

Aldeyra Therapeutics, Inc.
Form S-1
March 27, 2015
Table of Contents

As filed with the Securities and Exchange Commission on March 27, 2015

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ALDEYRA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

20-1968197
(I.R.S. Employer
Identification Number)

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131 Hartwell Avenue, Suite 320

Lexington, MA 02421

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

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

President and Chief Executive Officer

Aldeyra Therapeutics, Inc.

131 Hartwell Avenue, Suite 320

Lexington, MA 02421

(781) 761-4904

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

Copies to:

Jay K. Hachigian

Keith J. Scherer

Gunderson Dettmer Stough Villeneuve

Franklin & Hachigian, LLP

One Marina Park Drive, Suite 900

Boston, MA 02210

(617) 648-9100

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

If 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. x

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

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

If this Form is a 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.

Large accelerated filer .. Accelerated filer ..
 Non-accelerated filer .. (Do not check if a smaller reporting company) Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered(1)	Proposed		Amount of Registration Fee(3)
		Maximum Aggregate Offering Price	Proposed Maximum Aggregate Offering Price(2)	
Common Stock, \$0.001 par value per share	211,528	\$10.74	\$2,271,810.72	\$263.99
Common Stock, par value \$0.001 per share underlying warrant	211,528	\$10.74	\$2,271,810.72	\$263.99
Total	423,056	\$10.74	\$4,543,621.44	\$527.98

(1) Represents shares offered by the selling stockholder. Includes an indeterminable number of additional shares of common stock, pursuant to Rule 416 under the Securities Act of 1933, as amended, that may be issued to prevent dilution from stock splits, stock dividends or similar transactions that could affect the shares to be offered by selling stockholder.

- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average high and low prices of the Registrant's common stock on March 23, 2015, as quoted on the NASDAQ Capital Market.
- (3) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

Table of Contents

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

SUBJECT TO COMPLETION, DATED MARCH 27, 2015

PRELIMINARY PROSPECTUS

Aldeyra Therapeutics, Inc.

423,056 Shares of Common Stock

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

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

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

The selling stockholder identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. For additional information on the methods of sale that may be used by the selling stockholder, see the section entitled **Plan of Distribution** on page 15. For a list of the selling stockholder, see the section entitled **Selling Stockholder** on page 13.

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

Our common stock is traded on The NASDAQ Capital Market under the symbol **ALDX**. On March 26, 2015, the closing sale price of our common stock on The NASDAQ Capital Market was \$10.40 per share. You are urged to obtain current market quotations for the common stock.

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

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

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

The date of this prospectus is _____, 2015.

Table of Contents

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

	Page
<u>SUMMARY</u>	1
<u>THE OFFERING</u>	4
<u>RISK FACTORS</u>	5
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA</u>	11
<u>USE OF PROCEEDS</u>	13
<u>SELLING STOCKHOLDER</u>	13
<u>PLAN OF DISTRIBUTION</u>	15
<u>MARKET PRICE OF OUR COMMON STOCK</u>	17
<u>DIVIDEND POLICY</u>	17
<u>DILUTION</u>	17
<u>PRINCIPAL STOCKHOLDERS</u>	18
<u>LEGAL MATTERS</u>	20
<u>EXPERTS</u>	20
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	20
<u>INCORPORATION OF DOCUMENTS BY REFERENCE</u>	20

Table of Contents

SUMMARY

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

Company Overview

Aldeyra was formed as a Delaware corporation in 2004, and from inception until December 20, 2012, we operated as Neuron Systems, Inc. and from December 2012 until March 2014 we operated as Aldexa Therapeutics, Inc. Since our incorporation, we have devoted substantially all of our resources to the preclinical and clinical development of our product candidates. Our ability to generate revenues largely depends upon our ability, alone or with others, to complete the development of our product candidates to obtain the regulatory approvals for and to manufacture, market and sell our products and product candidates. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business and industry, risks relating to intellectual property and other legal matters, risks related to our common stock, and other risks that are detailed in the section of this annual report on Form 10-K entitled Risk Factors.

