\$	19,009,100
Warrants liability	18,9	06,300		-
Allocation of fair value to preferred stock		-		(6,264,914)
Change in fair value	1	02,800		(4,557,486)
Expiration of rights		-		(8,186,700)
Balance at end of period	\$ 19,0	09,100	\$	-

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 4. FAIR VALUE MEASUREMENTS continued

Convertible preferred stock rights option liability Series B Preferred Stock related parties:

		Year Ended December 31,		•,
	2012		20	2013
Balance at beginning of period	\$	-	\$ 5,22	4,800
Exercise of warrants purchase rights into Series B Warrants			(1,79	3,600)
Warrant liability		5,202,100		-
Change in fair value		22,700	(1,07	(1,500)
Expiration of rights option		-	(2,35	(9,700)
Balance at end of period	\$	5,224,800	\$	-

The Company s preferred stock liabilities were classified as level 3 and valued using the Black-Scholes model. The fair values were derived by applying the assumptions described below (see also Notes 11, 12 and 13). These liabilities increased or decreased each period based on the fluctuations of the fair value of the underlying preferred security.

The table below shows the inputs used by instrument to determine the fair value measurements by reporting period:

December 31,	December 31,
2012	2013

#### Preferred stock warrant liability Series A

Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	\$48.48	\$45.20
Exercise price	\$12.24	\$12.24
Expected life (years)	6.28	5.28
Risk free interest rate	1.01%	1.75%
Preferred stock warrant liabilities Series B		

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Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	\$25.56	\$19.92
Exercise price	\$5.16	\$5.16
Expected life (years)	4.97	3.97 6.89
Risk free interest rate	0.71%	0.78% 2.45%

# ALDEYRA THERAPEUTICS, INC.

#### (A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 4. FAIR VALUE MEASUREMENTS continued

December 31,	December 31,
2012	2013

## Preferred stock investor purchase rights liability Series B

Expected dividend yield	0%
Anticipated volatility	88.57%
Estimated stock price	\$25.56
Exercise price	\$5.16
Expected life (years)	0.75
Risk free interest rate	0.14%
Preferred stock warrants purchase rights liability Series B	

Expected dividend yield	0%
Anticipated volatility	88.57%
Estimated stock price	\$22.44
Exercise price	
Expected life (years)	0.75
Risk free interest rate	0.14%

#### 5. ACCRUED EXPENSES

Accrued expenses at December 31, 2012 and 2013 were:

	2012	2013
Accrued payroll taxes	\$ 8,837	\$ 8,837
Legal expenses	88,758	38,102
Research and development expenses	8,000	4,410
Compensation accruals	12,883	
Taxes		7,256
Accounting and tax		54,486

Interest		2,772
Issuance costs	5,750	
Other accruals		2,010
	\$ 124,228	\$117,873

# 6. CONVERTIBLE NOTES PAYABLE RELATED PARTIES

On December 21, 2010, the Company issued convertible notes pursuant to a loan agreement with Domain Associates, L.L.C. and Johnson & Johnson Development Corporation, related parties, ( Convertible Notes ) with a principal amount of \$2.2 million which was the fair value of the Convertible Notes on date of issuance (Note 4). The outstanding principal of the Convertible Notes, together with all accrued and unpaid interest thereon, was payable in full on the earlier to occur of (i) written election of the holders on or after August 31, 2011 or (ii) or an event of default. Since the holders of these notes could elect to redeem on or after August 31, 2011, the Company included these Convertible Notes payable in current liabilities. All borrowings outstanding carried a 12% interest rate per year. The Convertible Notes would automatically convert upon a financing of at least \$10.0 million in gross proceeds or a liquidating transaction. Upon a liquidating transaction, the number of shares of Series A Preferred Stock would be determined by dividing the outstanding principal and interest on that date by \$12.24. Upon a financing transaction, the number of shares in the new stock being issued would be determined by dividing the outstanding principal and interest on that date by the

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 6. CONVERTIBLE NOTES PAYABLE RELATED PARTIES continued

per share purchase price of the equity stock in the financing. On December 20, 2012, the loan agreement was amended to allow for conversion of the Convertible Notes upon a financing of \$2.0 million in gross proceeds. This resulted in the automatic conversion of the then outstanding convertible notes payable principal balance amount of \$2.2 million plus accrued interest of \$593,474 into 541,496 shares of Series B Preferred Stock at the Original Issue Price of \$5.16 per share, which is the stated value of the Series B Preferred Stock.

In October 2013, the Company issued a convertible promissory note to Domain Partners VI, L.P., a related party, in a principal amount of \$170,000, which was amended in February 2014 to extend its maturity date. The note accrues interest at a rate of 6% per annum, and will become due and payable in June 2014 unless it is converted into shares of the Company s capital stock prior to such time pursuant to its terms. The note provides that it shall automatically convert at the first to occur of:

a Next Equity Financing, as defined, into shares of the equity security issued and sold in the Next Equity Financing at a conversion price equal to the purchase price per share of the equity securities issued and sold to the purchasers thereof in the Next Equity Financing.

an Initial Public Offering, as defined, into shares of the equity securities issued and sold in the Initial Public Offering at a conversion price equal to the purchase price per share of the equity security issued and sold to the public in the Initial Public Offering.

a Change in Control, as defined, into shares of the Series B Preferred Stock of the Company at the conversion price then in effect for such Series B Preferred Stock.

at the Maturity Date of June 14, 2014 into shares of, at the holder s election, the Series B Voting Preferred Stock or Series B Nonvoting Preferred Stock of the Company, at the Series B Conversion Price then in effect. The Company recorded the difference between the current Series B Preferred Stock Conversion price and the fair value of the Series B Preferred Stock at the date of issuance, limited to the face amount of the convertible promissory note of \$170,000, as a beneficial conversion feature. This is reflected as a debt discount and is being amortized to interest expense through the note s maturity date. At December 31, 2013, the note is shown on the accompanying balance sheet net of a debt discount of \$85,000.

