Aldeyra Therapeutics, Inc.
Form 10-Q
November 14, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36332

ALDEYRA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-1968197**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
131 Hartwell Avenue, Suite 320	
Lexington, MA	**02421**
(Address of principal executive offices)	**(Zip Code)**

(781) 761-4904

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of November 14, 2016, there were 12,576,326 shares of the registrant s common stock issued and outstanding.

Table of Contents

Aldeyra Therapeutics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2016

INDEX

		Page
PART I FINANCIAL INFORMATION		
ITEM 1.	Condensed Financial Statements:	3
	Balance Sheets at September 30, 2016 (Unaudited) and December 31, 2015	3
	Statements of Operations for the three and nine months ended September 30, 2016 and 2015 (Unaudited)	4
	Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015 (Unaudited)	5
	Statements of Cash Flows for the nine months ended September 30, 2016 and 2015 (Unaudited)	6
	Notes to Condensed Financial Statements	7
ITEM 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	13
ITEM 3.	Quantitative and Qualitative Disclosures about Market Risk	19
ITEM 4.	Controls and Procedures	19
PART II OTHER INFORMATION		
ITEM 1.	Legal Proceedings	19
ITEM 1A.	Risk Factors	19
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	44
ITEM 3.	Defaults Upon Senior Securities	44
ITEM 4.	Mine Safety Disclosures	44
ITEM 5.	Other Information	44
ITEM 6.	Exhibits	44
Signatures		45
Exhibits		46

Table of Contents

Part I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

ALDEYRA THERAPEUTICS, INC.

BALANCE SHEETS

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,568,508	$ 14,648,866
Marketable securities	14,307,073	12,941,776
Prepaid expenses and other current assets	250,206	497,552
Total current assets	29,125,787	28,088,194
Deferred offering costs		36,236
Fixed assets, net	65,690	80,334
Total assets	$ 29,191,477	$ 28,204,764
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 733,560	$ 851,160
Accrued expenses (Note 6)	1,476,592	1,186,429
Current portion of credit facility	426,505	77,546
Total current liabilities	2,636,657	2,115,135
Credit facility, net of current portion and debt discount	883,282	1,211,310
Total liabilities	3,519,939	3,326,445
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding as of September 30, 2016 and December 31, 2015		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 12,568,563 shares issued and outstanding as of September 30, 2016 and 9,712,521 shares issued and outstanding as of December 31, 2015	12,569	9,713
Additional paid-in capital	98,302,346	83,478,851
Accumulated other comprehensive income (loss), net of tax	6,528	(8,361)
Accumulated deficit	(72,649,905)	(58,601,884)

Total stockholders equity	25,671,538	24,878,319
Total liabilities and stockholders equity	$ 29,191,477	$ 28,204,764

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 3,379,711	$ 2,076,410	$ 9,728,494	$ 4,461,941
General and administrative	1,396,734	1,261,196	4,314,483	3,188,176
Loss from operations	(4,776,445)	(3,337,606)	(14,042,977)	(7,650,117)
Other income (expense):				
Interest income	27,792		74,463	
Interest expense	(26,654)	(28,081)	(79,507)	(84,314)
Total other income (expense), net	1,138	(28,081)	(5,044)	(84,314)
Net loss	$ (4,775,307)	$ (3,365,687)	$ (14,048,021)	$ (7,734,431)
Net loss per share - basic and diluted	$ (0.38)	$ (0.35)	$ (1.28)	$ (0.94)
Weighted average common shares outstanding - basic and diluted	12,474,609	9,712,521	10,942,127	8,270,405

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (4,775,307)	$ (3,365,687)	$ (14,048,021)	$ (7,734,431)
Other comprehensive income:				
Unrealized gain on marketable securities, net of tax	1,825		14,889	
Total other comprehensive income	1,825		14,889	
Comprehensive loss	$ (4,773,482)	$ (3,365,687)	$ (14,033,132)	$ (7,734,431)

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (14,048,021)	$ (7,734,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,159,714	1,639,930
Amortization of debt discount non-cash interest expense	20,931	28,061
Net amortization of premium on debt securities available for sale	182,963	
Depreciation	26,454	10,649
Change in assets and liabilities:		
Prepaid expenses and other current assets	247,346	(374,767)
Accounts payable	(117,600)	402,329
Accrued expenses	290,163	(278,401)
Net cash used in operating activities	(11,238,050)	(6,306,630)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(11,810)	(86,119)
Purchases of marketable securities	(15,378,371)	
Sales of marketable securities	13,845,000	
Net cash used in investing activities	(1,545,181)	(86,119)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	12,702,873	28,505,808
Deferred offering costs paid in cash		(21,998)
Net cash provided by financing activities	12,702,873	28,483,810
NET (DECREASE) INCREASE IN CASH	(80,358)	22,091,061
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	14,648,866	8,527,304
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 14,568,508	$ 30,618,365
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 58,722	$ 55,775
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:		

Offering costs of public offering not yet paid	$	$ 36,236

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALDEYRA THERAPEUTICS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

1. NATURE OF BUSINESS

Aldeyra Therapeutics, Inc. (the Company or Aldeyra), a Delaware corporation, is developing new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to naturally occurring toxic and pro-inflammatory chemical species known as aldehydes.

The Company s principal activities to date include raising capital and research and development activities.

2. BASIS OF PRESENTATION

The accompanying interim unaudited condensed financial statements and related disclosures are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company s financial statements and related footnotes for the year ended December 31, 2015 included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission on March 30, 2016. The financial information as of September 30, 2016, the three and nine months ended September 30, 2016 and 2015 is unaudited, but in the opinion of management, all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation of the financial position, results of operations and cash flows at the dates and for the periods presented of the results of these interim periods have been included. The balance sheet data as of December 31, 2015 was derived from audited financial statements. The results of the Company s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

On June 1, 2016, the Company closed an underwritten public offering in which it sold, an aggregate of approximately 2.8 million shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by Aldeyra.

The Company s management believes that its currently available resources, including amounts potentially available under its credit facility (Note 7), will provide sufficient funds to enable the Company to meet its expected obligations through approximately the second quarter of 2018 based on the Company s current business plan. However, these amounts will not be sufficient for the Company to commercialize its product candidates or conduct any substantial, additional development requirements requested by the U.S. Food and Drug Administration (FDA). Additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to secure additional capital, or meet financial covenants that could be implemented under the Company s term loans in certain circumstances, it will be required to significantly decrease the amount of planned expenditures, and may be required to cease operations.

Curtailment of operations would cause significant delays in the Company s efforts to introduce its products to market, which is critical to the realization of its business plan and the future operations of the Company.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-15 (ASU 2016-15), Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The standard is intended to reduce the diversity in practice around how certain transactions are classified within the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. ASU 2016-15 may be adopted retrospectively or prospectively if it is impractical to apply the amendments retrospectively. The Company does not expect this standard to have a material impact on its financial statements.

