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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of November 14, 2018, there were 26,244,434 shares of the registrant's common stock issued and outstanding.

Aldeyra Therapeutics, Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2018

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Part I – FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

ALDEYRA THERAPEUTICS, INC.

BALANCE SHEETS

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,008,652	$ 2,023,337
Cash equivalents - reverse repurchase agreements	11,000,000	18,000,000
Marketable securities	17,133,925	22,923,462
Prepaid expenses and other current assets	1,702,533	1,018,967
Total current assets	36,845,110	43,965,766
Deferred offering costs	43,000	165,930
Fixed assets, net	243,483	43,262
Total assets	$ 37,131,593	$ 44,174,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,442,370	$ 1,000,963
Accrued expenses	3,746,037	2,236,465
Current portion of credit facility	465,278	116,319
Total current liabilities	7,653,685	3,353,747
Credit facility, net of current portion and debt discount	882,841	1,220,192
Total liabilities	8,536,526	4,573,939
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock, voting, $0.001 par value; 150,000,000 authorized and 20,989,302 and 19,137,639 shares issued and outstanding, respectively	20,989	19,138
Additional paid-in capital	156,481,258	139,241,635
Accumulated other comprehensive loss	(5,196)	(17,831)
Accumulated deficit	(127,901,984)	(99,641,923)
Total stockholders' equity	28,595,067	39,601,019
Total liabilities and stockholders' equity	$ 37,131,593	$ 44,174,958

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

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS (Unaudited)

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 7,880,822	$ 3,539,368	$ 21,274,032	$ 10,757,279
General and administrative	3,065,912	1,475,904	7,330,142	4,684,574
Loss from operations	(10,946,734)	(5,015,272)	(28,604,174)	(15,441,853)
Other income (expense):				
Interest income	163,015	56,651	427,361	136,652
Interest expense	(28,846)	(27,578)	(83,248)	(80,878)
Total other income (expense), net	134,169	29,073	344,113	55,774
Net loss	$ (10,812,565)	$ (4,986,199)	$(28,260,061)	$ (15,386,079)
Net loss per share - basic and diluted	$ (0.52)	$ (0.32)	$ (1.40)	$ (1.04)
Weighted average common shares outstanding - basic and diluted	20,969,913	15,581,426	20,168,633	14,844,914

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

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

	Three Months ended September 30,		Nine Months ended September 30,	
	2018	2017	2018	2017
Net loss	$ (10,812,565)	$ (4,986,199)	$(28,260,061)	$(15,386,079)
Other comprehensive income/(loss):				
Unrealized gain/(loss) on marketable securities	(2,637)	3,638	12,635	(1,131)
Total other comprehensive income/(loss)	$ (2,637)	$ 3,638	$ 12,635	$ (1,131)
Comprehensive loss	$ (10,815,202)	$ (4,982,561)	$(28,247,426)	$(15,387,210)

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

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS (Unaudited)

	Nine months ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(28,260,061)	$(15,386,079)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,126,919	2,122,669
Amortization of debt discount – non-cash interest expense	11,608	15,588
Net amortization/(accretion) of premium/(discount) on debt securities available for sale	(82,996)	165,562
Depreciation	48,161	29,927
Change in assets and liabilities:		
Prepaid expenses and other current assets	(683,566)	(923,045)
Accounts payable	2,441,407	209,826
Accrued expenses	1,509,572	(438,793)
Net cash used in operating activities	(21,888,956)	(14,204,345)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(248,382)	(11,592)
Purchases of marketable securities	(21,573,832)	(20,198,275)
Sales of marketable securities	27,459,000	18,122,000
Net cash provided by/(used in) investing activities	5,636,786	(2,087,867)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	14,194,871	37,474,106
Proceeds from issuance of common stock in Employee Stock Purchase Plan	85,614	45,555
Deferred offering costs paid in cash	(43,000)	(138,661)
Net cash provided by financing activities	14,237,485	37,381,000
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,014,685)	21,088,788
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	20,023,337	12,015,061
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 18,008,652	$ 33,103,849
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 81,968	$ 64,024

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

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 next-generation medicines to improve the lives of patients with immune-mediated diseases.

The Company's principal activities to date include 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, 2017 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission on March 29, 2018. The financial information as of September 30, 2018, the three and nine months ended September 30, 2018 and 2017 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, 2017 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.

In June 2017, the Company entered into a Controlled Equity Offering^{SM} Sales agreement (Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which the Company offered and sold, from time to time through Cantor, shares of the Company's common stock, par value $0.001 per share, providing for aggregate sales proceeds of up to $20,000,000. Under the Sales Agreement, Cantor sold such shares of common stock in sales deemed to be an "at the market offering" (ATM) as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, with the Company setting the parameters for the sale of shares thereunder, including the number of shares to be sold, the time period during which sales were requested to be made, any limits on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The Sales Agreement provided that Cantor was entitled to compensation for its services equal to 3.0% of the gross proceeds from the sale of shares sold pursuant to the Sales Agreement. The Company had no obligation to sell any shares under the Sales Agreement. From January 1, 2018 through September 30, 2018, the Company sold an aggregate of 1,796,306 shares of common stock and received $14.2 million after deducting commissions related to the Sales Agreement and other offering costs.

Based on its current operating plan, the Company believes that its cash, cash equivalents, reverse repurchase agreements, and marketable securities as of September 30, 2018, together with the $67.6 million in net proceeds from its public offering in October 2018 (Note 12), will be adequate to fund its currently anticipated operating expenses through the end of 2020. The Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of the Company's planned research and development activities; 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 develop and introduce its products to market, which is critical to the realization of its business plan and the future operations of the Company.

Certain reclassifications have been made to prior period financial statements to conform to the current period presentation, specifically cash equivalents and reverse repurchase agreements are disclosed separately on the balance sheet for current and prior periods presented.

Use of estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions, including fair value estimates for investments that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's financial statements relate to accruals, including research and development costs, accounting for income taxes and the related valuation allowance and accounting for stock based compensation and the related fair value. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Recent Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2018-07, *Compensation — Stock Compensation (Topic 718)* (ASU 2018-07). The amendments in ASU 2018-07 expand the scope of the employee share-based payments guidance to include share-based payments issued to non-employees. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards to non-employees. The Company has adopted the provisions of ASU 2018-07 in the quarter ended September 30, 2018 and it did not have a material impact on the Company's financial statements. When adopting the provisions of ASU 2018-07, the Company changed the expense recognition for share-based payments to non-employees to an amount determined at grant or modification date instead of a variable amount to be valued at each reporting period.

In August 2016, the FASB issued ASU No. 2016-15 (ASU 2016-15), *Statement of Cash Flows*. The standard is intended to reduce the diversity in practice around how certain transactions are classified within the statement of cash flows. The Company adopted ASU 2016-15 in the quarter ended March 31, 2018, and it did not have a material impact on the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instrument-Credit Losses* (ASU 2016-13). ASU 2016-13 requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. The Company does not expect this standard to have a material impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02 (ASU 2016-02), *Leases*. ASU 2016-02 requires lessees to recognize on the balance sheet a right-of-use asset, representing its right to use the underlying asset for the lease term, and a lease liability for all leases with terms greater than 12 months. The guidance also requires qualitative and quantitative disclosures designed to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard requires the use of a modified retrospective transition approach, which includes a number of optional practical expedients that entities may elect to apply. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. We are currently evaluating the impact of the guidance on our condensed financial statements and related processes and internal controls. While we expect the implementation to result in the recognition of right-of-use assets and lease liabilities for most of our operating lease commitments, we do not expect the guidance to have material impact on our statements of cash flows.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* (ASU 2016-01). ASU 2016-01 amends the guidance on the classification and measurement of financial instruments. Although ASU 2016-01 retains many current requirements, it significantly revises accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. ASU 2016-01 also amends certain disclosure requirements associated with the fair value of financial instruments. The Company adopted ASU 2016-01 in the quarter ended March 31, 2018, and it did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The Company adopted ASU 2014-09 in the quarter ended March 31, 2018, and it did not have a material impact on the Company's financial statements.

3. NET LOSS PER SHARE

As of September 30, 2018 and 2017, diluted weighted average common shares outstanding is equal to basic weighted average common shares due to the Company's net loss position.