# 7. CREDIT FACILITY

On April 12, 2012, the Company entered into a loan and security agreement (Credit Facility) with a bank with availability in the amount of \$500,000, to help fund the operations of the Company. Under the terms of this agreement, the Company may take advances on the Credit Facility for general working capital purposes and for capital expenditures. Interest shall accrue from the date of each advance equal to the greater of (a) 2.75% above the prime rate then in effect, or (b) 6.50%. Any amounts outstanding shall be payable in 24 equal monthly installments of principal, plus all accrued interest, beginning on May 12, 2013 until the loan maturity date of April 13, 2015. There will be no penalties for prepayment of the principal balance. The Credit Facility is subject to certain financial covenants. The interest rate since inception of this loan has been in accordance with (b) above, 6.50%. The Credit Facility is secured by all of the property of the Company. In conjunction with obtaining the Credit Facility, the Company issued a warrant to purchase for 2,042 shares of Series A Preferred Stock (Note 12). The warrant was valued at \$88,100 on the date of issuance and recorded as a discount on the Credit Facility and is being amortized using the effective interest method through the maturity date of the Credit Facility.

During 2012, the Company received two advance payments totaling \$500,000, the maximum borrowings under the Credit Facility. In accordance with this agreement, the Company was only required to make monthly interest payments until April 12, 2013, at which time the Company would begin to make monthly principal payments in a fixed amount of \$20,833 plus interest.

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

## 7. CREDIT FACILITY continued

On November 20, 2013, the Company amended their Credit Facility with the same bank. The amendment provided an additional \$1.0 million of available funds under the facility. The Company received an advance payment of \$1.0 million in November 2013 through a term loan. The amended Credit Facility calls for interest only payments at a 6.50% interest rate from November 2013 through November 2014 for all amounts outstanding, inclusive of those amounts originally drawn during 2012 prior to the amendment, at which point, the Company is required to make principal payments of \$58,160 plus interest through the maturity date of the term loans in November 2016. The Credit Facility, as amended, will have financial covenants established at a future date if the Company has not completed a financing transaction described in the agreement by March 31, 2014.

Both the original Credit Facility and the Credit Facility, as amended, are secured by all the intellectual property of the Company.

Future maturities of the existing term loans under the Credit Facility as of December 31, 2013 are as follows:

Years	Amount
2014	\$ 58,160
2015	697,920
2016	639,754

\$ 1,395,834

In conjunction with obtaining the amended credit facility, the Company issued a warrant exercisable for 9,692 shares of Series B Preferred Stock with an exercise price of \$5.16 per share and a term of seven years (Note 12). The warrant was valued at \$177,952 and, together with the fair value of the warrant issued in connection with the April 12, 2012 Credit Facility (\$88,100), was recorded as a discount on the Credit Facility. These discounts are being amortized using the effective interest method through the current maturity date of the Credit Facility in November 2016. The amendment to the credit facility was determined to be a modification in accordance with ASC 470, *Debt* and did not result in extinguishment.

At December 31, 2012 and 2013, the Credit Facility is shown net of a debt discount of \$67,080 and \$208,659, respectively.

#### 8. INCOME TAXES

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

Significant components of the Company s deferred tax assets and liabilities at December 31, 2012 and December 31, 2013, are as follows:

	December 31, 2012	December 31, 2013
Security deposits	\$ 1,159	\$ -
Intangibles - net	1,627,594	1,395,749
Accounts payable and accrued expenses	77,290	336,324
Federal NOL carryforward	3,159,488	3,691,627
State NOL carryforward	432,717	515,355
Federal R&D credit carryforward	183,786	232,734
State R&D credit carryforward	6,472	16,372
Stock options	85,886	735,595
Other assets	(1,159)	(3,833)
Note discounts	-	(133,791)
Equipment	107	-
Less valuation allowance	5,573,340	(6,786,132)
Net deferred tax assets (liabilities)	\$ -	\$ -

# ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 8. INCOME TAXES...continued

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

At December 31, 2012 and 2013, the Company had federal net operating loss carry forwards of approximately \$9.3 million and \$10.9 million, respectively, and state net operating loss carry forwards of approximately \$8.2 million and \$9.8 million, respectively, available to reduce federal and state taxable income expiring in varying amounts through 2033. As of December 31, 2013, the Company had federal and state tax carryovers of credits for increasing research activities ( R&D tax credits ) of approximately \$233,000 and \$25,000, respectively, which will expire at various dates through 2033.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company s ownership may result in a limitation on the amount of net operating loss carryforwards which can be used in future years.

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

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

	Year ended	
	December 31,	
	2012	2013
Statutory tax rate	34.00 %	34.00%
State taxes, net of federal benefits	0.24 %	-%
Mark to market items	(31.86)%	(42.85)%
Federal research and development credits	0.06 %	(0.37)%
Change in valuation allowance	(2.48)%	8.99%
Other	0.03 %	0.23%
Effective tax rate	0.00~%	0.00%

The Company accounts for uncertain tax positions pursuant to ASC 740 which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having

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the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes. Management is not aware of any uncertain tax positions.

# 9. STOCK INCENTIVE PLAN

The Company has three incentive plans. One was adopted in 2004 (2004 Plan) and provided for the granting of stock options and restricted stock awards to employees, board members and consultants and generally prescribed a contractual term of seven years. The 2004 Plan terminated in August 2010. However, grants made under the 2004 Plan are still governed by that plan. As of December 31, 2012 and 2013, options to purchase 23,954 shares of common stock at an exercise price of \$3.24 per share remained outstanding under the 2004 Plan.

The Company approved an incentive plan in 2010, the 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan). The 2010 Plan was approved by the board of directors in September 2010 under the provision of Internal Revenue Code Section 422. The 2010 Plan provides for the granting of stock options and restricted stock awards to certain employees, members of the board of directors and consultants of the Company. The 2010 Plan became effective on

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 9. STOCK INCENTIVE PLAN...continued

adoption and, with respect to new grants as of September 2010, replaced the Company s 2004 Plan. As of December 31, 2013, the number of shares of common stock authorized for issuance in connection with the 2010 Plan was 681,788. As of December 31, 2012 and 2013, there were 106,309 and 14,649 shares, respectively, that were available for issuance under the 2010 Plan.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2010 Plan. Options granted by the Company typically vest over a four year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options may be granted for a term of up to ten years from the date of grant. The exercise price for options granted under the 2010 Plan must be at a price no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided that with an incentive stock option granted to an employee who at the time of grant owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price shall be no less than 110% of the estimated value on the date of grant.