In April 2016 and May 2016, the FASB issued ASU No. 2016-10 (ASU 2016-10), Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations & Licensing which provides further clarification for the implementing the new revenue recognition standard, ASU 2014-09. The effective date and transition requirements for ASU 2016-10 are the same as the effective date of ASU 2014-09. The Company does not expect this standard to have a material impact on its financial statements.

Table of Contents

In March 2016, the FASB issued ASU No. 2016-09 Improvements to Employee Share-Based Payment Accounting (ASU 2016-09), to simplify the accounting for stock compensation. This update focuses on income tax accounting, award classification, estimating forfeitures, and cash flow presentation. The ASU becomes effective in 2017 for public companies and in 2018 for all other entities. Early adoption is permitted. Certain disclosures and detailed transition provisions apply. The Company does not believe that ASU 2016-09 will have a material impact on its financial statements.

3. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share of the Company:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss basic and diluted	$ (4,775,307)	$ (3,365,687)	$ (14,048,021)	$ (7,734,431)
Weighted-average number of common shares basic and diluted	12,474,609	9,712,521	10,942,127	8,270,405
Net loss per share basic and diluted	$ (0.38)	$ (0.35)	$ (1.28)	$ (0.94)

The following potentially dilutive securities outstanding, prior to use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average shares outstanding, because such securities had an antidilutive impact:

	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
Options to purchase common stock	1,604,841	1,038,530	1,604,841	1,038,530
Warrants to purchase common stock	1,384,608	1,384,608	1,384,608	1,384,608
Restricted common stock units	27,096		27,096	
Total of common stock equivalents	3,016,545	2,423,138	3,016,545	2,423,138

4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

At September 30, 2016, cash, cash equivalents and marketable securities were comprised of:

	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable

						Securities
Cash	$ 424,613	$	$	$ 424,613	$ 424,613	$
Money market funds	43,895			43,895	43,895	
U.S. reverse repurchase agreements	14,100,000			14,100,000	14,100,000	
U.S. government agency securities	14,300,545	6,530	(2)	14,307,073		14,307,073
Available for Sale(1)	28,400,545	6,530	(2)	28,407,073	14,100,000	14,307,073
Total Cash, cash equivalents and current marketable securities					$ 14,568,508	$ 14,307,073

(1) Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of all available for sale securities were less than one year at September 30, 2016.

5. FAIR VALUE MEASUREMENTS

Financial instruments, including cash and accounts payable, are carried in the financial statements at amounts that approximate their fair value based on the short maturities of those instruments. The carrying amount of the Company s term loans under its credit facility approximates market rates currently available to the Company.

Table of Contents

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820, *Fair Value Measurements*, establishes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 Quoted prices in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

There were no liabilities measured at fair value at September 30, 2016 or December 31, 2015. The following table presents information about the Company s assets measured at fair value at September 30, 2016 and December 31, 2015:

	September 30, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 43,895	$	$	$ 43,895
U.S. Reverse repurchase agreements		14,100,000		14,100,000
U.S. government agency securities		14,307,073		14,307,073
Total assets at fair value	$ 43,895	$ 28,407,073	$	$ 28,450,968

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 35,886	$	$	$ 35,886
Repurchase agreements		12,950,000		12,950,000
U.S. government agency securities		12,941,776		12,941,776
Total assets at fair value	$ 35,886	$ 25,891,776	$	$ 25,927,662

6. ACCRUED EXPENSES

Accrued expenses at September 30, 2016 and December 31, 2015 were:

	September 31, 2016	December 31, 2015
Accrued compensation	$ 957,328	$ 394,773
Accrued research and development	415,060	550,323
Accrued general and administrative	104,204	192,676
Accrued other		48,657
Accrued expenses	$ 1,476,592	$ 1,186,429

7. CREDIT FACILITY

In April 2012, the Company entered into a loan and security agreement (the Credit Facility) with Pacific Western Bank (Pacific Western, formerly Square 1 Bank) which was subsequently amended in November 2013 to provide the Company with $1.5 million of available funds. The amended Credit Facility called for interest only payments at a 6.50% interest rate from November 2013 through November 2014 for all amounts outstanding, at which point the Company was scheduled to make principal payments of $58,160 plus interest through the maturity date in November 2016. In November 2014, the Credit Facility was further amended. Pursuant to the further amended Credit Facility, Pacific Western agreed to make term loans in a principal amount of up to $5.0 million available to the Company with proceeds to be used, first, to refinance outstanding loans from Pacific Western, second, to fund expenses related to the Company s clinical trials, and the remainder for general working capital purposes. The term loans are to be made available to the Company upon the following terms: (i) $2.0 million was made available in November 2014; and (ii) $3.0 million (the Tranche B Loan) became available to the Company following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. Any term loan made was payable as interest-only prior to November 2015 and thereafter was scheduled to be payable in monthly installments of principal plus accrued interest through the maturity date in October 2019. The amended Credit

Table of Contents

Facility was amended again in November 2015 extending the interest only period, the period to satisfy the Tranche B Loan conditions and the maturity date, October 2019. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. The annualized interest rate as of September 30, 2016 was 5.60%. Any term loan made is payable as interest-only prior to November 2016 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. The Credit Facility is collateralized by the Company s assets, including its intellectual property. As of September 30, 2016, $1.4 million was outstanding under the Credit Facility.

At September 30, 2016, the Credit Facility is shown net of a remaining debt discount of $86,046 which is being amortized using the effective interest method through the current maturity date of the Credit Facility, October 2019.

8. INCOME TAXES

No provision for federal taxes and state has been recorded as the Company has incurred losses since inception for tax purposes. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

In assessing the realizability of net deferred taxes in accordance with ASC 740, *Income Taxes*, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Based on the weight of available evidence, primarily the incurrence of net losses since inception, anticipated net losses in the near future, reversals of temporary differences and expiration of various federal and state attributes, the Company does not consider it more likely than not that some or all of the net deferred taxes will be realized. Accordingly, a 100% valuation allowance has been applied against net deferred taxes.

Under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and certain other tax assets (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). Transactions involving the Company s common stock, even those outside the Company s control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on the Company s ability to utilize some or all of its NOLs or credits could have a material adverse effect on the Company s results of operations and cash flows. Prior to 2016, Aldeyra has undergone two ownership changes. However, the Company s management believes that it had sufficient Built-In-Gain to offset the Section 382 of the Code limitation generated by such ownership changes. Any future ownership changes, including those resulting from Aldeyra s recent or future financing activities, may cause the Company s existing tax attributes to have additional limitations.