The following potentially dilutive securities outstanding 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,	
	2018	2017	2018	2017
Options to purchase common stock	3,512,163	2,236,857	3,512,163	2,236,857
Warrants to purchase common stock	60,000	1,384,608	60,000	1,384,608
Restricted stock units	212,297	157,128	212,297	157,128
Total of common stock equivalents	3,784,460	3,778,593	3,784,460	3,778,593

4. CASH, CASH EQUIVALENTS, REVERSE REPURCHASE AGREEMENTS AND MARKETABLE SECURITIES

At September 30, 2018, cash, cash equivalents, reverse repurchase agreements and marketable securities were comprised of:

	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value	Cash Equivalents	Reverse Repurchase Agreements	Current Marketable Securities
Cash	$ 5,905,553	$ —	$ —	$ 5,905,553	$ 5,905,553	$ —	$ —
Money market funds	1,103,099	—	—	1,103,099	1,103,099	—	—
Reverse repurchase agreements	11,000,000	—	—	11,000,000	—	11,000,000	—
U.S. government agency securities	17,139,121	—	(5,196)	17,133,925	—	—	17,133,925
Available for Sale(1)	28,139,121	—	(5,196)	28,133,925	—	11,000,000	17,133,925
Total cash, cash equivalents, reverse repurchase agreements, and current marketable securities					$ 7,008,652	$11,000,000	$17,133,925

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

The contractual maturities of all available for sale securities were less than one year at September 30, 2018.

5. FAIR VALUE MEASUREMENTS

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, 2018 or December 31, 2017. The following table presents information about the Company's assets measured at fair value at September 30, 2018 and December 31, 2017:

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (a)	$1,103,099	$ —	$ —	$ 1,103,099
Reverse repurchase agreements (b)	—	11,000,000	—	11,000,000
U.S. government agency securities (b)	—	17,133,925	—	17,133,925
Total assets at fair value	$1,103,099	$28,133,925	$ —	$29,237,024

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (a)	$1,043,852	$ —	$ —	$ 1,043,852
Reverse repurchase agreements (b)	—	18,000,000	—	18,000,000
U.S. government agency securities (b)	—	22,923,462	—	22,923,462
Total assets at fair value	$1,043,852	$40,923,462	$ —	$41,967,314

(a) Money market funds included in cash and cash equivalents in the consolidated balance sheets, are valued at quoted market prices in active markets.

(b) Reverse repurchase agreements and U.S. government agency securities are recorded at fair market values, which are determined based on the most recent observable inputs for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active or are directly or indirectly observable.

Financial instruments including cash equivalents 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 loan under its credit facility approximates market value currently available to the Company. Marketable securities are carried at fair value.

6. ACCRUED EXPENSES

Accrued expenses at September 30, 2018 and December 31, 2017 were comprised of:

	September 30, 2018	December 31, 2017
Accrued compensation	$ 1,176,329	$ 788,570
Accrued research and development	2,141,474	1,327,103
Accrued general & administrative	428,234	120,792
Accrued expenses	$ 3,746,037	$2,236,465

7. CREDIT FACILITY

The Company's long-term debt obligation consists of amounts the Company is obligated to repay under its credit facility with Pacific Western (Credit Facility), of which $1.4 million was outstanding as of September 30, 2018. The Company entered into the Credit Facility in April 2012 and it has been subsequently amended to make term loans in a principal amount of up to $5,000,000 available to the Company with proceeds to be used first to refinance outstanding loans from Pacific Western, second to fund expenses related to its clinical trials, and the remainder for general working capital purposes. The term loans are to be made available upon the following terms: (i) $2,000,000 was made available on November 10, 2014; and (ii) $3.0 million (the Tranche B Loan) which was made available to the Company in May 2016 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. In November 2017, the Company amended its Credit Facility such that any term loan the Company draws is payable as interest-only prior to October 2018 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.

In conjunction with obtaining and amending the Credit Facility, the Company issued warrants to the bank with an aggregate fair value of $266,000, which were recorded as a debt discount. This discount is being amortized using the effective interest method through the current maturity date of the Credit Facility in October 2021. All amendments to the credit facility were determined to be modifications in accordance with ASC 470, *Debt* and did not result in extinguishment.

At September 30, 2018 and December 31, 2017, the Credit Facility is shown net of a remaining debt discount of $48,000 and $59,000, respectively.

8. INCOME TAXES

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

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 existing 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 had undergone two ownership changes and it is possible that additional ownership changes have occurred since. However, the Company's management believes that it had sufficient "built-in-gain" to offset any Section 382 of the Code limitation generated by known ownership changes. Any future ownership changes, including those resulting from the Company'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 equity 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, 2018, 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 in May 2014 upon the Company's initial public offering (Initial Public Offering). However, grants made under the 2010 Plan are still governed by that plan. As of September 30, 2018, options to purchase 413,130 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. The 2013 Plan was amended in June 2018. The amended 2013 Plan provides that commencing in 2019, on January 1 of each year the aggregate number of common shares that may be issued under the 2013

Plan shall automatically increase by such a number of shares equal to the lower of (a) 6% of the total number of shares of common stock outstanding on the last calendar day of the prior fiscal year and (b) a number of shares of common stock determined by the Company's board of directors. As of September 30, 2018, options to purchase 3,075,079 shares of common stock at a weighted average exercise price of $6.73 per share and 212,297 shares of common stock underlying restricted stock units (RSU's) remained outstanding under the 2013 Plan. As of September 30, 2018, there were 418,406 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,	
	2018	2017	2018	2017
Research and development expenses	$ 396,940	$ 224,341	$ 1,135,342	$ 691,747
General and administrative expenses	876,780	434,998	1,991,577	1,430,921
Total stock-based compensation expense	$ 1,273,720	$ 659,339	$ 3,126,919	$ 2,122,668

Stock Options

The table below summarizes activity relating to stock options under the incentive plans for the nine months ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value(a)
Outstanding at December 31, 2017	2,246,857	$ 4.87		
Granted	1,265,306	8.27		
Outstanding at September 30, 2018	3,512,163	$ 6.10	7.94	$27,056,003
Exercisable at September 30, 2018	1,725,007	$ 4.99	6.82	$15,195,549

(a) The aggregate intrinsic value in this table was calculated on the positive difference, if any, between the closing price per share of the Company's common stock on September 30, 2018 of $13.80 and the per share exercise price of the underlying options.

As of September 30, 2018, unamortized stock-based compensation for all stock options was $8,377,364 and will be recognized over a weighted average period of 2.85 years.

Restricted Stock Units

Terms of RSUs agreements, including vesting requirements, are determined by the board of directors or its compensation committee, subject to the provisions of the 2013 Plan. RSUs granted by the Company typically vest over a four year period. In the event that the employees' employment with the Company terminates any unvested shares are forfeited and revert to the Company. Restricted stock units are not included in issued and outstanding common stock until the shares are vested and released. The table below summarizes activity relating to RSUs for the nine months ended September 30, 2018:

	Number of Shares
Outstanding at December 31, 2017	157,128
Granted	96,144
Vested/released	(40,975)
Outstanding at September 30, 2018	212,297

The weighted-average fair value of RSUs granted was $8.60 per share for the nine months ended September 30, 2018. As of September 30, 2018, the outstanding restricted stock units had unamortized stock-based compensation of $1.2 million with a weighted-average remaining recognition period of 2.97 years and an aggregate intrinsic value of $3.1 million.

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 issuance of up to a total of 414,639 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. Participating employees purchase stock under the 2016 ESPP at a price equal to the lower of 85% of the closing price on the applicable offering commencement date or 85% of the closing price on the applicable offering termination date. The fair value of the purchase rights granted under this plan was estimated on the date of grant using the Black-Scholes option-pricing model using assumptions, which were derived in a manner similar to those discussed above relative to stock options. At September 30, 2018, the Company had 368,772 shares available for issuance under the 2016 ESPP. A summary of the weighted-average grant-date fair value, shares issued and total stock-based compensation expense recognized related to the 2016 ESPP as of September 30, 2018 and 2017 are as follows:

	2018	2017
Weighted-average grant-date fair value per share	$ 2.97	$ 1.77
Total shares issued	34,345	11,522
Total stock-based compensation expense	$56,514	$44,720

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. 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 was $9.50 per share. The warrants expired unexercised in January 2018.

In connection with the Initial Public Offering, the Company issued the underwriter of the offering warrants to purchase up to 60,000 shares of common stock. The warrants were 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 and were outstanding at September 30, 2018.

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, patent or other intellectual property 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.