The Company also approved an incentive plan in 2013, the 2013 Equity Incentive Plan (2013 Plan). The 2013 Plan was approved by the board of directors in October 2013 under the provision of Internal Revenue Code Section 422. The 2013 Plan provides for the granting of stock options, restricted stock, stock appreciation rights, stock units, and performance cash awards to certain employees, members of the board of directors and consultants of the Company. The 2013 Plan became effective on adoption, although no awards may be granted prior to the Registration Date of the Company s initial public offering. As of December 31, 2013, the number of shares of common stock authorized for issuance in connection with the 2013 Plan was 625,000. As of the first business day of each fiscal year of the Company during the term of the Plan, commencing on the first day of the Company s 2015 fiscal year, the aggregate number of common shares that may be issued under the Plan shall automatically increase by a number equal to the least of (a) 4% of the total number of common shares outstanding on the last calendar day of the prior fiscal year, (b) subject to adjustment for certain corporate transactions, 333,333 common shares, or (c) a number of common shares determined by the Company s board of directors.

The following table summarizes option activity under the incentive plans:

		Weighte	ed-Average
	Stock Options Outstanding	Exerc	vise Price
Options outstanding at January 1, 2012	51,037	\$	3.24
Granted	28,695	\$	3.24

	,	
Forfeited	(12,500)	\$ 3.24
Options outstanding at December 31, 2012	67,232	\$ 3.24
Granted	542,610	\$ 1.26
Options outstanding at December 31, 2013	609,842	\$ 1.48

Included with the options granted for the year ended December 31, 2013 are two grants of options exercisable for a total of 32,014 common shares for which vesting is contingent on certain performance conditions. For options granted containing performance conditions, the fair value is determined on the date of grant. For the year ended December 31, 2013, there was no expense recorded relating to the options as the performance conditions were not considered to be probable of being met.

In June 2013, the Company issued 12,948 restricted stock awards, the only restricted stock awards issued by the Company since inception, and then modified the terms on September 8, 2013 to fully vest the awards. Accordingly, the value of the award of \$216,000 was fully expensed during the year ended December 31, 2013. The fair value of the award was determined on the grant date fair market value per share. The Company recorded a reduction to the contributed services expense of approximately \$173,000 during the year ended December 31, 2013 related to this award as the individual holder of this award transferred 80% of the rights to this award to a stockholder of the Company during September 2013 (Note 10).

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

#### 9. STOCK INCENTIVE PLAN...continued

The following table summarizes information about stock options outstanding at:

	Number	Outstanding Shares Weighted- Average Remaining Contractual	Exercisable Shares Weighted- Average Remaining Contractual
Period Ending	Exercisable	Life	Life
December 31, 2013	96,949	9.32	7.41
December 31, 2012	38,760	7.13	1.15

The Company records stock-based compensation related to stock options granted at fair value. During the years ended December 31, 2012 and 2013, the Company used the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management s best estimates. The assumptions used in determining fair value of the employee stock options for the years ended December 2012 and 2013, are as follows:

	December 31, 2012	December 31, 2013
Expected dividend yield	0%	0%
Expected volatility	88.57%	88.57%
Estimated stock price	\$3.24 - \$14.64	\$10.56 - \$11.03
Exercise price	\$3.24	\$0.552 - \$4.56
Expected life (years)	7.24	5.47 - 7.85
Risk free interest rate	1.24% - 2.23%	1.71% - 2.34%

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

the timing and number of shares that are most likely to vest. This incremental compensation cost is being recorded over approximately four years, which is the approximate number of years that the Monte Carlo simulations predict that the Closing Market Capitalization could be reached.

At December 31, 2013, there is approximately \$4.8 million of unrecognized compensation cost relating to stock options outstanding, which the Company expects to recognize over a weighted average period 3.4 years. Total unrecognized compensation cost will be adjusted for future forfeitures, if necessary.

The Company has also issued stock options to non-employees at various grant dates from inception. In determining the expense associated with their vesting, those non-employee stock options were valued using the Black-Scholes option-pricing model using the fair value of the common stock and the following assumptions:

	December 31, 2012	December 31, 2013
Expected dividend yield	0%	0%
Anticipated volatility	88.57%	88.57%
Estimated stock price	\$3.24 - \$14.64	\$11.85
Exercise price	\$3.24	\$3.24
Expected life (years)	2.86 - 8.25	3.27 - 3.35
Risk free interest rate	0.36% - 1.11%	0.78%

### ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 9. STOCK INCENTIVE PLAN...continued

There were no options granted to consultants during the year ended December 31, 2012. There were 4,802 options issued to consultants during the year ended December 31, 2013. The related stock-based compensation is subject to remeasurement and is being expensed over the related service term.

The total intrinsic value of options exercised in the year ended December 31, 2012 was \$142,500. There were no options exercised during the year ended December 31, 2013. The total aggregate intrinsic value of stock options outstanding as of December 31, 2012, and 2013 was \$7.9 million and \$6.3 million, respectively. The intrinsic value of options vested as of December 31, 2012 and 2013 was \$529,340 (total fair value of \$667,887) and \$925,498 (total fair value of \$1.1 million), respectively. The weighted average exercise price of fully vested shares as of December 31, 2012 and 2013 was \$3.04 and \$2.06, respectively. The total weighted average grant date fair value of stock options for the years ended December 31, 2012 and 2013 was \$2.52 and \$10.64 per share, respectively.

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

		r Ended mber 31, 2013	from 2004	ulative Period n August 13, 4 (Inception) to ecember 31, 2013
Research and development				
expenses General and administrative	\$ 79,415	\$ 481,598	\$	741,740
expenses	4,986	1,220,115		1,264,439
Total stock-based				
compensation expense	\$ 84,401	\$1,701,713	\$	2,006,179

### **10. COMMON STOCK**

The rights and preferences of Non-Voting Common Stock are substantially identical to those of the Voting Common Stock, except that such shares shall have no voting rights.

