Aldeyra Therapeutics, Inc.
Form S-1/A
April 07, 2014

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As filed with the Securities and Exchange Commission on April 7, 2014.

Registration No. 333-193204

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4

to

FORM S-1

REGISTRATION STATEMENT

Under

THE SECURITIES ACT OF 1933

ALDEYRA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

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

Incorporation or Organization)	**Classification Code Number)**	**Identification Number)**

15 New England Executive Park

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

Telephone: (781) 270-0630

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

Copies to:

Jay K. Hachigian	**Scott L. Young**	**Ivan K. Blumenthal**
Keith J. Scherer	**Chief Operating Officer**	**Avisheh Avini**
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Franklin & Hachigian, LLP	**Burlington, MA 01803**	**666 Third Avenue**
850 Winter Street	**Telephone: (781) 270-0630**	**New York, NY 10017**

Waltham, MA 02451 **Telephone: (212) 935-5000**

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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)			

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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.

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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 7, 2014

2,275,000 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 Risk Factors 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(1)	$	$
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 341,250 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 that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus or in any free writing prospectus that we may authorize to be delivered or made available to you. Neither the delivery of this prospectus nor the sale of our common stock means that the information contained in this prospectus or any free writing prospectus is correct after the date of this prospectus or such free writing prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy the shares of common stock in any circumstances under which the offer or solicitation is unlawful.

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

Aldeyra Therapeutics and our 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 ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable holder will not assert its rights, to these trademarks and tradenames.

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PROSPECTUS SUMMARY

This summary highlights 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 the following diseases: Sjögren-Larsson Syndrome (SLS), a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes; discoid lupus, an autoimmune condition that affects skin; acute anterior uveitis, an inflammatory eye disease; and ocular rosacea with meibomian gland dysfunction, a dry eye disease associated with rosacea, an inflammatory dermal condition.

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 or ocular rosacea with meibomian gland dysfunction. We believe that therapies for discoid lupus are moderately to poorly effective in controlling or curing the disease without drug related toxicity. 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, discoid lupus, 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 trials with our NS2 eye drop in acute anterior uveitis and in ocular rosacea with meibomian gland dysfunction;

- Phase II/III clinical trial in SLS with a topical dermatologic formulation of NS2;

- Phase II clinical trial in discoid lupus with a topical dermatologic formulation of NS2; and

- Phase I clinical trial of NS2 administered orally to healthy volunteers.

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.

- 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.

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The Offering

Common stock offered by us	2,275,000 shares of our common stock.
Common stock to be outstanding after this offering	6,245,164 shares of our common stock.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 341,250 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	ALDX

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:

- 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;

- 91,000 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.

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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.

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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 December 31,		Cumulative for the Period from August 13, 2004 (Inception) to December 31, 2013
	2012	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

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	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	$ 25,135,354
Working capital	2,665,755	2,665,755	24,538,755
Total assets	3,743,233	3,743,233	25,143,766
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	23,487,839

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 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), and (3) our sale of 2,275,000 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 $2.0 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 (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) 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;

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- 91,000 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 Ended December 31, 2012	December 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.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information 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

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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 does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

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.

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.

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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 or discoid lupus and we have not amended our active IND for NS2 administered as an eye drop to include acute anterior uveitis and ocular rosacea with meibomian gland dysfunction. Submission of an IND for NS2 as a treatment for SLS and discoid lupus 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 ocular rosacea 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 five clinical trials in 2014: a Phase I trial of orally administered NS2 in healthy volunteers, a Phase II/III trial of NS2 administered as a topical dermatologic to patients with SLS, a Phase II trial of NS2 administered as a topical dermatologic to patients with discoid lupus, and two Phase II trials of NS2 administered as an eye drop to patients with acute anterior uveitis and ocular rosacea with meibomian gland dysfunction. 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;

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- 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, it will delay our plans for our clinical trials. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND, 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 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

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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

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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, discoid lupus, 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.

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

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

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

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

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

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. With the exception of SLS, there are a variety of drug candidates in development for the indications that we intend to test. 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. Discoid lupus, uveitis, and ocular rosacea with meibomian gland dysfunction 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:

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

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- 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.

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

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

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

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

- 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

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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:

- decreased demand for NS2 or our other product candidates;

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

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- 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.

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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.

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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:

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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, 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.

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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;

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- 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.

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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 $7.30 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.

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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 58.5% 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 6,245,164 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 2,275,000 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 58.3% 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 91,000 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.

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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, can, would, expect, project, target, design, estimate, predict, potential, plan or the negative of these terms, and similar expressi 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.

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USE OF PROCEEDS

We estimate that our net proceeds from the sale of the common stock that we are offering will be approximately $21.9 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 $25.3 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 $2.0 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 number of shares we are offering. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $10.1 million, assuming the assumed initial public offering price stays the same.

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 $10.0 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 five 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.