12. SUBSEQUENT EVENT

In October 2018, the Company closed an underwritten public offering in which it sold, 5,250,000 shares of its common stock. The net proceeds of the offering were approximately $67.6 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

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," "intend," "may," "plan," "contemplates," "predict," "project," "target," "likely," "potential," "continue," "ongoing," "design," "might," "objective," "will," "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, 2017, which was filed with the SEC on March 29, 2018 (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.

Overview

Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with immune-mediated diseases. Our lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. We are leveraging our experience in ocular inflammation to develop other product candidates for systemic inflammatory disease and in other immune-mediated diseases, including cancer. We intend to commercialize our products directly and through collaborations that expand global reach.

Inflammation is a significant component of many different diseases, including cardiovascular, metabolic, neurological, and musculoskeletal conditions, affecting tens of millions of patients in the United States and hundreds of millions of patients worldwide. Given the complexity of immune dysregulation, which involves many mediators and signaling pathways, rarely is any single therapeutic approach effective, and most inflammatory diseases are inadequately treated. As such, we believe inflammatory diseases represent considerable unmet medical need, and new immune-modulating therapies are therefore in high demand. In aggregate, we believe the potential markets for novel therapeutics that treat inflammation are considerable, representing in excess of $50 billion worldwide.

Our first immune-modulating therapeutic approach is, we believe, mechanistically novel, and is focused on the sequestration of pro-inflammatory aldehyde-containing mediators, which we refer to as RASP (Reactive Aldehyde Species). We have developed a family of novel small molecule RASP scavengers, led by our product candidate reproxalap, which has been shown in multiple clinical trials to diminish inflammation. In addition to the RASP scavenger platform, we intend to discover or license other immune-modulating product candidates with novel mechanisms of action. For example, we have in-licensed a clinical-stage product candidate ADX-1612, which inhibits Heat Shock Protein 90 (Hsp90), a mechanistically differentiated potential approach for treatment of a number of inflammatory diseases.

As a topical ophthalmic solution, reproxalap was developed for the treatment of ocular inflammation, and has now demonstrated statistically and clinically significant improvement across an aggregate of five Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. Utilizing our experience in ocular inflammation, we intend to develop other RASP scavengers for systemic immune disease. In addition to our internal product development for systemic inflammatory diseases, we announced in February 2018 a partnership with Janssen, a Johnson & Johnson company, to develop other RASP scavengers for systemic immune-mediated diseases. In the future, we may enter into additional partnerships that facilitate the development and commercialization of our product candidates.

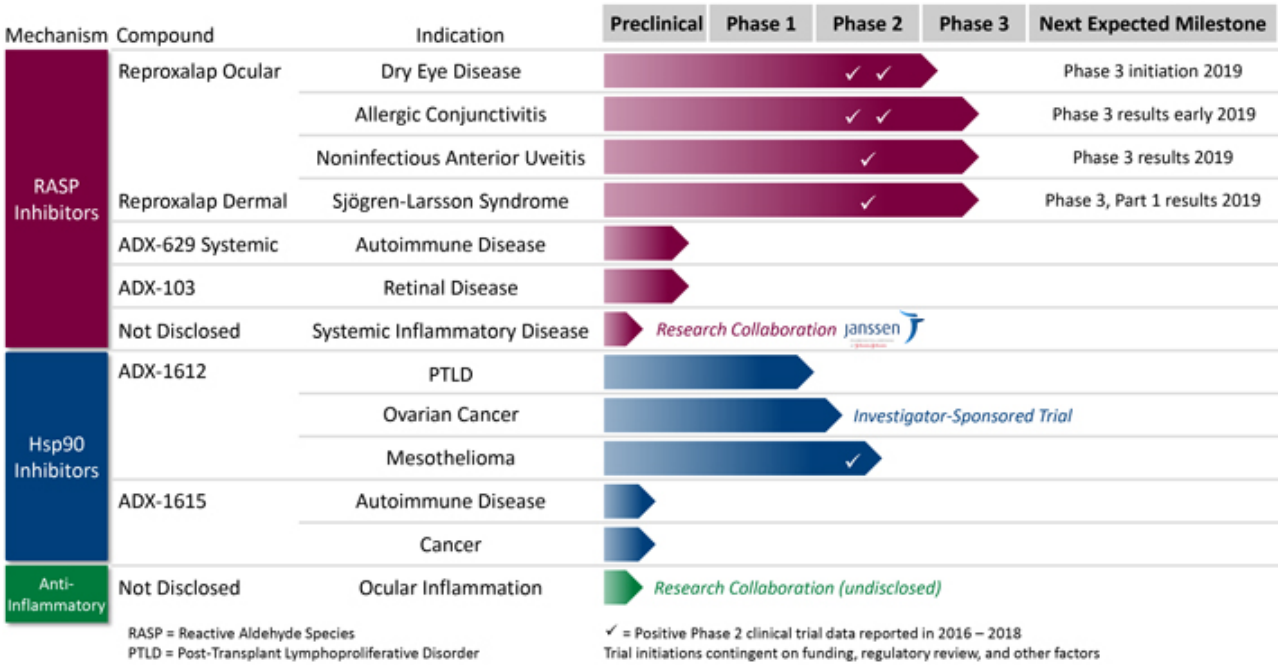
As a topical dermatologic formulation, reproxalap demonstrated activity in improving the dermatologic disease in patients with Sjögren-Larsson Syndrome (SLS), a rare inborn error of metabolism caused by genetic mutations in fatty aldehyde dehydrogenase, leading to accumulation of toxic aldehydes. SLS patients suffer from severe and generally intractable dermatologic and neurological disease. There is no therapy specifically for SLS that has been approved by the United States Food & Drug Administration (FDA), and no therapy is generally effective for the treatment of the skin disorder associated with SLS. As with our inflammation programs, we intend to continue to develop and, if approved by regulatory authorities, commercialize reproxalap for the treatment of the skin disease associated with SLS.

Our programs in SLS, noninfectious anterior uveitis, and allergic conjunctivitis have begun Phase 3 clinical testing. Results from the allergic conjunctivitis Phase 3 clinical trial are expected in early in 2019 and results from the first part of the SLS Phase 3 clinical trial and the noninfectious anterior uveitis Phase 3 clinical trial are expected in the second half of 2019. For allergic conjunctivitis, the ongoing Phase 3 clinical trial was designed to assess ocular itching following administration of allergen directly to the eye. In addition, as we prepare for a subsequent Phase 3 clinical trial in allergic conjunctivitis, we have initiated two clinical methods development studies to assess the feasibility of measuring ocular itching following environmental exposure to allergen.

In September 2018, we announced the results of a randomized, vehicle-controlled, parallel-group, multi-center, double-masked Phase 2b clinical trial of 0.1% and 0.25% concentrations of reproxalap topical ophthalmic solution versus vehicle in dry eye disease. Relative to patients treated with vehicle, patients treated with the 0.25% concentration of reproxalap statistically significant and clinically relevant reductions in the Four-Symptom Ocular Dryness Score ($p<0.05$) and the Overall Ocular Discomfort Symptom Score ($p<0.05$). Symptom improvement greater than that of vehicle was consistently observed across all measures, and activity versus vehicle was evident as early as two weeks (the first assessment following initiation of therapy). The early onset of symptomatic improvement is consistent with the Phase 2a clinical trial of topical ocular reproxalap in dry eye disease, and is supportive of a differentiated product profile relative to standard of care. Patients treated with the 0.25% concentration of reproxalap also demonstrated reductions in ocular fluorescein staining score that were statistically superior to those of patients treated with vehicle ($p<0.05$). Both 0.1% and 0.25% reproxalap concentrations demonstrated activity relative to vehicle, and a clear dose response was observed. Consistent with previous clinical trials, topical ocular reproxalap was well-tolerated, and reported adverse events were generally mild. Following discussion with regulatory authorities, we plan to initiate a Phase 3 program in dry eye disease in 2019.