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

We initiated a clinical trial of NS2, for the treatment of a disease called Sjögren-Larsson Syndrome (SLS), a rare condition that we believe afflicts approximately 1,000 patients in the United States. The disease is caused by mutations in an enzyme that metabolizes free fatty (generally 16-18 carbon) aldehydes, resulting in high levels of toxic aldehydes that are the suspected cause of severe skin disease, mental delay, spasticity, and, in some patients, retinal dysfunction. NS2 has demonstrated fatty aldehyde trapping in human skin cells in preclinical studies. In order to attempt to improve the dermatologic symptoms of SLS, we initiated Phase II clinical testing of NS2 applied topically to the skin of SLS patients in March 2015. We are not aware of any therapy for SLS that has been approved by the FDA.

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

We believe that inflammatory diseases of the eye may also be mediated in part by free aldehyde toxicity. We have developed an eye drop formulation of NS2 that has completed Phase I clinical testing for safety and tolerability in healthy volunteers. In March 2015, we initiated a Phase II clinical trial of the NS2 eye drop formulation in a serious and, we believe, poorly treated ocular disease called noninfectious anterior uveitis. In noninfectious anterior uveitis, aldehydes may mediate, at least in part, inflammation, fibrotic changes, and lipid destruction leading to dryness and

surface irritation. Patients with noninfectious anterior uveitis generally experience severe pain, sensitivity to light, and vision loss. We believe that novel medications are needed to improve symptoms and deter disease progression, especially in order to reduce dependence on topical corticosteroids, which can lead to cataracts (ocular lens opacities resulting in vision impairment) and glaucoma (increased intraocular pressure that can, in some cases, lead to blindness).

Table of Contents

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

Risks Associated with Our Business

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

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

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

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

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

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials, including NS2, may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Because NS2 and our other product candidates are, to our knowledge, new chemical entities, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of these product candidates and obtain the necessary regulatory approvals for commercialization.

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

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

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

Any product candidate we or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

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

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

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

Table of Contents

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

Our Corporate Information

Our principal executive offices are located at 131 Hartwell Avenue, Suite 320, Lexington, MA 02421, and our telephone number is (781) 761-4904. On March 17, 2014, we changed our name from Aldexa Therapeutics, Inc. to Aldeyra Therapeutics, Inc. Our website address is www.aldeyra.com. 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 December 31, 2019, or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual gross revenue, the date at which we become a large accelerated filer, or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

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

We have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act and, as a result, we will adopt new or

revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Private Placement of Common Stock and Warrant

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

Table of Contents

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

THE OFFERING

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

The number of shares of our common stock outstanding is based on 5,565,413 shares of our common stock outstanding as of December 31, 2014, plus the 211,528 shares of our common stock issued to the selling stockholder in January 2015 in a private placement and 1,113,080 shares of our common stock issued to accredited investors in a prior private placement in January 2015 and excludes the following:

874,032 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2014, at a weighted-average exercise price of approximately \$3.10 per share;

360,810 shares of common stock reserved for future grants under our 2014 Equity Incentive Plan as of December 31, 2014, plus an additional 222,617 shares of common stock added to the plan on January 1, 2015 (subject to automatic annual adjustment in accordance with the terms of the plan);

60,000 shares of our common stock issuable upon exercise of warrants at an exercise price of \$10.00 per share; and

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1,324,608 shares of our common stock issuable upon exercise of warrants at an exercise price of \$9.50 per share, 211,528 of which are held by the selling stockholder.

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

Table of Contents

RISK FACTORS

Investing in our common stock involves risks including, without limitation, those set forth below. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. If any of the risks described below or in any document incorporated by reference herein actually occurs, our business, financial condition and results of operations would likely suffer. In that event, the market price of our common stock could decline and investors in our common stock could lose all or part of their investment. You should carefully consider all of the information set forth in this prospectus and the documents incorporated by reference herein and annexed hereto, and, in particular, the risk factors described in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2014, filed with the SEC, which are incorporated by reference into this prospectus, with your respective legal counsel, tax and financial advisors and/or accountants prior to purchasing our common stock.

Risks Related to Ownership of Our Common Stock

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

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

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

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

our ability to enroll patients in our planned clinical trials;

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

regulatory developments in the United States and foreign countries;

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

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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;

Table of Contents

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

additions or departures of key personnel; and

intellectual property, product liability or other litigation against us.

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

Our quarterly operating results may fluctuate significantly.