All tax years are open for examination by the taxing authorities for both federal and state purposes.

The Company accounts for uncertain tax positions pursuant to ASC 740 which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes. Management is not aware of any uncertain tax positions.

9. STOCK INCENTIVE PLAN

The Company has three incentive plans. One was adopted in 2004 (2004 Plan) and provided for the granting of stock options and restricted stock awards and generally prescribed a contractual term of seven years. The 2004 Plan terminated in August 2010. However, grants made under the 2004 Plan are still governed by that plan. As of September 30, 2016, options to purchase 23,954 shares of common stock at a weighted average exercise price of $3.24 per share remained outstanding under the 2004 Plan.

The Company approved the 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan) in September 2010 to replace the 2004 Plan. The 2010 Plan provided for the granting of stock options and restricted stock awards. The 2010 Plan terminated upon the Initial Public Offering. However, grants made under the 2010 Plan are still governed by that plan. As of September 30, 2016, options to purchase 489,846 shares of common stock at a weighted average exercise price of $1.58 per share remained outstanding under the 2010 Plan.

The Company approved the 2013 Equity Incentive Plan (2013 Plan) in October 2013. The 2013 Plan became effective immediately on adoption although no awards were to be made under it until the effective date of the Registration Statement for the Initial Public Offering. The 2013 Plan provides for the granting of stock options, restricted stock, stock appreciation rights, stock units, and performance cash awards to certain employees, members of the board of directors and consultants of the Company. As of December 31, 2014, the number of shares of common stock authorized for issuance in connection with the 2013 Plan was 625,000. On January 1 of each year the aggregate number of common shares that may be issued under the Plan

Table of Contents

shall automatically increase. As of January 1, 2016, the number of shares of common stock that may be issued under the 2013 Plan was automatically increased by 333,333 shares. In June 2016, the 2013 Plan was amended to provide an increase of 700,000 shares of common stock authorized for issuance increasing the number of shares of common stock available for issuance under the 2013 Plan to 1,880,950 shares and that the annual increase would equal a number of shares equal to the least of (a) 7% of the total number of common shares outstanding on the last calendar day of the prior fiscal year, (b) subject to adjustment for certain corporate transactions, 1,000,000 common shares, or (c) a number of common shares determined by the Company s board of directors. As of September 30, 2016, options to purchase 1,091,041 shares of common stock at a weighted average exercise price of $5.98 per share and restricted stock units of 27,096 remained outstanding under the 2013 Plan. As of September 30, 2016, there were 762,814 shares of common stock available for grant under the 2013 Plan.

Terms of stock award agreements, including vesting requirements, are determined by the Company s board of directors or its compensation committee, subject to the provisions of the respective plan they were granted. Awards granted by the Company typically vest over a four year period. Certain of the awards are subject to acceleration of vesting in the event of certain change of control transactions. The awards may be granted for a term of up to ten years from the date of grant. The exercise price for options granted under the 2013 Plan must be at a price no less than 100% of the fair market value of a common share on the date of grant.

The Company recognizes stock-based compensation expense over the requisite service period. The Company s share-based awards are accounted for as equity instruments. The amounts included in the consolidated statements of operations relating to stock-based compensation are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expenses	$ 475,026	$ 181,081	$ 972,237	$ 649,305
General and administrative expenses	401,999	355,188	1,187,477	990,625
Total stock-based compensation expense	$ 877,025	$ 536,269	$ 2,159,714	$ 1,639,930

Stock Options

The table below summarizes activity relating to stock options for the nine months ended September 30, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value[(a)]
Outstanding at December 31, 2015	1,077,330	$ 3.98		
Granted	721,814	$ 5.35		
Cancelled	(62,104)	$ 4.83		
Forfeited	(36,157)	$ 5.68		
Expired				
Exercised	(96,042)	$ 0.55		

Outstanding at September 30, 2016	1,604,871	$	4.76	8.18	$ 5,211,390
Exercisable at September 30, 2016	759,251	$	4.21	7.30	$ 3,195,987
Exercisable at September 30, 2015	802,921	$	5.35	7.10	$ 3,701,212

(a) The aggregate intrinsic value in this table was calculated on the positive difference, if any, between the closing market value of the Company s common stock on September 30, 2016 of $7.82 and the price of the underlying options.

As of September 30, 2016, unamortized stock-based compensation for all awards was $4,057,855 and will be recognized over a weighted average period of 2.54 years.

Restricted Stock Units

Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. During the nine months ended September 30, 2016, the Company granted a restricted stock unit award for 27,096 underlying shares of common stock with a weighted-average grant date fair value of $6.33 per share. As of September 30, 2016, the outstanding restricted stock units had unamortized stock-based compensation of $144,352 with a weighted-average remaining recognition period of 3.58 years and no aggregate intrinsic value.

Table of Contents

Employee Stock Purchase Plan

In March 2016, the Company s Board of Directors approved the 2016 Employee Stock Purchase Plan (2016 ESPP), which became effective in June 2016 following the approval of the Company s stockholders. The 2016 ESPP authorizes the initial issuance of up to a total of 97,500 shares of the Company s common stock to participating employees. The number of shares reserved for issuance under the 2016 ESPP automatically increases on the first business day of each fiscal year, commencing in 2017, by a number equal to the lesser of (i) 1% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (ii) the number of shares determined by the Company s Board of Directors. Unless otherwise determined by the administrator of the 2016 ESPP, two offering periods of six months duration will begin each year on January 1 and July 1. As of September 30, 2016, there was no activity under the 2016 ESPP.

10. STOCK PURCHASE WARRANTS

On January 14, 2015, the Company sold, in a private placement, an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. The Company raised approximately $7.1 million in net proceeds in the private placement of common stock and warrants. Additionally, on January 21, 2015, in a subsequent private placement, the Company sold an aggregate of 211,528 shares of common stock at a price of $9.33 per share and a warrant to purchase up to 211,528 shares of common stock at a price of $0.125 per share subject to the warrant. The Company raised approximately $1.9 million in net proceeds in the private placement of common stock and a warrant to purchase common stock. In both transactions, the exercise price of the warrants is $9.50 per share. The warrants will expire 3 years from their respective date of issuance. The warrants do not include a net-exercise feature. The warrants may be redeemed by the Company at a price of $0.001 per share upon notice to the holders thereof in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is at least 50,000 shares per day. Following Aldeyra s notification to the warrant holders of its exercise of the redemption right under the warrants, the warrant holders will have the option to exercise the warrants prior to the redemption date rather than having them redeemed.

In connection with the Initial Public Offering, the Company issued the underwriters of the offering warrants to purchase up to 60,000 shares of common stock. The warrants are exercisable beginning on May 1, 2015 for cash or on a cashless basis at a per share price of $10.00. The warrants will expire on May 1, 2019.