### President and CEO contributed services

The Company s President and Chief Executive Officer (CEO) was hired on January 6, 2012 on a half-time basis and on April 15, 2013, he began working full-time for the Company. During the period from January 6, 2012 through October 14, 2013, he was not paid a salary by the Company and was an employee and paid a salary by Domain Associates, LLC (Domain), a related party. The value of his services has been reflected in the statement of operations as an expense and recorded as a contribution of capital. For the year ended December 31, 2012, the value of his services was \$170,000. For the year ended December 31, 2013, the value of his services was \$219,167. The amount of contributed services for the year ended December 31, 2013 of \$219,167 was then reduced by \$172,779 as a result of vested shares of restricted stock issued to the CEO and then assigned to Domain during that same period. The value of restricted stock is included as a component of stock-based compensation expense for the year ended December 31, 2013.

## 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK

Series A Preferred Stock

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

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK...continued

In connection with the sale of Series A Preferred Stock, in June 2008, the Company recorded a separate preferred stock liability as the investors received the right to purchase from the Company, on the same terms, 248,311 additional shares of Series A Preferred Stock in a second tranche (Series A Rights). The original purchasers of the Series A Preferred Stock in the June transaction had the ability to sell some of the shares of the Series A Preferred Stock and still retained the ability to exercise the right to the future purchase of Series A Preferred Stock and, accordingly, the Series A Rights were determined to be a freestanding derivative liability instrument.

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

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

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

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

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

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

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

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

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

## Series B Preferred Stock

In December 2012, the Company authorized a total of 36,205,634 shares of Series B redeemable, convertible preferred stock (Series B Preferred Stock) of which 387,499 shares were issued for \$5.16 per share resulting in gross proceeds of \$2.0 million and 541,496 shares were issued in connection with the conversion of \$2.2 million of convertible notes and related \$593,474 of accrued interest (see Note 6).

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK...continued

Each investor participating in the December 2012 Series B financings, including those holding the Convertible Notes that were converted in connection with the December Series B Preferred Stock financing, received warrants exercisable for a number of shares of Series B Preferred Stock (Series B Warrants) equal to the 25% of the shares of Series B Preferred Stock purchased in the financing transaction. There was a total of 96,921 shares underlying Series B Warrants issued in connection with the transaction. The Series B Warrants have an exercise price of \$5.16 per share, are immediately exercisable and have a term of five years. As the Series B Warrants are exercisable for redeemable shares, the Company recorded a liability in accordance with ASC 480 for the initial fair value of the Series B Warrants. The Series B Warrants were valued at \$2.2 million using the Black-Scholes pricing model with the following assumptions: a term of 5 years, a risk-free rate of 0.77%, volatility of 88.57% and fair value on date of issuance of \$25.44 per share.

In connection with the sale of Series B Preferred Stock in December 2012, the Company recorded a separate preferred stock liability as the investors received the right to purchase from the Company, on the same terms, 928,995 additional shares of Series B Preferred Stock, in a second tranche (Series B Rights). The Series B Right also provided for warrants (Series B Rights-Warrants) exercisable for Series B Preferred Stock to be issued with the shares exercised under Series B Rights with the same terms and conditions as those warrants issued to the purchasers of the Series B Preferred Stock in the first tranche (Series B Rights-Warrants). The Series B Rights provided warrants for 25% of the shares of the Series B Preferred Stock exercised under the right for purchase in the second tranche. The original purchasers of the Series B Preferred Stock in the December transaction had the ability to sell some of the shares of the Series B Preferred Stock and still retained the ability to exercise the right to the future purchase of Series B Preferred Stock and, accordingly, the Series B Rights were determined to be a freestanding derivative liability instrument.

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

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

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

In August 2013, the Series B investors exercised their right and purchased 387,686 additional shares of Series B Preferred Stock in connection with the second tranche. The second tranche sale resulted in gross proceeds of \$2.0 million. The Company performed a final valuation of the exercised Series B Rights immediately prior to exercise resulting in a valuation of approximately \$6.3 million and reclassified the fair value upon extinguishment to the Series B Preferred Stock purchased in the second tranche. The combination of the \$2.0 million gross cash proceeds and the \$6.3 million fair value of the Series B Rights resulted in an initial fair value of the Series B Preferred Stock issued in August 2013 of \$8.3 million, prior to any discounts for direct costs associated with the transaction. The resulting

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK...continued

warrants associated with the exercised Series B Rights were initially recorded at the final fair value of the Series B warrant purchase rights on the date of exercise and continued to be carried at fair value and those warrants remain outstanding as of December 31, 2013. The unexercised Series B Rights for 541,309 shares of Series B Preferred Stock and the associated Series B Rights-Warrants expired on October 1, 2013. As the unexercised Series B Rights and associated Series B Rights-Warrants had intrinsic value on the date of expiration, the Company recorded a gain of \$10.5 million relating to the final fair value measurement adjustment on the date of expiration.

The following is a summary of the Company s redeemable convertible preferred stock.