In September 2018, we announced positive results from the MESO-2 investigator-sponsored Phase 1/2 clinical trial of ADX-1612 in patients with pleural malignant mesothelioma. ADX-1612, when combined with standard pemetrexed and platinum therapy, resulted in partial response rates that exceeded historical standard of care. ADX-1612 is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone that controls the folding and activation of client proteins involved in DNA repair and cell division. The MESO-2 investigator-sponsored dose escalation clinical trial was designed to assess the safety, tolerability, and efficacy of ADX-1612 in combination with standard pemetrexed and platinum therapy, using either cisplatin or carboplatin. Twenty-seven patients with pleural malignant mesothelioma were enrolled at a single site in the United Kingdom, and were divided into one of three cohorts receiving 100, 150, or 200 mg/m^2 of ADX-1612 on days 1 and 15 every 21 days. Of 23 evaluable patients, 22 patients (96%) manifested stable disease or clinical response, and one patient (4%) with non-epithelial histology progressed, as measured by via RECIST (Response Evaluation Criteria in Solid Tumors) criteria. The overall response rate was 61%, relative to historical standard of care response rates of 20 to 40%. The response rate in patients with epithelial histology was 76%. In seven patients, reduction of tumor burden was greater than 50%. One patient remained progression-free after 37 months. ADX-1612 was observed to be well-tolerated, and dose-limiting toxicity was observed in three patients, all of whom were enrolled in the highest dose group. Pending discussions with regulatory authorities, we plan to initiate a Phase 2 clinical trial of ADX-1612 in mesothelioma.

Our systemic inflammation programs for our RASP scavenger platform and ADX-1612 are expected to begin clinical testing in 2019. In addition, a novel RASP scavenger is in preclinical development for retinal disease. All of our development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, funding, and other factors that could delay the initiation, completion, or reporting of clinical trials. Our product candidate development pipeline is illustrated below.



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 October 2018, we closed an underwritten public offering in which we sold 5,250,000 shares of our common stock. The net proceeds of the offering were approximately $67.6 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by us.

We will need to raise additional capital in the form of debt or equity or through partnerships to fund additional development of our product candidates, and we may in-license, acquire, or invest in complementary businesses or products. In addition, contingent on capital resources, we may augment, diminish, or otherwise modify the clinical development plan described herein.

Since our incorporation, we have devoted substantially all of our resources to the preclinical and clinical development of our product candidates. Our ability to generate revenues largely depends upon our ability, alone or with others, to complete the development of our product candidates to obtain the regulatory approvals for and to manufacture, market, and sell our products and product candidates. The results of our operations will vary significantly from year-to-year and quarter-to-quarter, and depend on a number of factors, including risks that are detailed in, or incorporated by reference into, the section of this quarterly report entitled “Risk Factors.”

Research and development expenses

We expense all of our 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; and
- employee-related expenses, including salaries, benefits, travel, and stock-based compensation expense.

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

- 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 design of the trials;
- the cost of manufacturing the drug;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the cost of vehicle or active 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;
- the phase of development the product candidate is in; and
- the efficacy and safety profile of the product candidate.

We do not expect reproxalap and our other product candidates 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, 2018 and 2017. Other general and administrative expenses include professional fees for auditing, tax, and legal services including patent related costs. 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.

Comprehensive loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. For the three months ended September 30, 2018, comprehensive loss is equal to our net loss of $10.8 million and an unrealized loss on marketable securities of $2,637. For the nine months ended September 30, 2018, comprehensive loss is equal to our net loss of $28.2 million and an unrealized gain on marketable securities of $12,635. For the three months ended September 30, 2017, comprehensive loss is equal to our net loss of $5.0 million and an unrealized gain of $3,638. For the nine months ended September 30, 2017, comprehensive loss is equal to our net loss of $15.4 million and an unrealized loss on marketable securities of $1,131.

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 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, 2018 compared to three months ended September 30, 2017

Research and development expenses. Research and development expenses were $7.9 million for the three months ended September 30, 2018, compared to $3.5 million for the three months ended September 30, 2017. The increase of $ 4.4 million is primarily related to increases in our external research and development expenditures, including clinical and manufacturing expenses and personnel costs, partially offset by a reduction in preclinical expenses.

General and administrative expenses. General and administrative expenses were $3.1 million for the three months ended September 30, 2018, and $1.5 million for the three months ended September 30, 2017. The increase of $1.6 million is primarily related to an increase in personnel costs and intellectual property legal expenses.

Other income (expense). Total other income (expense), net was $134,169 and $29,073 for the three months ended September 30, 2018 and 2017, respectively. For the three months ended September 30, 2018 and 2017, other income (expense) primarily consisted of interest income, which was partially offset by interest expense related to our Credit Facility.

Nine months ended September 30, 2018 compared to nine months ended September 30, 2017

Research and development expenses. Research and development expenses were $21.3 million for the nine months ended September 30, 2018, compared to $10.8 million for the nine months ended September 30, 2017. The increase of $10.5 million is primarily related to the increases in our external research and development expenditures, including clinical and manufacturing expenses and personnel costs, partially offset by a reduction in preclinical expenses.

General and administrative expenses. General and administrative expenses were $7.3 million for the nine months ended September 30, 2018, compared to $4.7 million for the nine months ended September 30, 2017. The increase of $2.6 million is primarily related to an increase in personnel costs, and legal costs.

Other income (expense). Total other income (expense), net was $344,113 and $55,774 for the nine months ended September 30, 2018 and 2017, respectively. For the nine months ended September 30, 2018 and 2017, other income (expense) primarily consisted of interest income, which was partially offset by 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. Since inception, we have incurred operating losses and negative cash flows from operating activities, and have devoted substantially all of our efforts towards research and development. At September 30, 2018, we had total stockholders' equity of approximately $28.6 million, and cash, cash equivalents, reverse repurchase agreements and marketable securities of $35.1 million. During the three months ended September 30, 2018, we had a net loss of approximately $10.8 million. We expect to generate operating losses for the foreseeable future.

We are a party to a loan and security agreement (the Credit Facility) with Pacific Western Bank (Pacific Western, formerly Square 1 Bank), which was originally entered into in April 2012 and has been subsequently 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 to fund expenses related to our clinical trials and general working capital purposes. The term loans were made available to us upon the following terms: (i) $2.0 million was made available in November 2014 (which was used in part to refinance then outstanding loans from Pacific Western); and (ii) $3.0 million became available to us in May 2016 following the satisfaction of certain conditions, including receipt of positive Phase 2 clinical trial results in noninfectious anterior uveitis. In November 2017, we amended our Credit Facility such that any term loan we draw is payable as interest only prior to October 2018 and thereafter is payable in monthly installments of principal plus accrued interest over 36 months. 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 December 31, 2017 was 6.56%. The Credit Facility is collateralized by our assets, including our intellectual property. As of September 30, 2018 and December 31, 2017, $1.4 million was outstanding under the Credit Facility. At September 30, 2018 and December 31, 2017, the Credit Facility is shown net of a remaining debt discount of $48,000 and $59,000 respectively, which is being amortized using the effective interest method through the current maturity date of the Credit Facility, September 2021.

In June 2017, we entered into a Controlled Equity Offering℠ Sales Agreement (Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which we offered and sold, from time to time through Cantor, shares of our common stock, par value $0.001 per share, providing for aggregate sales proceeds of up to $20,000,000. Under the Sales Agreement, Cantor sold such shares of common stock in sales deemed to be an “at the market offering” (ATM) as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, and we may set the parameters for the sale of shares thereunder, including the number of shares to be sold, the time period during which sales were requested to be made, any limits on the number of shares that may be sold in any one trading day, and any minimum price below which sales may not be made. The Sales Agreement provided that Cantor was entitled to compensation for its services equal to 3.0% of the gross proceeds from the sale of shares sold pursuant to the Sales Agreement. We had no obligation to sell any shares under the Sales Agreement. From January 1, 2018 through September 30, 2018, we sold an aggregate of 1,796,306 shares of our common stock and received $14.2 million after deducting commissions related to the Sales Agreement and other offering costs.

In October 2018, we closed an underwritten public offering in which we sold 5,250,000 shares of our common stock. The net proceeds of the offering were approximately $67.6 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by us.

Based on our current operating plan, we believe that our cash, cash equivalents, reverse repurchase agreements, and marketable securities as of September 30, 2018, together with the $67.6 million in net proceeds from our public offering in October 2018, will be adequate to fund our currently anticipated operating expenses through the end of 2020, including the currently planned announcements of top-line data from Phase 3 clinical trials in allergic conjunctivitis, noninfectious anterior uveitis, SLS (Part 1), and dry eye disease. We will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of our planned research and development activities; 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 reproxalap and our other product candidates. 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 reproxalap 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 reproxalap or our other product candidates that 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 reproxalap and our other product candidates;
- the outcome, costs, and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing reproxalap and our other product candidates 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 reproxalap and our other product candidates;
- 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, 2018 and 2017:

	Nine Months ended September 30,	
	2018	2017
Net cash used in operating activities	$(21,888,956)	$(14,204,344)
Net cash provided by/(used in) investing activities	5,636,786	(2,087,867)
Net cash provided by/(used in) financing activities	14,237,485	37,381,000
Net increase (decrease) in cash and cash equivalents	$ (2,014,685)	$ 21,088,789

Operating Activities. Net cash used in operating activities was $21.9 million for the nine months ended September 30, 2018, compared to net cash used in operating activities of $14.2 million for the same period in 2017. 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, 2018 as compared to 2017 was due to an increase in research and development expenses, including clinical and manufacturing activities, and general and administrative expenses.