All of the warrants above were outstanding at September 30, 2016.

11. COMMITMENTS AND CONTINGENCIES

In the ordinary course of its business, the Company may be involved in various legal proceedings involving contractual and employment relationships, trademark rights, and a variety of other matters. The Company is not aware of any pending legal proceedings that would reasonably be expected to have a material impact on the Company s financial position or results of operations.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

Various statements throughout this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, anticipate, believe, estimate, expect, int may, plan, contemplates, predict, project, target, likely, potential, continue, ongoing, design, would, should, could, or the negative of these terms and similar expressions or words, 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. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

- the timing of enrollment, commencement and completion of our clinical trials;
- 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 and pricing for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency or use 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; and

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

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission (SEC).

We encourage you to read Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors, as well as our unaudited financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission on March 30, 2016 (Annual Report), which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in our Annual Report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the SEC from time to time, including Forms 10-Q, 8-K and 10-K, which may supplement, modify, supersede or update those risk factors. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

Table of Contents

Overview

We are a biotechnology company focused primarily on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes. We are developing ADX-102 (formerly NS2), as well as other novel product candidates that are designed specifically to sequester aldehydes, for the treatment of:

- Noninfectious Anterior Uveitis, a rare severe inflammatory eye disease that can lead to blindness;
- Allergic Conjunctivitis, a common disease that affects more than 20% of the population worldwide, and related rare allergic ocular diseases that are characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, swelling, and redness;
- Dry Eye Syndrome, a common inflammatory disease characterized by insufficient moisture and lubrication associated with the anterior surface of the eye, leading to ocular irritation, burning, stinging, and, in severe cases, loss of vision;
- Sjögren-Larsson Syndrome, a rare inborn error of metabolism caused by mutations in an enzyme that metabolizes fatty aldehydes, resulting in severe skin and neurological disorders; and
- Succinic Semi-Aldehyde Dehydrogenase Deficiency, a rare inborn error of metabolism caused by genetic mutations in an aldehyde-metabolizing enzyme that lead to severe neurological disease.

In February 2016, we announced that the results of a randomized, parallel-group, double-masked, vehicle-controlled Phase IIa clinical trial of ADX-102 ophthalmic solution in patients with allergic conjunctivitis demonstrated statistically and clinically significant activity of ADX-102 over vehicle in reducing ocular itching and tearing. In May 2016, we announced that the results of our randomized, parallel-group, investigator-masked, active-controlled Phase II clinical trial of ADX-102 ophthalmic solution in patients with noninfectious anterior uveitis demonstrated that ADX-102 reduced inflammatory cell count in the anterior chamber of the eye to a degree similar to that of standard-of-care corticosteroid therapy (which may lead to cataracts and glaucoma in some patients), but without the intraocular pressure elevations that were observed in subjects treated with corticosteroids. In August 2016, we announced that the results of a randomized, parallel-group, double-blind, vehicle-controlled clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of Sjögren-Larsson Syndrome (SLS) demonstrated clinically relevant activity of ADX-102 in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. There were no serious adverse events reported in any of these trials.

In September 2016, based on feedback from the U.S. Food and Drug Administration (FDA), we announced our intention to initiate, in the first half of 2017, a Phase III clinical trial in noninfectious anterior uveitis and a Phase IIb clinical trial in allergic conjunctivitis. We also announced that we intend to initiate a dry eye syndrome Phase IIa clinical trial in the first half of 2017, and that we intend to solicit feedback from the FDA and European regulatory agencies on a Phase III clinical trial in SLS, which we expect to initiate in the second half of 2017. Clinical trials of an orally administered aldehyde trap are expected to begin in late 2017 or 2018. For our ocular program in dry eye

syndrome, as well as for our oral programs in SLS and Succinic Semi-Aldehyde Dehydrogenase Deficiency, we may select ADX-102 or other aldehyde traps for clinical testing. All of our development timelines could be subject to adjustment depending on recruitment rate, regulatory agency review, and other factors that could delay the initiation and completion of clinical trials.

We have no products approved for sale. We will not receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or until we potentially enter into agreements with third parties for the development and commercialization of product candidates. If our development efforts for any of our product candidates result in regulatory approval or we enter into collaboration agreements with third parties, we may generate revenue from product sales or from such third parties. We have primarily funded our operations through the sale of our convertible preferred stock, common stock, convertible promissory notes, warrants and borrowings under our loan and security agreements.

In May 2014, we closed our Initial Public Offering (IPO) whereby we received net proceeds of approximately $10.0 million, after underwriter discounts, expenses and commissions, through the sale of 1,500,000 shares of our common stock at $8.00 per share. In January 2015, we received net proceeds of approximately $9.0 million, after placement agent fees and expenses from two private placements of common stock and warrants to purchase common stock. In addition, in May 2015, we raised approximately $19.5 million, after deducting underwriting discounts and commissions and other offering expenses through the issuance and sale of 2,822,500 shares of common stock in a follow-on public offering, including shares sold pursuant to the underwriters exercise of their option to purchase additional shares of common stock. On June 1, 2016, we closed an underwritten public offering in which we sold, an aggregate of 2,760,000 shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by us.

Table of Contents

We will need to raise additional capital in the form of debt or equity or through partnerships to fund additional development of ADX-102 and other aldehyde traps, and we may in-license, acquire or invest in complementary businesses or products. In addition, as capital resources permit, we may augment or otherwise modify the clinical development plan described herein.

Research and development expenses

We expense all research and development expenses as they are incurred. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until 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 ADX-102. We expect our research and development expenses to increase for the foreseeable future as we advance ADX-102 and other compounds through pre-clinical and clinical development. 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 ADX-102 and our future product candidates. 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 candidates.

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 ADX-102 to be commercially available, if at all, for the next several years.

General and administrative expenses

Our general and administrative expenses consisted primarily of payroll expenses, benefits and stock-based compensation for our full-time employees during the three and nine months ended September 30, 2016 and 2015. Other general and administrative expenses include professional fees for auditing, tax, and legal services. We expect that general and administrative expenses will increase in the future as we expand our operating activities and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and SEC 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 and interest expense incurred on our outstanding debt.

Critical Accounting Policies

The preparation of our 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 our financial statements, as well as the reported

Table of Contents

revenues and expenses during the reported periods. 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments as described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report.

Results of Operations

We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including the progress of our research and development efforts, the timing and outcome of clinical trials and regulatory requirements. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses.

Three months ended September 30, 2016 compared to three months ended September 30, 2015

Research and development expenses. Research and development expenses were $3.4 million for the three months ended September 30, 2016, compared to $2.1 million for the three months ended September 30, 2015. The increase of $1.3 million is primarily related to the increase in our external research and development expenditures, including manufacturing and pre-clinical activities and an increase in personnel costs, including stock-based compensation associated with an increase in headcount.