Preferred stock consisted of the following as of December 31, 2012:

	Preferred Shares Authorized	Issuance Date	Preferred Shares Issued and Outstanding	R	edemption Value	Carrying Value
Series A - voting	11,786,216	June 2008 and February 2010	875,995	\$	10,722,191	\$ 24,485,280
Series A - nonvoting	11,786,216	June 2008 and February 2010	104,396	\$	1,277,807	4,577,887
						\$ 29,063,167
Series B - voting	18,102,817	December 2012	829,823	\$	4,280,891	\$ 138,684
Series B - nonvoting	18,102,817	December 2012	99,172	\$	511,609	27,983
						\$ 166,667

Preferred stock consisted of the following as of December 31, 2013:

Preferred		Preferred Shares		
Shares		Issued and	Redemption	Carrying
Authorized	Issuance Date	Outstanding	Value	Value

		June 2008 and				
Series A - voting	12,000,000	February 2010	875,995	\$ 10,722,191	\$	24,695,300
Series A -		June 2008 and				
nonvoting	12,000,000	February 2010	104,396	\$ 1,277,807		4,596,565
8	, ,	5	,	, ,		, ,
					\$	29,291,865
					Ŷ	_,,_,
		December 2012				
Series B - voting	19,000,000	and August 2013	1,182,854	\$ 6,102,107	\$	7,834,317
Series B -		December 2012				
nonvoting	19,000,000	and August 2013	133,827	\$ 690,387		1,191,116
		-				
					\$	9,025,433
						, ,

The differences between the respective preferred stock redemption values and carrying values are being accreted over the period from the date of issuance to the earliest redemption date of June 23, 2015. Costs incurred in connection with the issuances of Series A - voting, Series A - nonvoting, Series B - voting and Series B - nonvoting redeemable convertible preferred stock, (collectively, the Preferred Stock ) through December 31, 2012, and 2013, were approximately

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK...continued

\$102,301 and \$119,501, respectively, which have been recorded as a reduction to the carrying amounts of Preferred Stock, and are being accreted to the carrying value of the applicable preferred stock to the earliest redemption date of June 23, 2015.

*Conversion* Each share of Preferred Stock is convertible into either shares of Voting Common Stock or Non-Voting Common Stock, at the election of the holder at any time after the date of issuance of such share. The conversion price is initially defined as the original issue price of \$12.24 for Series A Preferred Stock and \$5.16 for Series B Preferred Stock. Preferred Stock is subject to adjustments from time to time for stock splits, stock dividends, and recapitalization. Additionally, the conversion price of each of the series of convertible preferred stock is subject to adjustment upon certain deemed sales of common stock at a price less than the then applicable conversion price. The conversion to common stock results from dividing the applicable original issue price by the applicable conversion price. Each share of Voting Preferred Stock and each share of Non-Voting Preferred Stock shall be convertible into one share of the same such series of Non-Voting Preferred Stock or one share of the same such series of Voting Preferred Stock without the payment of any additional consideration by the holder. The Series A and Series B preferred stock is automatically and separately convertible into shares of Voting Common Stock or Non-Voting Common Stock at the election of the holder in the event of (i) election of at least 67% of the respective outstanding Series A and Series B Preferred Stock holders (Series A and Series B voting as separate single classes (ii) each share of Preferred Stock shall be automatically converted upon the closing of an initial public offering of at least \$30.0 million in proceeds to the corporation and a public offering price per share equal to at least \$15.4764 (subject to adjustments for stock dividends, splits, combinations and similar events).

As of December 31, 2012 and December 31, 2013, there were no changes in the applicable conversion price for the Series B. As of December 31, 2012 and 2013, the applicable conversion price for the Series A was reduced to \$9.0252 and \$5.16, respectively as a result of the two issuances of Series B preferred stock.

*Liquidation Preference and Participation* In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, sale of substantially all of the assets of the Company or consolidation or merger of the Company with or into another entity whereby less than 50% ownership is maintained by the holders of Common Stock and Preferred Stock, each share of the Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of Common Stock, an amount equal to three times the applicable original issue price per share (calculated to be \$36.72 per Series A share and \$15.4764 per Series B share), plus any dividends declared but unpaid on such shares. As of December 31, 2013, the liquidation values of Series A and Series B Preferred Stock are \$36.0 million and \$20.4 million, respectively. Each share of preferred stock after receipt of the liquidation preference, participates equally per share with common stockholders.

*Dividends* Prior and in preference to any declaration or payment of any dividends to the holders of shares of Common Stock, the holders of shares of the Preferred Stock shall be entitled to receive dividends, at the rate of 8% of the

applicable Original Issue Price of the applicable original issue price per share per annum. Such dividends shall be payable when, as and if declared by the board of directors, and shall not be cumulative. After payment of the dividend, the Preferred Stock shall share in dividends with holders of Common Stock in proportion to the number of shares of common stock the preferred stockholders would convert into on an as-converted basis. No dividends have been declared to date.

*Voting Rights* The voting preferred stock, voting as a single class, shall be entitled to elect two members of the board of directors (the Preferred Directors ); the voting common stock, voting as a separate class, shall be entitled to elect one member to the board of directors; and the Voting Common Stock and the Series A Voting Preferred Stock, voting together as a single class on an as-converted basis, shall be entitled to elect the remaining members to the board of directors. These rights terminate upon the earlier of a closing of an IPO resulting in proceeds to the Company of \$30 million and a price per share price of \$15.4764 (subject to adjustments for stock dividends, splits, combinations and similar events) or a liquidating transaction as described upon in the liquidation preference.

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 11. REDEEMABLE CONVERTIBLE PREFERRED STOCK...continued

**Redemption** At any time after June 23, 2015, the holders of at least two-thirds of the voting power of all then outstanding shares of Preferred Stock, voting together as a single class, may elect to require the Company to redeem for cash all of the then outstanding shares of Preferred Stock. The Company will effect such redemption by paying in cash in exchange for each series of preferred stock the original issue price of each such series in three annual installments with the first being due 60 days after receiving notice of redemption. All declared but unpaid dividends shall be paid concurrently with any redemption.

### **12. STOCK PURCHASE WARRANTS**

On April 12, 2012, in connection with the signing of the Credit Facility agreement (Note 8), the Company granted warrants to purchase 2,042 shares of Series A Preferred Stock (Series A Warrants) at an exercise price of \$12.24 per share to a commercial bank. The warrant was exercisable immediately and had a seven-year life. As the Series A Warrants were exercisable for shares of redeemable stock, they were classified as a liability in accordance with ASC 480-10 and will be marked to market at each reporting period with changes in fair value being reported as a component of operating income/expense in the statement of operations and comprehensive income (loss). The Series A Warrants were initially valued at \$88,100 using the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 1.44%; dividend yield of zero; expected volatility rate of 88.57%; with an expected life of seven years.