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

variations in the level of expenses related to our clinical trial and development programs;

addition or termination of clinical trials;

any intellectual property infringement lawsuit in which we may become involved;

regulatory developments affecting NS2 and our other product candidates;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;

nature and terms of stock-based compensation grants; and

derivative instruments recorded at fair value.

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

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

If 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

Table of Contents

transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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

Our management will have broad discretion in the application of our cash and cash equivalents. Because of the number and variability of factors that will determine our use of our cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our cash and cash equivalents in ways that ultimately increase the value of your investment. We expect to use of our cash and cash equivalents to fund our planned clinical trials of NS2, development of other molecules that may relate to our aldehyde trapping platform, and the remainder for working capital and other general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash and cash equivalents in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

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

Table of Contents

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

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

A substantial number of shares of our common stock could be sold into the public market in the near future, which could depress our stock price.

Sales of substantial amounts of our common stock in the public market could reduce the prevailing market prices for our common stock. Substantially all of our outstanding common stock are eligible for sale as are common stock issuable under vested and exercisable stock options. If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer, if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three year period

before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Table of Contents

We are incurring significant increased costs and demands upon management as a result of operating as a public company.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC, and The NASDAQ Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years from our Initial Public Offering. We intend to continue to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

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

Table of Contents

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

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

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

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

We could be subject to securities class action litigation.

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

Risks Related to Our Business, Our Intellectual Property, Our Financial Position and Need for Capital and Other Matters

Please see Item 1A - Risk Factors contained in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2014 which is incorporated by reference herein, for risk factors related to our business and industry and other matters.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

the timing and success of preclinical studies and clinical trials conducted by us and our development partners;

the ability to obtain and maintain regulatory approval of our clinical trials and product candidates, and the labeling for any approved products;

the scope, progress, expansion, and costs of developing and commercializing our product candidates;

the size and growth of the potential markets for our product candidates and the ability to serve those markets;

our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;

the rate and degree of market acceptance of any of our product candidates;

our expectations regarding competition;

our anticipated growth strategies;

our ability to attract or retain key personnel;

our ability to establish and maintain development partnerships;

our expectations regarding federal, state and foreign regulatory requirements;

regulatory developments in the United States and foreign countries;

our ability to obtain and maintain intellectual property protection for our product candidates;

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

the use of our cash or cash equivalents.

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

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

Table of Contents

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

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

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

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

Table of Contents**USE OF PROCEEDS**

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

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

SELLING STOCKHOLDER

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

The table below lists the selling stockholder and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholder. The second column lists the number of shares of common stock beneficially owned by the selling stockholder, based on its ownership of the common stock and warrant, as of March 15, 2015, assuming exercise of all warrants held by the selling stockholder on that date, without regard to any limitations on exercise.

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

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

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior	Maximum Number of Shares of Common Stock to	Number of Shares of Common Stock
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	to Offering	be Sold Pursuant to this Prospectus	Owned After Offering (1)
Cowen Investments LLC	423,056(2)	423,056	0

- (1) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (ii) no other shares of common

Table of Contents

stock will be acquired or sold by the selling stockholder before completion of this offering. However, the selling stockholder may sell all, part or none of its shares of common stock offered pursuant to this prospectus and may sell all, part or none of its common stock pursuant to one or more exemptions from the registration provisions of the Securities Act of 1933, as amended.

- (2) Includes 211,528 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of \$9.50 per share, which may be exercised after July 21, 2015 and expires on January 21, 2018. RCG LV Pearl, LLC is the sole member of Cowen Investments LLC. RCG LV Pearl, LLC disclaims beneficial ownership of the shares held by Cowen Investments LLC. Cowen Group, Inc. is the sole member of RCG LV Pearl, LLC. Cowen Group, Inc. disclaims beneficial ownership of the shares held by Cowen Investments LLC. Peter A. Cohen, the Chairman and Chief Executive Officer of Cowen Group, Inc., has voting and investment control over the shares held by Cowen Investments LLC. Mr. Cohen disclaims beneficial ownership of these shares. An affiliate of Cowen Investments LLC is a FINRA member. However, this affiliate will not sell any shares to be offered by Cowen Investments LLC through the prospectus and will receive no compensation whatsoever in connection with sales of shares by Cowen Investments LLC through the prospectus. The address for Cowen Investments LLC is 599 Lexington Avenue, New York, NY 10022.

Table of Contents