General and administrative expenses. General and administrative expenses were $1.4 million for the three months ended September 30, 2016, compared to $1.3 million for the three months ended September 30, 2015. The increase of $0.1 million is primarily related to an increase in legal and personnel costs, including stock-based compensation due to increased headcount.

Other income (expense). Total other income (expense), net was $1,138 and $(28,081) for the three months ended September 30, 2016 and 2015, respectively. For the three months ending September 30, 2016, other income (expense) primarily consisted of interest income, which was partially offset by interest expense related to our credit facility. For the three months ending September 30, 2015, other income (expense) consisted of interest expense related to our credit facility.

Nine months ended September 30, 2016 compared to nine months ended September 30, 2015

Research and development expenses. Research and development expenses were $9.7 million for the nine months ended September 30, 2016, compared to $4.5 million for the nine months ended September 30, 2015. The increase of $5.2 million is primarily related to the increase in our external research and development expenditures, including manufacturing and preclinical activities, an increase in personnel costs (primarily stock-based compensation associated with an increase in headcount), and clinical development costs.

General and administrative expenses. General and administrative expenses were $4.3 million for the nine months ended September 30, 2016, compared to $3.2 million for the nine months ended September 30, 2015. The increase of $1.1 million is primarily related to an increase in legal and professional service costs and personnel costs, including stock-based compensation due to increased headcount.

Other income (expense). Total other income (expense), net was $(5,044) for the nine months ended September 30, 2016 and consisted of interest expense related to our credit facility, which was partially offset by interest income. Total other income (expense), net was $(84,314) for the nine months ended September 30, 2015 and consisted of interest expense related to our credit facility.

Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and convertible equity securities and borrowings under our Credit Facility discussed below. We have incurred operating losses since inception and negative cash flows from operating activities in devoting substantially all of our efforts towards research and development. At September 30, 2016, we had total stockholders equity of approximately $25.7 million and cash, cash equivalents and marketable securities of $28.9 million. During the three and nine months ended September 30, 2016, we had a net loss of approximately $4.8 million and $14.0 million, respectively. We expect to generate operating losses for the foreseeable future.

In April 2012, we entered into a loan and security agreement (the Credit Facility) with Pacific Western Bank (Pacific Western, formerly Square 1 Bank) that was subsequently amended in November 2013 to provide us with $1.5 million of available funds. The amended Credit Facility called for interest only payments at a 6.50% interest rate from November 2013 through November 2014 for all amounts outstanding, inclusive of those amounts originally drawn during 2012 prior to the amendment, at which point, we were scheduled to make principal payments of $58,160 plus interest through the maturity date of the term loans in November 2016. In

Table of Contents

November 2014, the Credit Facility was further amended. Pursuant to the Credit Facility, Pacific Western agreed to make term loans in a principal amount of up to $5.0 million available to us with proceeds to be used first to refinance outstanding loans from Pacific Western second to fund expenses related to our clinical trials, and the remainder for general working capital purposes. The term loans are to be made available to us upon the following terms: (i) $2.0 million was made available in November 2014; and (ii) $3.0 million (the Tranche B Loan) became available to us following the satisfaction of certain conditions, including receipt of positive phase 2 data in noninfectious anterior uveitis. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. Any term loan made was payable as interest-only prior to November 2015 and thereafter was scheduled to be payable in monthly installments of principal plus accrued interest through the maturity date in October 2019. The amended Credit Facility was amended again in November 2015 extending the interest only period, the period to satisfy the Tranche B Loan conditions and the maturity date, October 2019. Each term loan accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum. The annualized interest rate as of September 30, 2016 was 5.60%. Any term loan made is payable as interest-only prior to November 2016 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. The Credit Facility is collateralized by our assets, including our intellectual property. As of December 31, 2015, and September 30, 2016, $1.4 million was outstanding under the Credit Facility.

At September 30, 2016, the Credit Facility is shown net of a remaining debt discount of $86,046 which is being amortized using the effective interest method through the maturity date of the Credit Facility, October 2019.

On January 14, 2015, we sold, in a private placement, an aggregate of approximately 1.1 million shares of common stock at a price of $7.00 per share. Investors received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $9.50. We raised approximately $7.1 million in net proceeds in the private placement of common stock and warrants. Additionally, on January 21, 2015, in a subsequent private placement, we sold an aggregate of 211,528 shares of common stock at a price of $9.33 per share and a warrant to purchase up to 211,528 shares of common stock at a price of $0.125 per share subject to the warrant. We raised approximately $1.9 million in net proceeds in the private placement of common stock and a warrant to purchase common stock. In both transactions, the exercise price of the warrants is $9.50 per share. The warrants will expire 3 years from their respective date of issuance. The warrants do not include a net-exercise feature. The warrants may be redeemed by us at a price of $0.001 per share upon notice to the holders thereof in the event that the closing bid for Aldeyra s common stock for each of the fifteen consecutive trading days prior to such redemption is at least $20.00 per share and the average trading volume of Aldeyra s common stock during such period is at least 50,000 shares per day. Following our notification to the warrant holders of our exercise of the redemption right under the warrants, the warrant holders will have the option to exercise the warrants prior to the redemption date rather than having them redeemed.

In addition, we raised approximately $19.5 million, after deducting underwriting discounts and commissions and other offering expenses, which closed on May 22, 2015, through the issuance and sale of 2,822,500 shares of common stock in a follow-on public offering, including shares sold pursuant to the underwriter s exercise of their option to purchase additional shares of common stock.

On June 1, 2016, we closed an underwritten public offering in which we sold, an aggregate of 2,760,000 shares of common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $12.6 million, after deducting the underwriting discounts and commissions and the other offering expenses payable by us.

We believe that our cash, cash equivalents and marketable securities as of September 2016, together with the amounts available under the Credit Facility, will be adequate to fund operations through approximately the second quarter of

2018 based on our current business plan. However, these amounts will not be sufficient for us to commercialize our product candidates or conduct 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 ADX-102. 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 to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the progress, costs, results of and timing of our clinical development program for ADX-102 and our other product candidates, including our current and planned clinical trials;

- the need for, and the progress, costs and results of, any additional clinical trials of ADX-102, including systemic formulations, 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 ADX-102;

- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;

Table of Contents

- the timing and costs associated with manufacturing ADX-102 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 ADX-102;
- 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.

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.

We will continue to incur costs as a public company, including, but not limited to, costs and expenses for directors fees; increased directors and officers insurance; investor relations fees; expenses for compliance with the Sarbanes-Oxley Act of 2002 and rules implemented by the SEC and NASDAQ, on which our common stock is listed; and various other costs. The Sarbanes-Oxley Act of 2002 requires that we maintain effective disclosure controls and procedures and internal controls.