On December 20, 2012, in connection with the sale and issuance of Series B Preferred Stock on that date, the Company granted warrants to purchase 96,921 shares of Series B Preferred Stock at an exercise price of \$5.16 per share to the Series B Preferred Stock investors. The warrants were exercisable immediately and have a five-year life. The December issuance of the warrants was initially valued at \$2.2 million using the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 0.77%; dividend yield of zero; expected volatility rate of 88.57%; with an expected life of five years.

On August 14, 2013, in connection with the sale and issuance of Series B Preferred Stock on that date, the Company granted warrants to purchase 96,921 shares of Series B Preferred Stock at an exercise price of \$5.16 per share to the Series B Preferred Stock investors. The warrants were exercisable immediately and had a five-year life. The August issuance of warrants was initially valued at \$1.8 million using the Black-Scholes pricing model with the following assumptions: risk-free interest rate of 1.48%; dividend yield of zero; expected volatility rate of 88.57%; with an expected life of five years.

On November 20, 2013, the Company granted a warrant exercisable for 9,692 shares of Series B Preferred Stock to Square 1 Bank in connection with the amendment to the Credit Facility. The warrant has an exercise price of \$5.16 and a term of seven years. The December 2012, August 2013 and November 2013 warrants are collectively referred to

as the Series B Warrants.

The Series A Warrants and Series B Warrants are classified as a liability in accordance with ASC 480 and are subject to remeasurement at each balance sheet date and changes to fair value are recognized as a component of other income (expense) in the statement of operations and comprehensive income (loss).

As of December 31, 2013, the following warrants to purchase Preferred Stock were outstanding:

Number of Underlying			
Shares	Exercise Price per Share	Warrant Expiration Date	Type of Equity Security
2,042	\$12.24	4/12/2019	Series A Preferred Stock
96,921	\$5.16	12/20/2017	Series B Preferred Stock
96,921	\$5.16	8/14/2018	Series B PreferredStock
9,692	\$5.16	11/20/2020	Series B Preferred Stock

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

### Notes to the Financial Statements (continued)

### 12. STOCK PURCHASE WARRANTS...continued

The Company recognizes all of its warrants in its balance sheet as liabilities as they are exercisable for redeemable preferred stock. The liability is revalued at each reporting period and changes in the fair value of the liability are included on the statement of operations and comprehensive income (loss). The initial recognition and subsequent changes in fair value of the liability have no effect on the Company s cash flows.

The Company estimates the fair value of the warrants at each reporting period using the Black-Scholes pricing model.

### 13. CONVERTIBLE PREFERRED STOCK RIGHTS AND RIGHTS OPTION LIABILITIES

As of December 31, 2012, the following investor rights to purchase Preferred Stock were outstanding:

Number of Underlying<br/>SharesExercise Price per ShareRights Expiration DateType of Equity Security928,995\$5.1610/1/2013Series B Preferred StockAs of December 31, 2012, the following warrant purchase rights to obtain 25% warrant coverage with the purchase of<br/>Series B Preferred Stock were outstanding:Series B

Number of Underlying			
Shares	Exercise Price per Share	<b>Rights Expiration Date</b>	Type of Equity Security
232,248	\$5.16	10/1/2013	Series B Preferred Stock
The Company recognized al	l of its preferred stock rights an	d rights options in its balance	e sheet as liabilities. The
liability was revalued at each	h reporting period and changes	in the fair value of the liabili	ty were included on the
statement of operations and	comprehensive income (loss). 7	The initial recognition and su	bsequent changes in fair value
of the liability had no effect	on the Company s cash flows.		

The Company estimated the fair value of the preferred stock rights and rights options at each reporting period using the Black-Scholes pricing model.

The preferred stock rights and rights options that were outstanding as of December 31, 2012 expired on October 1, 2013. Included within other income (expense) for the years ended December 31, 2012 and 2013 are a loss of approximately \$125,500 and a gain of approximately \$16.2 million, respectively, related to the fair value adjustments and expiration of the Company s preferred stock rights and rights option liabilities.

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## **14. RELATED PARTY TRANSACTIONS**

*Severance Agreement* - During June 2011, the majority common stockholder of the Company was terminated from employment with the Company. As a result of his termination, the Company entered into a termination agreement whereby the Company would pay approximately \$12,000 along with approved reimbursable expenses by the Company. In addition, the Company will pay an additional monthly salary continuation of approximately \$24,000 for 12 months following termination of employment. During 2012, the Company paid the remaining \$75,000 and no obligation exists going forward.

In November 2013, the Company entered into a letter agreement with each of its Chief Executive Officer (CEO) and Chief Operating Officer (COO) that will become effective on the effective date of the Company s initial public offering. The letter agreements were subsequently amended in February 2014. Pursuant to these letter agreements, if the Company terminates the employment of its CEO or COO without cause or if such executive resigns for good reason, then he will be eligible to receive: continued payment of base salary for 12 months; a lump-sum cash payment equal to the greater of such executive s target bonus for the year in which such termination occurs or the actual bonus paid to the

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 14. RELATED PARTY TRANSACTIONS...continued

executive with respect to our most recently completed fiscal year; payment by the Company of the monthly premiums under COBRA for such executive and their eligible dependents for up to 12 months following the termination of such executive s employment; and accelerated vesting and exercisability with respect to all equity or equity-based awards held by such executive officer as if such executive officer has completed an additional 12 months of service with the Company, and up to 12 months following such termination to exercise any then-outstanding stock options or stock appreciation rights. Such payments are contingent on the officer s executing and not revoking a release of claims against the Company. As of December 31, 2013, the Company has assessed the likelihood for these events to occur and has determined that a liability related to these agreements is not likely to occur and therefore has not been recorded.

*Preferred Stock Financings* - In sales occurring in June of 2008 and February of 2010, the Company issued and sold to investors affiliated with Domain Associates, L.L.C. and Johnson & Johnson Development Corporation an aggregate of 980,391 shares of the Company s Series A Preferred Stock at a purchase price of \$12.24 per share, for aggregate consideration of approximately \$12.0 million.