Investing Activities. Net cash provided by investing activities was $5.6 million for the nine months ended September 30, 2018, and $2.1 million used in investing activities for the nine months ended September 30, 2017. The primary use of cash for investing activities was for the purchase of marketable securities, and for the cost of leasehold improvements, and the purchase of furniture, fixtures, and computers and related equipment for the nine months ended September 30, 2018 and September 30, 2017. The primary source of cash for investing activities for the nine months ended September 30, 2018 and September 30, 2017 was from the sale of marketable securities.

Financing Activities. Net cash provided by financing activities was $14.2 million for the nine months ended September 30, 2018, compared to $37.4 million for the nine months ended September 30, 2017. The net cash provided by financing activities for the nine months ended September 30, 2018 was related to our Sales Agreement with Cantor, under which we sold an aggregate of 1,796,306 shares of our common stock, resulting in $14.2 million in proceeds after deducting commissions and other offering costs. The net cash provided by financing activities for the nine months ended September 30, 2017 was related to our February 2017 underwritten public offering.

Off-Balance Sheet Arrangements

Through September 30, 2018, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations

Except as set forth below, there have been no material changes since December 31, 2017 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, 2017, other than payments made or received in the ordinary course of business.

In December 2016, we entered into a license agreement with Madrigal Pharmaceuticals, Inc. pursuant to which we obtained an exclusive, worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize Hsp90 Inhibitors, including ADX-1612. Under the terms of the license agreement, we are obligated to make milestone payments up to make future regulatory and development and sales-dependent milestone payments of less than $340 million in the aggregate (over 80% of such amount being tied to our achievement of increasingly greater annual worldwide net sales milestones), as well as royalty payments at a rate which, as a percentage of net sales, is in the high single digits for products containing ADX-1612 and mid-single digits for any other Hsp90 Inhibitor product. The amounts payable pursuant to this license agreement are not included in the contractual obligations table included in the Annual Report as the timing of the payments is uncertain.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest rates

Our exposure to market risk is currently confined to our cash, our 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, 2018. 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.

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

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, 2017 filed with the SEC on March 29, 2018, 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 reproxalap and our other product candidates. Net loss for the three months ended September 30, 2018 and 2017 was approximately $10.8 million and $5.0 million, respectively. As of September 30, 2018, we had total stockholders' equity of $28.6 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 reproxalap 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 reproxalap 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, reproxalap. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, reproxalap.

Our product candidates, including reproxalap, 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 candidate. We have only one product candidate that has been the focus of significant clinical development: reproxalap, 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 in part dependent on successful continued development and ultimate regulatory approval of reproxalap 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 reproxalap. We will need to raise sufficient funds for, and successfully enroll and complete, our current and planned clinical trials of reproxalap and our other product candidates. The future regulatory and commercial success of our product candidates 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 reproxalap and our other product candidates;
- we may not be able to provide evidence of safety and efficacy for reproxalap and our other product candidates;
- 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 our later phase 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;
- the results of our clinical trials may not meet the endpoints, or level of statistical or clinical significance required by the FDA, or comparable foreign regulatory bodies for marketing approval;
- the FDA, or comparable foreign regulatory bodies, may implement new standards, or change the interpretation of existing standards or requirements for the regulatory approval, in general or with respect to the indications our product candidates are being developed to treat;
- the FDA, or comparable foreign bodies, may require clinical data in addition to the clinical trial programs we expect or may require changes to the designs and endpoints of the subsequent clinical trials;
- patients in our clinical trials for our product candidates may suffer other adverse effects or die for reasons that may or may not be related to reproxalap and our other product candidates;
- if approved for certain diseases, reproxalap and our other product candidates will compete with well-established and other products or therapeutic options already approved for marketing by the FDA, or comparable foreign regulatory bodies;
- the effects of legislative or regulatory reform of the health care system in the United States or other jurisdictions in which we may do business; 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 NDA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market reproxalap and our other product candidates, 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 that reproxalap and our other product candidates 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, reproxalap and our other product candidates, we may not be able to generate sufficient revenue to continue our business.

Because the Company has no experience in commercializing pharmaceutical products, there is a limited amount of information about us upon which to evaluate our product candidates and business prospects.

The Company has not yet demonstrated an ability to successfully overcome many of the pre-commercial and commercial 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, regulatory, quality, manufacturing, compliance, sales, distribution, and marketing capabilities on our own or through third parties;
- price our product candidates, if approved, at expected levels and obtain and maintain sufficient insurance and reimbursement from insurers and other programs; 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 earlier 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 reproxalap, 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 and may evolve and change from phase to phase or within the same phase, the vehicles or controls 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. Success in earlier clinical trials or clinical trials focused on a different indication 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 other phases of clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. Moreover, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Because 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 or require additional trials.

Our clinical focus is on the development of new products for inflammation and an inborn error of metabolism. Our Phase 3 vehicle-controlled clinical program in noninfectious anterior uveitis and our Phase 3 clinical program in SLS represent the first such clinical trials performed. Further, we have proposed to the FDA a novel assessment methodology for our Phase 3 clinical program in allergic conjunctivitis, which may require changes to the design of subsequent Phase 3 clinical trials. Thus, the timing and likelihood of success in our late-stage clinical programs cannot necessarily be predicted.

We could also face challenges in designing clinical trials and obtaining regulatory approval of our product candidates due to the lack of historical clinical trial experience for novel classes of therapeutics. Thus, it is difficult to determine whether regulatory agencies will be receptive to the approval of our product candidates and to predict the time and costs associated with obtaining regulatory approvals. 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, take longer and require more trial data 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 our 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 new technologies may arise that can cause us to delay, suspend or terminate our development efforts. As a result, short and long-term safety, as well as prospects for efficacy, are not fully understood and are difficult to predict. Regulatory approvals of new product candidates can be more expensive and take longer than approvals for well-characterized or more extensively studied pharmaceutical product candidates.

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

While the primary day-to-day complaint of SLS patients and their caregivers are symptoms associated with severe skin disease, SLS patients also manifest varying degrees of delay in mental development, spasticity, seizures, and retinal disease. In August 2016, we announced that the results of our randomized, parallel-group, double-masked, vehicle-controlled clinical trial of a dermatologic formulation of reproxalap for the treatment of the skin manifestations of SLS demonstrated clinically relevant activity of reproxalap in diminishing the severity of ichthyosis, a serious dermatologic disease characteristic of SLS. Given the expected low systemic exposure of reproxalap when administered topically to the skin, it is not possible to anticipate the effect of reproxalap on the non-dermatologic conditions of SLS. Lack of effect in neurologic and ocular manifestations of SLS may negatively impact the potential market for reproxalap in SLS, and may also negatively impact reimbursement, pricing, and commercial acceptance of reproxalap, if approved.

Reproxalap 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 and subsequent commercial success is never guaranteed.

Reproxalap and our other product candidates and the activities associated with development and potential commercialization, including 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 potentially 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 pricing or 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 but not limited to:

- such authorities may disagree with the design or implementation of our or any of our future development partners' clinical trials, including the endpoints of our clinical trials;
- such authorities may require clinical data in addition to clinical trial programs we expect, or may require changes to the designs and endpoints of subsequent 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 if 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;

- changes in the leadership or operation of such authorities, which may result in, among other things, the implementation of new standards, or changes to the interpretation or enforcement of existing regulatory standards and requirements;
- 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, standards or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

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

Moreover, we cannot predict healthcare reform initiatives, including potential reductions in federal funding or insurance coverage, that may be adopted in the future and whether or not any such reforms would have an adverse effect on our business and our ability to obtain regulatory approval for our current or future product candidates. There are evolving legal requirements and other statutory and regulatory regimes that will continue to affect our business.