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
Net cash used in operating activities	$ (11,238,050)	$ (6,306,630)
Net cash used in investing activities	(1,545,181)	(86,119)

Net cash provided by financing activities	12,702,873	28,483,810
Net increase (decrease) in cash and cash equivalents	$ (80,358)	$ 22,091,061

Operating Activities. Net cash used in operating activities was $11.2 million for the nine months ended September 30, 2016 compared to net cash used in operating activities of $6.3 million for the nine months ended September 30, 2015. The primary use of cash was to fund our operations. The increase in the amount of cash used in operating activities for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 was due to an increase in both research and development and general and administrative expenses.

Investing Activities. Net cash used in investing activities was $(1.5) million and $(0.1) million for the nine months ended September 30, 2016 and 2015, respectively. The primary use of cash for investing activities was for the purchase of marketable securities and the purchase of computers and related equipment.

Financing Activities. Net cash provided by financing activities was $12.7 million for the nine months ended September 30, 2016 compared to net cash provided by financing activities of $28.5 million for the nine months ended September 30, 2015. The net cash provided by financing activities for the nine months ended September 30, 2016 was related to our June 2016 offering.

Off-Balance Sheet Arrangements

Through September 30, 2016, 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.

Table of Contents

Contractual Obligations

Other than as set forth below, there have been no material changes since December 31, 2015 to our contractual obligations from the information provided in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations , included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, other than payments made or received in the ordinary course of business.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest rates

Our exposure to market risk is currently confined to our cash and cash equivalents and our credit facility. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash, cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments. Our Credit Facility accrues interest from its date of issue at a variable annual interest rate equal to the greater of 2.0% plus prime or 5.25% per annum.

Effects of inflation

Inflation has not had a material impact on our results of operations.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Financial Officer and Chief Executive Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of September 30, 2016. Based on our management s evaluation (with the participation of our Chief Executive Officer and President and our Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and President and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below together with the other information set forth in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 30, 2016, which could materially affect our business, financial condition and future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, prospects, financial condition and operating results.

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 ADX-102 and our other product candidates. Net loss for the three months ended September 30, 2016 and 2015 was approximately $4.8 million and $3.4 million, respectively. Net loss for the nine months ended September 30, 2016 and 2015 was approximately $14.0 million and $7.7 million, respectively. As of

Table of Contents

September 30, 2016, we had total stockholders equity of $25.7 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 ADX-102 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 ADX-102 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, ADX-102. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, ADX-102.

Our product candidates are in the early stage of development and will require additional preclinical studies, substantial clinical development and testing, and regulatory approval prior to commercialization. We have not yet completed development of any product. We have only one product candidate that has been the focus of significant development: ADX-102, a novel small molecule chemical entity that is believed to trap and allow for the degradation of 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 ADX-102. We will need to raise sufficient funds for, and successfully enroll and complete, our current and planned clinical trials of ADX-102. 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 ADX-102;
- we may not be able to provide evidence of safety and efficacy for ADX-102;
- we may not be able to timely or adequately finalize the design or formulation of any product candidate or demonstrate that a formulation of our product candidate will be stable for commercially reasonable time periods;
- the safety and efficacy results of later phases or larger clinical trials may not confirm the results of our earlier trials;
- there may be variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;

we may be required to perform additional clinical trials to support approval;

the results of our clinical trials may not meet the end points, or level of statistical or clinical significance required by the FDA, or comparable foreign regulatory bodies for marketing approval;

patients in our clinical trials may suffer other adverse effects or die for reasons that may or may not be related to ADX-102;

if approved for certain diseases, ADX-102 will compete with well-established products already approved for marketing by the FDA, including corticosteroids and other agents that have demonstrated varying levels of efficacy in some of the diseases for which we may attempt to develop ADX-102; 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 ADX-102, 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 ADX-102 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, ADX-102, 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

Table of Contents

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 designing and completing our clinical trial programs and product design and formulation of future product candidates;
- 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 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 ADX-102, 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, as product candidates proceed through development, the trial designs may often be different from phase to phase, the vehicles may be modified from trial to trial and the product formulations or manufacturing process may differ due to the need to test product candidate samples that can be manufactured on a commercial scale. For instance, we plan to modify the vehicle utilized in our expected Phase IIb allergic conjunctivitis trial from the vehicle used in our prior Phase IIa trial. 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 clinical 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.

In addition, the presumed mechanisms of aldehyde-mediated inflammation are distinct from the presumed aldehyde-mediated pathology in inborn errors of metabolism, and the efficacy and safety of ADX-102 in one indication does not predict the efficacy and safety of ADX-102 in other indications.

Because we are developing novel product candidates for the treatment of diseases in a manner which there is little clinical drug development experience and, in some cases, are using new endpoints or methodologies, the regulatory pathways for approval are not well defined, and, as a result, there is greater risk that our clinical trials will not result in our desired outcomes.

Our clinical focus is on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to naturally occurring toxic and pro-inflammatory chemical species known as aldehydes. Our Phase III vehicle-controlled clinical program in noninfectious anterior uveitis and our Phase III clinical program in Sjögren-Larsson Syndrome (SLS) represent the first such clinical trials performed, and thus the comparative effects of vehicle and drug are unpredictable.

We could also face challenges in designing clinical trials and obtaining regulatory approval of aldehyde sequestering agents due to the small number of historical clinical trial experience for this novel class of therapeutics. Because no aldehyde sequestering agents have received regulatory approval anywhere in the world, it is difficult to determine whether regulatory agencies will be receptive to the approval of our product candidates and to predict the time and cost associated with obtaining regulatory approval. The clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied classes of product candidates. Any inability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, and to obtain regulatory approvals for our product candidates, would have an adverse impact on our business, prospects, financial condition and results of operations.

Because ADX-102 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. Although we have seen signs of efficacy and observed ADX-102 to be well tolerated in our clinical trials to date, because ADX-102 is a novel chemical entity with limited use in humans, short and long-term safety, as well as prospects for efficacy, are poorly understood and difficult to predict due to our and regulatory agencies lack of experience with them. Regulatory approval of new product candidates such as ADX-102 can be more expensive and take longer than approval for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates.

Our dermatologic topical formulation of ADX-102 is unlikely to affect other clinical manifestations of Sjögren-Larsson Syndrome, which may decrease the likelihood of commercial acceptance.