In sales occurring in December of 2012 and August of 2013, the Company issued and sold to investors affiliated with Domain Associates, L.L.C. and Johnson & Johnson Development Corporation an aggregate of 1,316,681 shares of the Company s Series B Preferred Stock at a purchase price of \$5.16 per share and issued such investors warrants to purchase an aggregate of 193,842 shares of the Company s Series B convertible preferred stock at exercise price of \$5.16 per share, for aggregate consideration of approximately \$6.8 million.

*Investors Rights Agreement* - In connection with the initial closing of the Series B Preferred Stock financing described above, the Company entered into an amended and restated investors rights agreement with their significant stockholders, including entities affiliated with Domain Associates, L.L.C and Johnson & Johnson Development Corporation. Pursuant to this agreement, the Company granted such stockholders certain registration rights with respect to shares of the Company s common stock and a right of first offer with respect to future issuances of the Company s securities. The rights of first offer terminate upon the consummation of an initial public offering.

*Convertible Promissory Note* - In October 2013, the Company issued a convertible promissory note to Domain Partners VI, L.P., in a principal amount of \$170,000, which was amended in February 2014 to extend its maturity date. The note accrues interest at a rate of 6% per annum, and will become due and payable in June 2014 unless it is converted into shares of the Company s capital stock prior to such time pursuant to its terms. The note provides that it shall automatically convert at the first to occur of:

a Next Equity Financing, as defined, into shares of the equity security issued and sold in the Next Equity Financing at a conversion price equal to the purchase price per share of the equity securities issued and sold to the purchasers thereof in the Next Equity Financing.

an Initial Public Offering, as defined, into shares of the equity securities issued and sold in the Initial Public Offering at a conversion price equal to the purchase price per share of the equity security issued and sold to the public in the Initial Public Offering.

a Change in Control, as defined, into shares of the Series B Preferred Stock of the Company at the conversion price then in effect for such Series B Preferred Stock.

at the Maturity Date of June 14, 2014 into shares of, at the holder selection, the Series B Voting Preferred Stock or Series B Nonvoting Preferred Stock of the Company, at the Series B Conversion Price then in effect. *Stock Option Grants to Executive Officers and Directors* - The Company has granted stock options to executive officers and certain directors (Note 9).

## ALDEYRA THERAPEUTICS, INC.

(A Development Stage Company)

#### Notes to the Financial Statements (continued)

### 14. RELATED PARTY TRANSACTIONS...continued

**Restricted Stock Awards to Executive Officers** - As described in Note 9, on September 8, 2013 the board of directors sold to the CEO of the Company 12,948 shares of a restricted stock award at a price of \$0.552 per share pursuant to the 2010 Plan. The stock was fully vested at the time of grant and subject to certain restrictions regarding transfer of the shares, including a right of first refusal for the benefit of the Company. On September 10, 2013, the CEO transferred 10,358 of such shares to Domain Associates L.L.C., an entity affiliated with certain of the Company s stockholders. All of the rights and restrictions that applied to the common stock granted to the CEO continue to apply to the shares following the transfer to Domain Associates L.L.C.

### **15. COMMITMENTS AND CONTINGENCIES**

*Guarantees and Indemnifications* - As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company s request in such capacity. The term of the indemnification is for the officer s or director s lifetime. Through December 31, 2013, the Company had not experienced any losses related to these indemnification obligations and no material claims were outstanding. The Company does not expect significant claims related to these indemnification obligations, and consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

*Rent Expense* - The Company leased facilities during 2012 and 2013, and recognized rent expense in accordance with the FASB ASC Topic, *Leases*. Under this Topic, rental expense is calculated by averaging the total rental payments under each respective lease and recognizing expense ratably over the life of the lease. During 2012, the Company did not renew their operating lease for office space and is leasing office space on a month-to-month basis going forward. The Company recorded \$7,428 and \$4,440 in rent expense for the periods ended December 31, 2012 and 2013, respectively. Total rent expense for the period from August 13, 2004 (inception) to December 31, 2013 was \$160,879.

*Litigation* - From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company currently is not a party to any expressly threatened or pending litigation and does not have contingency reserves established for any litigation liabilities.

*Other Contractual Arrangements* - In February 2010, the Company entered into a license and supply agreement providing the Company with an exclusive license to certain technology and access to purchase materials at certain costs. Under the terms of the license and supply agreement, the Company is obligated to make milestone payments up to an aggregate of \$2.15 million upon reaching certain development and regulatory milestones in the development of the Company s product. Upon commercialization of the Company s product containing the licensed technology, the Company would be obligated to pay royalties based on net sales subject to an annual cap. The license and supply

agreement runs through the 7th anniversary of the expiration of all patents licensed under the agreement, which the Company estimates to be April 2036, unless terminated earlier.

## **16. SUBSEQUENT EVENTS**

On March 17, 2014, the Company changed its name from Aldexa Therapeutics, Inc. to Aldeyra Therapeutics, Inc.

1,200,000 Shares

**Common Stock** 

PROSPECTUS

## **Aegis Capital Corp**

Until , 2014 (25 days after the commencement of this offering) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

## 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	\$	4,220
FINRA filing fee	Ŷ	4,820
NASDAQ Capital Market listing fee		50,000
Printing and engraving expenses		140,000
Legal fees and expenses		425,000
Accounting fees and expenses		450,000
Blue sky fees and expenses		10,000
Custodian and transfer agent fees		4,500
Miscellaneous fees and expenses		61,460
Total	\$1,	150,000

## Item 14. Indemnification of Directors and Officers.

In connection with the completion of this offering, the Registrant s amended and restated certificate of incorporation will contain 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 to be in effect immediately prior to the completion of this offering 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.

Prior to the consummation of this offering, the Registrant expects to enter 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.