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 reproxalap or other product candidates could significantly affect our product development costs and timeline. 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, or an institutional review board, or IRB, failing to grant permission to proceed or placing a 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 reproxalap or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe, serious or unexpected drug-related adverse effects, whether drug-related or otherwise;
- a facility manufacturing reproxalap, 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 a clinical trial or expiration of materials intended for use in a 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, current 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 IRB, that require us or others to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold in part or 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 reproxalap or our other product candidates or if we need to perform more, larger, or longer clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we or our partners 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, if any, 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 reproxalap 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 reproxalap and our other product candidates, 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 products 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. 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 or development program. 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 or others 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 full extent of adverse events that will be observed in subjects that receive any of our product candidates. 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 reproxalap or our other product candidates by the FDA or other regulatory authorities 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, assuming the results of the trials are successful, and the submission of an NDA, we cannot predict whether or when we will obtain regulatory approval to commercialize reproxalap or our other product candidates and we cannot, therefore, predict the timing of any future revenue. We cannot commercialize reproxalap 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 reproxalap 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 reproxalap 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 reproxalap 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 candidates, when and if any 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 other potential additional clinical trials. Following approval, if any, of reproxalap or any other product candidate, 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 seriousness, severity, or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for reproxalap 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 (REMS) 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 reproxalap 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 reproxalap or any other product candidate, we still may not be able to successfully commercialize 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. In addition, we may not be able to price our products at the expected level or at levels that make successful commercialization viable. The pricing of our products will be subject to numerous factors, many of which are outside of our control, including the pricing of similar products. The degree of market acceptance of our product candidates will depend on a number of factors, including but not limited to:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient populations and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulations by health care providers and their patients;
- the prevalence, seriousness and severity of any adverse effects;
- new procedures or methods of treatment that may be more effective in treating 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; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on the pricing of and anticipated revenues from our current or future product candidates for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

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 reproxalap 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. The reimbursement levels may be significantly less than the currently anticipated pricing of our product candidates. As a result of negative trends in the general economy in the United States 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. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the United States healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. More recently, the current presidential administration and many members of the United States Congress have attempted to repeal and replace the Patient Protection and Affordable Care Act (PPACA), but they have been unsuccessful in doing so as of the date of the filing of this report. We cannot predict the ultimate form or timing of any repeal or replacement of PPACA or the effect such repeal or replacement would have on our business. Regardless of the impact of repeal or replacement of PPACA on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments, or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers, and other third-party payers for our current and future product candidates, if any, for which we are able to obtain regulatory approval. Some of these changes and proposed changes could result in reduced reimbursement rates for such product candidates, if approved, which would adversely affect our business strategy, operations, and financial results.

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 use of newly approved drugs, which in turn could lower drug pricing. 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 diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to continue to in-license or acquire other product candidates, as well as commercial products, to treat patients suffering from immune-mediated 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. In-licensed product candidates may have been unsuccessfully developed by others in indications similar to those that we may pursue. 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, adequately priced, successfully commercialized, or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Orphan drug designation, Breakthrough therapy designation or Fast track designation from the FDA may be difficult or impossible to obtain, and if we are unable to obtain one or both such designations for reproxalap or our other product candidates, regulatory and commercial prospects may be negatively impacted.

The FDA designates orphan drug designation 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. Drugs that receive an orphan drug designation do not require prescription drug user fees at the time of marketing application, may qualify the drug development sponsor for certain tax credits, and can be marketed without generic competition for seven years. In April 2017, we announced that the FDA granted reproxalap orphan drug designation for the treatment of congenital ichthyosis, a severe skin disease characteristic of SLS. In addition, it may be difficult or not possible to obtain from the FDA orphan drug designation or a designation that facilitates and expedites development and review of certain new drugs, including breakthrough therapy designation, fast track designation or any other expedited status that we may apply for in the future, for reproxalap or our other product candidates. We believe that reproxalap and certain of our other product candidates may qualify as an orphan drug for noninfectious anterior uveitis, and possibly other diseases that we may test. However, we cannot guarantee that we will be able to receive orphan drug designation for indications other than treatment of ichthyosis or Breakthrough therapy designation from the FDA for reproxalap or our other product candidates. If we are unable to secure orphan drug designation, Breakthrough therapy designation or Fast track designation for reproxalap 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 reproxalap and our other product candidates.

As of September 30, 2018, we had only 16 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 required of publicly traded companies. We may have limited control over third parties and we cannot guarantee that any third party will perform its obligations in an effective and timely manner.

In addition, during challenging and uncertain economic environments 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 any third party does not meet our deadlines or otherwise conduct the trials as required and in accordance with regulations, 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 reproxalap and for our other 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.

Some of our product candidates may be studied in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have minimal or no control over the conduct of such trials.

We currently anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our product candidates, including ADX-1612, will involve investigator-initiated clinical trials. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this “Risk Factor” section relating to our internal clinical trials. While investigator-initiated trials may provide us with clinical data that can inform our future development strategy, we generally have less control over the conduct and design of the trials. Because we are not the sponsors of investigator-initiated trials, we do not control the protocols, administration, or conduct of the trials, including follow-up with patients and ongoing collection of data after treatment. As a result, we are subject to risks associated with the way investigator-initiated trials are conducted. In particular, we may be named in lawsuits that would lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-initiated clinical trials could have a material adverse effect on our prospects and the perception of our product candidates. As a result, our lack of control over the conduct and timing of, and communications with the FDA regarding, investigator-sponsored trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates.

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 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. Furthermore, if any of our contract manufacturers cannot successfully manufacture material that conforms to our specifications within regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We 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 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, 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 account for 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 have in the past, and may in the future, choose to enter into development or other strategic partnerships, 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 other development partnerships or other alternative arrangements for any of our product candidates or programs because our research and development pipeline may be insufficient, our product candidates or 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 or 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 below expectations. 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 competitiveness, if approved.

Moreover, if we fail to maintain partnerships related to our product candidates:

- 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 not realize the benefits of our current or future strategic alliances.

We have in the past, and may in the future, 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 the continued development or commercialization of reproxalap or our other product candidates. Strategic alliances 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 reproxalap or our other product candidates because third parties may view the risk of development failure 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 market. 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 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. Other parties may discover and patent treatment 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 reproxalap or our other product candidates. Inflammatory diseases may be treated with general immune suppressing therapies, including corticosteroids, some of which are generic. Our potential competitors in inflammatory diseases may be developing novel immune modulating therapies that may be safer or more effective than our product candidates.

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

We have no internal sales, marketing, or distribution capabilities. If reproxalap 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 reproxalap 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 reproxalap 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 senior management team 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 four individuals and certain other employees: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; Joshua Reed, our Chief Financial Officer; David J. Clark, M.D., our Chief Medical Officer and David B. McMullin, our Senior Vice President, Corporate Development and Strategy. Our current management team has only been working together for a relatively short period of time. Our future performance will depend significantly on our ability to successfully integrate our new Chief Financial Officer and our new Senior Vice President, Corporate Development and Strategy into our management team, and on those officers' ability to develop and maintain an effective working relationship. Our failure to integrate these recently hired executive officers with 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. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, and 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, adversely affecting 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, 2018, we only had 16 full-time employees, we will need to grow our organization to continue development and pursue the potential commercialization of reproxalap and our other product candidates, as well as function as a public company. As we seek to advance reproxalap and other product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing, and sales capabilities, or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train, and integrate additional management, clinical and regulatory, financial, administrative and sales, and marketing personnel. We may not be able to accomplish these tasks, and our failure to so accomplish could prevent us from successfully growing our company.

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

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

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

In the United States, the Medical Modernization Act of 2003 (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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, PPACA), 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 impose additional health policy reforms. Effective October 1, 2010, the PPACA's definition of "average manufacturer price" was revised for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, beginning in 2011, the PPACA imposed 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. The law appears likely to continue the pressure on pharmaceutical pricing, especially under Medicare, and may also increase our regulatory burdens and operating costs.

More recently, the current presidential administration and many members of the United States Congress have attempted to repeal and replace PPACA, but have been unsuccessful in doing so as of the date of the filing of this report. We cannot predict the ultimate form or timing of any repeal or replacement of PPACA or the effect such repeal or replacement would have on our business. Regardless of the impact of repeal or replacement of PPACA on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

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

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

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formula managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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

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

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

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory, and policy changes.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Currently, the FDA Commissioner position is vacant, pending the appointment of a new Commissioner by the new presidential administration. The confirmation process for a new commissioner may not occur efficiently. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

In December 2016, the 21st Century Cures Act was signed into law, and was designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. In the past, the FDA was often unable to offer key leadership candidates (including scientists) competitive compensation packages as compared to those offered by private industry. The 21st Century Cures Act is designed to streamline the agency's hiring process and enable the FDA to compete for leadership talent by expanding the narrow ranges that are provided in the existing compensation structures.