While the primary day-to-day complaint of SLS patients and their caregivers are symptoms associated with severe skin disease, SLS patients also manifest varying degrees of delay in mental development, spasticity, seizures and retinal disease. In August 2016, we announced that the results of our randomized, parallel-group, double-masked, vehicle-controlled clinical trial of a dermatologic formulation of ADX-102 for the treatment of the skin manifestations of SLS demonstrated clinically relevant activity of ADX-102 in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. There were no serious adverse events reported in any of these trials. However, due to expected low systemic exposure of ADX-102 when administered topically to the skin, it is unlikely that ADX-102 will significantly affect the non-dermatologic conditions of SLS. Lack of effect in neurologic and ocular manifestations of SLS may negatively impact the potential market for ADX-102 in SLS and may also negatively impact reimbursement, pricing and commercial acceptance of ADX-102, if it is approved.

Table of Contents

ADX-102 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.

ADX-102 and the activities associated with its development and potential commercialization, including its testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other jurisdictions.

Our ongoing research and development activities and planned clinical development for our product candidates may be delayed, modified or ceased for a variety of reasons, including:

- determining that a product candidate is ineffective or causes harmful side effects during preclinical studies or clinical trials;
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;
- difficulties in manufacturing a product candidate, including the inability to manufacture a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under processes acceptable to the FDA for marketing approval;
- the proprietary rights of third parties, which may preclude us from developing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop or commercialize, or may fail to achieve market acceptance or adequate reimbursement;
- our inability to secure strategic partners which may be necessary for advancement of a product candidate into clinical development or commercialization; or

our prioritization of other product candidates for advancement.

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, including the end points of our clinical trials;
- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the design of such 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.

Table of Contents

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 clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the commencement or completion of our planned clinical trials for ADX-102 or other product candidates could significantly affect our product development costs. We do not know whether future trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed or placing the clinical trial on hold;
- subjects failing to enroll or remain in our clinical trials at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing ADX-102 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 ADX-102, 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;
- inability to timely manufacture sufficient quantities of the applicable product candidate for the clinical trial or expiration of materials intended for use in the clinical trial;

- 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 ADX-102 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 ADX-102 or other product candidates could be significantly reduced.

We may find it difficult to enroll patients in our clinical trials or identify patients during commercialization (if our products are approved by regulatory agencies) for product candidates addressing orphan or rare diseases.

As part of our business strategy, we plan to evaluate the development and commercialization of product candidates for the treatment of orphan and other rare diseases. Given that we are in the early stages of clinical trials for ADX-102, we may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients willing and able to participate in the clinical trials required by the FDA or other non-United States regulatory agencies. In addition, if others develop product candidates for the treatment of similar diseases, we would potentially compete with them for the enrollment in these rare patient populations, which may adversely impact the rate of patient enrollment in and the timely completion of our current and planned clinical trials.

Table of Contents

Additionally, insufficient patient enrollment, may be a function of many other factors, including the size and nature of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the timing and magnitude of disease symptom presentation, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. Our inability to identify and enroll a sufficient number of eligible patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates. Further, if our products are approved by regulatory agencies, we may not be able to identify sufficient number of patients to generate significant revenues.

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. ADX-102, for example, has been observed to be toxic at high concentrations in *in vitro* human dermal tissue. In addition, there was transient and generally mild stinging noted in the ADX-102 treatment arm of our Phase IIa clinical trial in allergic conjunctivitis, with two patients out of the 50 patients in the treatment arm dropping out of the trial during treatment. There was an increased frequency of ocular stinging and burning in the ADX-102 treated arms of our Phase II clinical trial in noninfectious anterior uveitis, with one subject in the ADX-102 treatment arm and one subject in combination ADX-102 and Pred Forte® arm dropping out of the trial during treatment for an adverse event of stinging. However, there were no serious adverse events in such trial. In preparation for clinical testing of systemically administered ADX-102, we believe that we have identified a preliminary No Adverse Effect Level in pre-clinical toxicology studies where ADX-102 is administrated intravenously. If any of our product candidates cause unacceptable adverse events in clinical trials, which may be larger or longer than those previously conducted, we may not be able to obtain regulatory approval or commercialize such product candidate.

Final marketing approval for ADX-102 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 ADX-102 or our other product candidates and we cannot, therefore, predict the timing of any future revenue. We cannot commercialize ADX-102 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 ADX-102 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 ADX-102 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 ADX-102 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 ADX-102 or any other product candidates, such candidate will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements, including those relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

Table of Contents

If we or the manufacturing facilities for ADX-102 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 ADX-102 or any of our other product candidates is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we receive regulatory approval for ADX-102 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.

Table of Contents

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 ADX-102 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. As a result of negative trends in the general economy in the U.S. or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. 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 choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from immune-mediated or orphan or other disorders with high unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Table of Contents

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 ADX-102 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 ADX-102 will qualify as an orphan drug for SLS and noninfectious anterior uveitis, and possibly other diseases that we may test. However, we cannot guarantee that we will be able to receive orphan drug status from the FDA for ADX-102. If we are unable to secure orphan drug status for ADX-102 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 ADX-102 and our other product candidates.

As of September 30, 2016, we had only ten 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.

In addition, during challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

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

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on third parties to conduct the clinical trials for ADX-102 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 we also rely on medical institutions, clinical investigators and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

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

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

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

Table of Contents

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.

Table of Contents

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

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

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

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of ADX-102 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 ADX-102 or our other product candidates because third parties may view the risk of success in our planned clinical trial as too significant or the commercial opportunity for our product candidate as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

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

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. With the exception of SLS, there are a variety of drug candidates in development for the indications that we intend to test. Many of our competitors have significantly greater financial, product candidate development, manufacturing, and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, universities and private and public research institutes may be active in aldehyde research, and some could be in direct competition with us. We also may compete with these organizations to recruit management, scientists, and clinical development personnel. We will also face competition from these third parties in establishing clinical trial sites, registering subjects for clinical trials, and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements

with large and established companies.

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. There are methods that can potentially be employed to trap aldehydes that we have not conceived of or attempted to patent, and other parties may discover and patent aldehyde trapping approaches and compositions that are similar to or different from ours. Competition in drug development is intense. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of ADX-102 or our other product candidates. Noninfectious anterior uveitis and other inflammatory diseases may be treated with general immune suppressing therapies, including corticosteroids, some of which are generic. Our potential competitors in these diseases may be developing novel immune modulating therapies that may be safer or more effective than ADX-102 or our other product candidates.

Table of Contents

We have no sales, marketing or distribution capabilities and we will have to invest significant resources to develop these capabilities.

We have no internal sales, marketing or distribution capabilities. If ADX-102 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 ADX-102 or any of our other product candidates will be approved. We may not be able to hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by ADX-102 or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

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

As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial, and financial expertise of our senior management team composed of three individuals and certain other employees: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; Stephen J. Tulipano, our Chief Financial Officer; and David J. Clark, M.D., our Chief Medical Officer. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, dermatologic drug development and ocular drug development consultants. The loss of such individuals or the services of future members of our management team could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business.