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

The Underwriting Agreement, the form of which is attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the underwriters, for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

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

### Item 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 2004 Employee, Director and Consultant Stock Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: in 2010, we granted stock options to purchase 106,170 shares of our common stock at an exercise price of \$3.24 per share.
- (2) 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 2010, we granted a stock option to purchase an aggregate of 14,583 shares of our common stock at an exercise price of \$3.24 per share, (b) in 2012, we granted stock options to purchase 28,695 shares of our common stock at an exercise price of \$3.24 per share, (c) 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 (d) 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.
- (3) In 2010, we issued and sold an aggregate of 248,311 shares of Series A convertible preferred stock to investors for an aggregate purchase price of \$3.0 million.
- (4) 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.
- (5) 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 will become exercisable for an aggregate of 4,844 shares of our common stock immediately prior to the closing of this offering assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant terminates seven years after the date issued.
- (6) 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 will become exercisable for an aggregate of 96,921 shares of our common stock immediately prior to the closing of this offering assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant terminates five years after the date issued.
- (7) 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 will become exercisable for an aggregate of 96,921 shares of our common stock immediately prior to the closing of this offering assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant terminates five years after the date issued.

- (8) 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.
- (9) 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 this offering. The note accrues interest at a rate of 6% per annum and will be convertible into shares of our common stock at the price per share of the common stock listed on the cover page of the prospectus contained in this registration statement.
- (10) 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 will become exercisable for an aggregate of 9,692 shares of our common stock immediately prior to the closing of this offering assuming no anti-dilution adjustments to the preferred stock prior to closing. This warrant terminates ten years after the date issued.

The offers, sales, grants and issuances of the securities described in paragraph (1), (2) and (8) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701. The recipients 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 (3), (4), (5), (6), (7), (9) and (10) 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.

Exhibit	Description
1.1#	Form of Underwriting Agreement
3.1#	Restated Certificate of Incorporation, as amended (currently in effect)
3.2#	Bylaws (currently in effect)
3.3#	Form of Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)
3.4#	Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)
4.1#	Specimen stock certificate evidencing the shares of common stock
4.2#	Investor Rights Agreement dated as of December 20, 2012
4.3#	Form of Representative s Warrant Agreement
5.1	Opinion of Gunderson Dettmer, LLP
10.1#	Form of Indemnity Agreement for Directors and Officers
10.2+#	Offer Letter, effective as of August 1, 2013, between the Registrant and Todd C. Brady, M.D., Ph.D.
10.3+#	Offer Letter, effective as of July 15, 2013, between the Registrant and Scott L. Young
10.4+#	Offer Letter, effective November 29, 2013 between the Registrant and Todd C. Brady, M.D., Ph.D.
10.4(a)+#	Offer Letter Amendment, effective February 19, 2014 between the Registrant and Todd C. Brady, M.D., Ph.D.
10.5+#	Offer Letter, effective November 27, 2013, between the Registrant and Scott L. Young
10.5(a)+#	Offer Letter Amendment, effective February 20, 2014 between the Registrant and Scott L. Young
10.6+#	2004 Employee, Director and Consultant Stock Plan, as amended, and form of option agreement thereunder
10.7+#	2010 Employee, Director and Consultant Equity Incentive Plan, as amended, and form of option agreement thereunder
10.8+#	2013 Equity Incentive Plan and form of option agreement thereunder
10.8(a)+#	Form Notice of Stock Option Grant under the 2013 Equity Incentive Plan
10.8(b)+#	Form Notice of Stock Unit Award under the 2013 Equity Incentive Plan

10.10 #	License and Supply Agreement dated as of February 19, 2010 between the Registrant and CyDex Pharmaceuticals, Inc.
10.11#	Loan and Security Agreement, dated as of April 12, 2012, between Square 1 Bank and the Registrant
10.12#	Amendment No. 1 to Loan and Security Agreement, date as of November 20, 2013 between Square 1 Bank and the Registrant
10.13#	Amended and Restated Intellectual Property Security Agreement dated as of November 20, 2013 between Square 1 Bank and the Registrant
23.1	Consent of BDO USA, LLP, independent registered public accounting firm
23.2	Consent of Gunderson Dettmer LLP (included in Exhibit 5.1)
24.1#	Power of Attorney

+ Indicates management contract or compensatory plan.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission.

# Previously filed.

### (b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

### Item 17. Undertakings.

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 to provide the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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 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.
- 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.
- 3. For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to

such date of first use.

4. In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 5 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 April 25, 2014.

### ALDEYRA THERAPEUTICS, INC.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 5 to this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Todd C. Brady, M.D., Ph.D.	Chief Executive Officer and Director	April 25, 2014
Todd C. Brady, M.D., Ph.D.	(principal executive officer and principal financial and accounting officer)	
*	Chairman of the Board of Directors	April 25, 2014
C. Boyd Clarke		
*	Director	April 25, 2014
Ben Bronstein, M.D.		
*	Director	April 25, 2014
Martin J. Joyce		
*	Director	April 25, 2014
Gary Phillips, M.D.		
*	Director	April 25, 2014
Jesse Treu, Ph.D.		
*	Director	April 25, 2014
Neal Walker, D.O.		

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\* <u>By: /s/ Todd C. Brady, M.D., Ph.D.</u> Todd C. Brady, M.D., Ph.D.

Attorney-in-Fact

# EXHIBIT INDEX

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10.8+#	2013 Equity Incentive Plan and form of option agreement thereunder
10.8(a)+#	Form Notice of Stock Option Grant under the 2013 Equity Incentive Plan
10.8(b)+#	Form Notice of Stock Unit Award under the 2013 Equity Incentive Plan
10.10 #	

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License and Supply Agreement dated as of February 19, 2010 between the Registrant and CyDex Pharmaceuticals, Inc.

- 10.11# Loan and Security Agreement, dated as of April 12, 2012, between Square 1 Bank and the Registrant
- 10.12# Amendment No. 1 to Loan and Security Agreement, date as of November 20, 2013 between Square 1 Bank and the Registrant
- 10.13# Amended and Restated Intellectual Property Security Agreement dated as of November 20, 2013 between Square 1 Bank and the Registrant
  - 23.1 Consent of BDO USA, LLP, independent registered public accounting firm
  - 23.2 Consent of Gunderson Dettmer LLP (included in Exhibit 5.1)
- 24.1# Power of Attorney

+ Indicates management contract or compensatory plan.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission.

# Previously filed.