Disruptions at the FDA and other governmental agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our operating results and business.

U.S. federal income tax reform could adversely affect us.

In December 2017, U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (TCJA), was signed into law, significantly reforming the Internal Revenue Code of 1986, as amended (IRC). The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system, and modifies or repeals many business deductions and credits.

We continue to examine the impact the TCJA may have on our business. The TCJA is a far-reaching and complex revision to the U.S. federal income tax laws with disparate and, in some cases, countervailing impacts on different categories of taxpayers and industries, and will require subsequent rulemaking and interpretation in a number of areas. The long-term impact of the TCJA on the overall economy, the industries in which we operate and our and our partners' businesses cannot be reliably predicted at this early stage of the new law's implementation. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, and future business operations. The estimated impact of the TCJA is based on our management's current knowledge and assumptions, following consultation with our tax advisors. Because of our valuation allowance in the U.S., ongoing tax effects of the Act are not expected to materially change our effective tax rate in future periods. The impact of the TCJA on holders of common stock is uncertain and could be materially adverse. This report does not discuss any such tax legislation or the manner in which it might affect investors in common stock. Investors should consult with their own tax advisors with respect to such legislation and the potential tax consequences of investing in common stock.

New legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial conditions.

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

We face an inherent risk of product liability as a result of the clinical testing of reproxalap 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 reproxalap 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 reproxalap 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 continue to develop or commercialize reproxalap or our other product candidates; and
- a decline in our stock price.

We maintain product liability insurance with $5.0 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 reproxalap or our other product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

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

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

If we and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities will require that we and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our 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 entered into, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies, or products, or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;

- spend substantial operational, financial and management resources in integrating new businesses, technologies and products; and
- assume substantial actual or contingent liabilities.

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

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

We rely on email and other messaging services in connection with our operations. We may be targeted by parties using fraudulent spoofing and phishing emails to misappropriate passwords, payment information, or other personal information, or to introduce viruses through Trojan horse programs or otherwise through our networks, computers, smartphones, tablets, or other devices. Despite our efforts to mitigate the effectiveness of such malicious email campaigns through a variety of control and non-electronic checks, spoofing and phishing may damage our business and increase our costs. Any of these events or circumstances could materially adversely affect our business, financial condition, and operating results.

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 reproxalap and our other product candidates. Our ability to obtain clinical supplies of reproxalap 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 or others may engage in misconduct or other improper activities including noncompliance with regulatory standards, regulatory requirements, and insider trading.

We are exposed to the risk of employee and others, fraud or other misconduct. Misconduct by employees, consultants, or agents 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. Our current and former employees, consultants or sub-contractors may also become subject to allegations of sexual harassment, racial and gender discrimination or other similar misconduct, which, regardless of the ultimate outcome, may result in adverse publicity that could significantly harm our company’s brand, reputation and operations. 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, employees, consultants, and other third parties 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 trading in our common stock on the basis of, or while having access to, material, nonpublic information. If any such person was to be investigated or an action were to be brought against them 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 the use of our product candidates or proprietary technologies 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 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 reproxalap, we cannot be certain that the claims in our patent applications covering composition-of-matter of our other product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are possibly treatment compositions and methods that we have not conceived of or attempted to patent, and other parties may discover and patent 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 our trade secrets or proprietary know-how 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 reproxalap 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 reproxalap 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 reproxalap 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 reproxalap or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing reproxalap 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, the lender, 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, 2018, 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 validity, 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 or future 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 technology licenses, including the in-license agreement for ADX-1612, and we may enter into additional licenses in the future. Such licenses do, and may in the future, impose commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we could lose valuable rights under our collaboration 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 replacement licensors, and a significant amount of time may be required to transition to a replacement licensor.

Our rights to develop and commercialize ADX-1612 are subject in part to the terms and conditions of a third party license, pursuant to which we have acquired exclusive rights to ADX-1612 and other intellectual property. Our rights with respect to the intellectual property to develop and commercialize ADX-1612 may terminate, in whole or in part, if we fail to meet certain milestones contained in our license agreement relating to the development and commercialization of ADX-1612. We may also lose our rights to develop and commercialize ADX-1612 if we fail to pay required milestones or royalties. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may be extinguished, which may have an adverse effect on our business and results of operations.

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our 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 biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity. Therefore, obtaining and enforcing biotechnology 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 or weakening the rights of patent owners. 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 reproxalap and certain of our other product candidates in the United States and other countries, filing, prosecuting, and defending patents on reproxalap 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 may 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 where 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 pharmaceuticals, 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, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Financial Position and Need for Capital

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

We will require substantial future capital in order to complete the remaining clinical development for reproxalap and our other product candidates, and to potentially commercialize these product candidates, if approved. We expect our spending levels to increase in connection with our clinical trials of reproxalap 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 reproxalap 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 reproxalap 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 reproxalap 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 reproxalap 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 product candidates that we may develop, in-license or acquire, including potential milestone or royalty payments;
- 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. Our existing capital resources are not sufficient to enable us to fund the completion of our clinical trials and remaining development through commercial introduction. We expect that we will need to raise substantial 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 state of the global economy and market instability has made the business climate volatile and more costly. Uncertain 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 reproxalap 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 that may require us to relinquish rights to our product candidates or other 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, 2018. As of September 30, 2018 and December 31, 2017, the outstanding principal balance under the Credit Facility was approximately $1.4 million. 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; 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, we had undergone two ownership changes and it is possible that additional ownership changes have occurred since. However, our management believes that we had sufficient "Built-In-Gain" to offset the Section 382 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. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. As a result of the passage of the Tax Cuts and Job Act, corporate tax rates in the United States will decrease in 2018, requiring remeasurement of our deferred tax assets at the new statutory rate, and a reduction in the value of our deferred tax assets in 2017. However, subject to annual limitations, NOLs generated in years 2018 and beyond will have an indefinite carryforward period and will not expire. Future changes in federal and state tax laws pertaining to NOLs carryforwards may also cause limitations or restrictions from us claiming such NOLs. If the NOLs carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

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

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

Our quarterly operating results may fluctuate significantly.

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

- variations in the level of expenses related to our clinical trial and development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting reproxalap 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. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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 (Nasdaq), such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would expect to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The Nasdaq Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

We may allocate our cash and cash equivalents 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, management's ultimate use of cash and cash equivalents may vary substantially from the 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 reproxalap and our other product candidates, development of other molecules that relate to immune-mediated disease, service our debt obligations 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. 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, 2018, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 42.0% 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, the provisions would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

We have never declared or paid any cash dividend on our common stock, and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our loan and security agreement with 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 the value of our common stock. 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 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. Existing stockholder sales might also make it more difficult for us to sell additional 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 (the Sarbanes-Oxley Act) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, 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 $1.07 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 emerging growth company 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, imposes 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 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, incurring unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may result in substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If public company rules and regulations divert the attention of our management and personnel from other business concerns, our business, financial condition, and results of operations could be adversely affected. Increased costs associated with public company expenses 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, public company 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 which 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 will be required 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. The risk of securities class action litigation is especially relevant for us because biotechnology and 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.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biotechnology industry over the last few years. We may be particularly vulnerable to activist stockholders due to the highly concentrated ownership of our common stock. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or stockholder dispute involving us or our partners because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

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 3.2 to the Registrant's Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference).
10.30	Offer Letter, effective as of July 30, 2018, between the Registrant and Joshua Reed.
10.31	Separation and Consulting Letter Agreement, effective as of July 27, 2018, between the Registrant and Stephen Tulipano.
10.32*	License Agreement, dated as of December 26, 2016, by and between Registrant and Madrigal Pharmaceuticals, Inc. (filed as Exhibit 99.2 to the Registrant's Current Report on Form 8-K as filed on September 25, 2018, 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, 2018 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Balance Sheets as of September 30, 2018 and December 31, 2017; (ii) Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2018 and 2017; (iii) Statements of Cash Flows for the three months ended September 30, 2018 and 2017; 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.

* Confidential treatment has been granted with respect to certain portions of this document.