If we fail to attract and retain senior management and key commercial personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. Our success also depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to intense competition among biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. If we are unable to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

We expect to expand our management team. Our future performance will depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the

development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Because, as of September 30, 2016, we only had ten full-time employees, we will need to grow our organization to continue development and pursue the potential commercialization of ADX-102 and our other product candidates, as well as function as a public company. As we seek to advance ADX-102 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.

Table of Contents

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

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

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

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

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

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

- the demand for any product candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;

our ability to generate revenue and achieve or maintain profitability;

the level of taxes that we are required to pay; and

the availability of capital.

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

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

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

Table of Contents

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 ADX-102 or our other product candidates.

We face an inherent risk of product liability as a result of the clinical testing of ADX-102 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 ADX-102 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 ADX-102 or our other product candidates;
- injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

the inability to commercialize ADX-102 or our other product candidates; and

a decline in our stock price.

We maintain product liability insurance with $3.0 million in coverage. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of ADX-102 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.

Table of Contents

We and our development partners, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time consuming or costly.

We and our development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our development partner, third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

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

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

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

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

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

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

among other things:

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

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could

Table of Contents

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 ADX-102 and our other product candidates. Our ability to obtain clinical supplies of ADX-102 or our other product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

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

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

Risks Relating to Our Intellectual Property

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

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

licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

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 ADX-102, 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

Table of Contents

indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are possibly methods that can be employed to trap aldehydes that we have not conceived of or attempted to patent, and other parties may discover and patent aldehyde trapping approaches and compositions that are similar to or different from ours.

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

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

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

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

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

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

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of ADX-102 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 ADX-102 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 ADX-102 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 ADX-102 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

Table of Contents

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 ADX-102 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 Pacific Western Bank. In the case of a continuing event of default under the loan, Pacific Western 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. Although as of September 30, 2016, we had sufficient cash and cash equivalents to repay all obligations owed to Pacific Western Bank if the debt was accelerated, in the event we do not or are not able to repay the obligations at the time a default occurred, Pacific Western Bank may elect to commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Pacific Western Bank under the loan, which includes our intellectual property.

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 and we may enter into additional licenses in the future. Such licenses may impose various commercial, contingent payment, royalty, insurance, indemnification, and or 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 could lose valuable rights under our license agreements and our ability to develop product candidates could be impaired. Additionally, should such a license agreement be terminated for any reason, there may be a limited number of licensors who would be suitable replacements and it may take a significant amount of time to transition to a replacement licensor.

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 ADX-102 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.

Table of Contents

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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 ADX-102 in the United States and other countries, filing, prosecuting and defending patents on ADX-102 and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals,

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

Table of Contents

Risks Related to Our Financial Position and Need for Capital

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize ADX-102 and our other product candidates.

We will require substantial future capital in order to complete the remaining clinical development for ADX-102 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 ADX-102 and our other product candidates, 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 ADX-102 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 ADX-102 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 ADX-102 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 ADX-102 and our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing collaborations, license agreements and other partnerships on terms favorable to us;
- costs associated with any other product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments;
- our ability to establish and maintain partnering arrangements for development; and

the costs associated with being a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources to be sufficient to enable us to fund the completion of our clinical trials and remaining development program through commercial introduction. We expect that we will need to raise additional funds in the near future.

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through collaboration agreements and public or private financings, including debt financings. The global economic downturn and market instability has made the business climate more volatile and more costly. In addition, the United Kingdom s recent decision to exit the European Union (Brexit) could contribute to instability and volatility in the global financial and foreign exchange markets. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. 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 or be excessively dilutive. 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 ADX-102 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 $5.0 million Credit Facility with Pacific Western that is secured by a lien covering all of our assets as of September 30, 2016. As of September 30, 2016 and December 31, 2015, the outstanding principal balance under the Credit Facility was approximately $1.4 million. Under the terms of the Credit Facility, (i) $2,000,000 was made available on November 10, 2014; and (ii) $3,000,000 (the Tranche B Loan) became available to us following the satisfaction of certain conditions, including receipt of

Table of Contents

positive phase 2 data (as determined by our Board of Directors) in either SLS or noninfectious anterior uveitis. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, restrictions on transferring any part of our business or property, changing our business, including changing the composition of our executive team or board of directors, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets and other financial covenants, in each case subject to customary exceptions. If we default under the terms of the loan agreement, including failure to satisfy our operating covenants, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender s right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the loan agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and certain other tax assets (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs or credits could have a material adverse effect on our results of operations and cash flows. Prior to 2016, Aldeyra has undergone two ownership changes. However, our management believes that we had sufficient Built-In-Gain to offset the Section 382 of the Code limitation generated by such ownership changes. Any future ownership changes, including those resulting from our recent or future financing activities, may cause our existing tax attributes to have additional limitations.

Risks Related to Our Common Stock

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

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

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

Our stock price has been and will likely continue to be volatile for the foreseeable future. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been

unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid. The market price for our common stock may be influenced by many factors, including:

our ability to enroll patients in our planned clinical trials;

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

regulatory developments in the United States and foreign countries;

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

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

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

Table of Contents

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 ADX-102 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 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.

Table of Contents

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

Our management has 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 ADX-102, 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 September 30, 2016, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 73.0% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and business affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. 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.

Table of Contents

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 Pacific Western 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 until December 31, 2019, although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer, if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC, and The NASDAQ Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate 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.

Table of Contents

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

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

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

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

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

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

publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We could be subject to securities class action litigation.

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

Table of Contents

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Registrant, (filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference).
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial and Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2016 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Balance Sheets as of September 30, 2016 and December 31, 2015; (ii) Statements of Operations and Comprehensive Income (Loss) for the three and six months ended September 30, 2016 and 2015; (iii) Statements of Cash Flows for the nine months ended September 30, 2016 and 2015; and (iv) Notes to Financial Statements.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aldeyra Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended,

whether made before or after the date of this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Aldeyra Therapeutics, Inc.

November 14, 2016 /s/ Todd C. Brady, M.D., Ph.D.
Todd C. Brady, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Aldeyra Therapeutics, Inc.

November 14, 2016 /s/ Stephen J. Tulipano
Stephen J. Tulipano
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Table of Contents

ALDEYRA THERAPEUTICS, INC.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Registrant, (filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference).
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial and Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2016 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Balance Sheets as of September 30, 2016 and December 31, 2015; (ii) Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2016 and 2015; (iii) Statements of Cash Flows for the nine months ended September 30, 2016 and 2015; and (iv) Notes to Financial Statements.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aldeyra Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.