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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 2,275,000 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	$ 25,135,354
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, 24,000,000 shares authorized; 980,391 shares issued and outstanding (Liquidation	29,291,865	-	-

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, 6,355,811 issued and outstanding, pro forma as adjusted	327	4,080	6,356

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	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	64,805,821
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	23,487,839
Total Capitalization	$ 2,802,014	$ 2,802,014	$ 24,675,014

(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 $2.0 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 (decrease) 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 (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders equity (deficit) 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;

- 91,000 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.

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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 2,275,000 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 $23.5 million, or approximately $3.70 per share. This amount represents an immediate increase in pro forma net tangible book value of $126.56 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $7.30 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	3.30	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		3.70
Dilution in pro forma as adjusted net tangible book value per share to new investors		$ 7.30

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 $0.33, and dilution in pro forma net tangible book value per share to new investors by approximately $0.67, 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 $0.87 per share and decrease the dilution to investors participating in this offering by approximately $0.87 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 offering expenses payable by us.

If the underwriters exercise their over-allotment option to purchase 341,250 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 $4.02 per share, the

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increase in pro forma net tangible book value per share to existing stockholders would be $0.33 per share and the dilution per share to new investors would be $6.98 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 Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders	4,080,811	64%	$ 12,571,086	33%	$ 3.08
New investors	2,275,000	36%	25,025,000	67%	
Total	6,355,811	100%	$ 37,596,086	100%	

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;
- 91,000 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 $3.33, and total dilution per share to new investors would be $7.67.

If the underwriters exercise their over-allotment option to purchase additional 341,250 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 60.3% 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 2,616,250, or approximately 39.7% of the total number of shares of our common stock outstanding after this offering.

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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 December 31,		Cumulative for the Period from August 13, 2004 (Inception) to December 31, 2013
	2012	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)
	$ (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.

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	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	$ 25,135,354
Working capital	2,665,755	2,665,755	24,538,755
Total assets	3,743,233	3,743,233	25,143,766
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	23,487,839

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 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 convertible 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), and (3) our sale of 2,275,000 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 $2.0 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 (decrease) 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 (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) 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;

- 91,000 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 Ended	
	December 31, 2012	**December 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.

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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 the following diseases: Sjögren-Larsson Syndrome (SLS), a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes; discoid lupus, an autoimmune condition that affects skin; acute anterior uveitis, an inflammatory eye disease; and ocular rosacea with meibomian gland dysfunction, an eye disease associated with rosacea, an inflammatory dermal condition. 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 Phase II trials in discoid lupus, acute anterior uveitis, and ocular rosacea with meibomian gland dysfunction. In addition, we plan to initiate a Phase I clinical trial of NS2 administered orally to healthy volunteers. 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

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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 $10.0 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 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.

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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:

Grant Dates	**Number of Common Shares Underlying Options Granted**	**Exercise Price per Common Share**	**Estimated Fair Value per Common 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:

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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 an enterprise based on the present 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 on such date.(1)

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 were granted rights to invest additional capital at defined prices, and, in the case of the initial purchasers of our 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.

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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 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 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 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 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 on 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. 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

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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, 2012	Year Ended December 31, 2013	Increase/ (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	$ 38,697,183

Research and Development Expenses. Research and development expenses were $469,270 for the year ended December 31, 2012 compared to $1.5 million for the year ended December 31, 2013. The increase of $1.1 million is primarily related to the increase in our external research and development expenditures and stock-based compensation.

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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

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- 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 $10.0 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 orally to healthy volunteers, and to assess the efficacy and safety of topically administered NS2 in patients with SLS, discoid lupus, acute anterior uveitis, and ocular rosacea with meibomian gland dysfunction;

- 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;

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- 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.

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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. For rare diseases, 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. In 2014, we plan to commence clinical testing of NS2 applied to the skin of patients with a rare and severe skin disease called Discoid Lupus Erythematosis (discoid lupus), characterized in part by inflammation, fibrosis (scarring), and delayed healing of skin lesions. We believe that currently available therapies for discoid lupus are moderately to poorly effective in controlling or curing the disease without drug-related toxicity, and that new therapeutic approaches are in high demand.

Similar to diseases of the skin, 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 two severe and, we believe, poorly treated ocular diseases, acute anterior uveitis and ocular rosacea with meibomian gland dysfunction. In both of these diseases, aldehydes may mediate, at least in part, inflammation, fibrotic changes, and lipid destruction leading to dryness and surface irritation. Acute anterior uveitis is a rare inflammatory condition that leads to pain, sensitivity to light, and vision loss. Ocular rosacea is an inflammatory condition that causes redness, burning, stinging, eyelid swelling, and damage to the front of the eye. A subset of ocular rosacea patients manifest dysfunction in lipid-secreting glands called meibomian glands, leading to tears that lack normal lubricating and moisturizing effectiveness. In anterior uveitis and ocular rosacea, 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). We are not aware of any therapy that has been approved by the FDA for ocular rosacea with meibomian gland dysfunction.

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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 tr