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, 2018

/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, 2018

/s/ Joshua Reed

Joshua Reed
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

ALDEYRA THERAPEUTICS, INC.
131 HARTWELL AVENUE, SUITE 320
LEXINGTON, MA 02421

July 5, 2018

Mr. Joshua Reed

Dear Joshua,

Aldeyra Therapeutics, Inc. (the "Company") is pleased to offer you employment on the following terms:

1. **Position**. Your title will be Chief Financial Officer and you will report to the Company's Chief Executive Officer, Todd C. Brady, M.D., Ph.D. This is a full-time position. While you render services to the Company, you will not engage in any other employment, consulting or other business activity (whether full-time or part-time) that would create a clear conflict of interest with the Company. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. The location of the position is in Lexington, MA. Accordingly, it is required that you relocate to a location within 60 miles radius of the Company's offices prior to September 1, 2019.

2. **Cash Compensation**. The Company will pay you a starting salary at the rate of $15,417 per pay period (twenty-four pay periods per year), payable in accordance with the Company's standard payroll schedule. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time**.** In addition, you will be eligible to be considered for an incentive bonus for each fiscal year of the Company. The bonus (if any) will be awarded based on objective or subjective criteria established by your supervisor and made known to you, and approved by the Company's Board of Directors or Compensation Committee acting in good faith. Your target bonus will be equal to 35% of your annual base salary. Any bonus for the fiscal year in which your employment begins will be prorated, based on the number of days you are employed by the Company during that fiscal year. Any bonus for a fiscal year is expected to be paid within 2.5 months after the close of that fiscal year, but only if you are still employed by the Company at the time of payment. The determinations of the Company's Board of Directors or its Compensation Committee with respect to your bonus will be final and binding, absent error.

3. **Employee Benefits**. As an executive employee of the Company, you will be eligible to participate in a number of Company-sponsored benefits. In addition, you will be entitled to 4 weeks paid time off in accordance with the Company's time off policy, as in effect from time to time. The Company performs annual employee evaluations and reviews, during which the potential for promotions, employee compensation adjustments, and other employment modifications is assessed.

4. **Stock Options**. Subject to the approval of the Company's Board of Directors or its Compensation Committee, you will be granted an option to purchase 75,000 shares of the Company's Common Stock (the "Option"). The exercise price per share of the Option will be determined by the Board of Directors or the Compensation Committee when the Option is granted. The Option will be subject to the terms and conditions applicable to options granted under the Company's 2013 Stock Plan (the "Plan") and the applicable Stock Option Agreement. You will vest in 25% of the Option shares after 12 months of continuous service with the Company, and the balance will vest in equal monthly installments over the next 36 months of continuous service, as described in the applicable Stock Option Agreement.

   The Option will be subject to acceleration in connection with a change of control, subject to the terms and conditions of the Company's Change in Control Plan effective as of March 28, 2017, as such plan may be amended or restated from time to time.

5. Severance Benefits.

a. **General.** If you are subject to an Involuntary Termination, then you will be entitled to the benefits described in this Section 5. However, this Section 5 will not apply unless you (i) have returned all Company property in your possession, (ii) have resigned as a member of the Boards of Directors of the Company and all of its subsidiaries, to the extent applicable, and (iii) have executed a general release of all claims that you may have against the Company or persons affiliated with the Company. The release must be materially in the form prescribed by the Company", a copy of which is attached hereto as **Exhibit A**. You must execute and return the release on or before the date specified by the Company in the prescribed form (the "Release Deadline"). The Release Deadline will in no event be later than 50 days after your Separation. If you fail to return the release on or before the Release Deadline, or if you revoke the release, then you will not be entitled to the benefits described in this Section 5.

b. **Salary Continuation.** If you are subject to an Involuntary Termination, then the Company will continue to pay your base salary for a period of 9 months after your Separation. Your base salary will be paid at the rate in effect at the time of your Separation and in accordance with the Company's standard payroll procedures. The salary continuation payments will commence within 60 days after your Separation and, once they commence, will include any unpaid amounts accrued from the date of your Separation. However, if the 60-day period described in the preceding sentence spans two calendar years, then the payments will in any event begin in the second calendar year on the first payroll date following expiration of any revocation period.

c. **Cash Bonus.** If you are subject to an Involuntary Termination, then the Company will pay you a lump-sum in cash equal to the greater of (i) your target bonus for the year in which the Involuntary Termination occurs or (ii) the actual bonus paid to you with respect to the Company's most recently completed fiscal year. Such payment will be made within 60 days after your Separation; however, if such 60-day period spans two calendar years, then the payment will in any event be made in the second calendar year.

d. **COBRA.** If you are subject to an Involuntary Termination and you elect to continue your health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") following your Separation, then the Company will pay the same portion of your monthly premium under COBRA as it pays for active employees and their eligible dependents until the earliest of (i) the close of the 9-month period following your Separation, (ii) the expiration of your continuation coverage under COBRA or (iii) the date when you become eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment. Such payments will be treated as taxable compensation income to you if required or advisable, in the Company's sole discretion, to avoid adverse consequences to you, the Company or the Company's other employees.

6. **Confidentiality, Non-Competition and Work Product Agreement**. Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard "Confidentiality, Non-Competition and Work Product Agreement", a copy of which is attached hereto as **Exhibit B**.

7. **Employment Relationship**. Employment with the Company is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without Cause or Good Reason, upon thirty (30) days written notice to the other, subject to the severance benefits you may be entitled to under this letter. Any contrary representations that may have been made to you are superseded by this letter agreement. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

8. **Tax Matters**.

a. Withholdings. All forms of compensation referred to in this letter agreement are subject to applicable withholding and payroll taxes and other deductions required by law.

b. Section 409A. To the extent that any payment or benefit described in this letter agreement constitutes "non-qualified deferred compensation" under Section 409A of the Internal Revenue Code (the "Code"), and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." It is intended that payments under this letter satisfy, to the greatest extent possible, the exemption from the application of Section 409A of the Code (the (and any state law of similar effect) provided under Treasury Regulation Section 1.409A-1(b)(4) (as a "short-term deferral"). The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A 1(h). The parties intend that this letter shall be administered in accordance with Section 409A of the Code. To the extent that any provision of this letter is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this letter is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A 2(b)(2). The parties agree that this letter may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

c. Tax Advice. You are encouraged to obtain your own tax advice regarding your compensation from the Company. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company, its Board of Directors or its Compensation Committee related to tax liabilities arising from your compensation.

9. **Relocation**. The Company will reimburse you the monthly costs of customary and standard temporary travel and housing expenses you expect to incur prior to your permanent relocation (the "Reimbursed Expenses"). The Reimbursed Expenses will not cover any expenses you incur after August 31, 2019 or after permanent relocation, whichever occurs sooner. At the time of your establishment of a permanent residence within a 60 miles radius of the Company's offices, the Company will pay you an additional amount (the "Second Payment") to cover direct moving costs. The Second Payment will be grossed up for income and payroll taxes, and will also include a tax gross up amount for the Reimbursed Expenses. The Second Payment is subject to you being actively employed in good standing with the Company. In the event your employment terminates or is suspended for any reason, or in the event that the establishment of a permanent residence within 60 miles of the Company's offices does not occur by September 1, 2019, the Second Payment will not be made. The Reimbursed Expenses and the Second Payment, in aggregate, shall not exceed $80,000, exclusive of tax gross up amounts. Further, prior to your permanent relocation, should you, prior to September 1, 2019, (i) voluntarily resign from the Company or (ii) be terminated for cause, you agree to repay the Company an amount equal to the total amount of Reimbursed Expenses made to you under this agreement.

10. **Interpretation, Amendment and Enforcement**. This letter agreement and Exhibit A supersede and replace any prior agreements, representations or understandings (whether written, oral, implied or otherwise) between you and the Company and constitute the complete agreement between you and the Company regarding the subject matter set forth herein. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by Massachusetts law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in Massachusetts in connection with any Dispute or any claim related to any Dispute.

Definitions. The following terms have the meaning set forth below wherever they are used in this letter agreement:

"Cause" means (a) your unauthorized use or disclosure of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company, (b) your material breach of any written agreement between you and the Company, (c) your material failure to comply with the Company's written policies or rules of which you are made aware, (d) your conviction of, or your plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State, (e) your gross negligence or willful misconduct in performance of your duties, (f) your continuing failure to perform assigned duties after receiving written notification of the failure from the Company's Board of Directors or (g) your failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested your cooperation.

"Good Reason" shall mean:

(i) a material diminution in your base salary or target bonus by more than 10% (unless in connection with a company wide cost reduction);

(ii) a material diminution in your authority, duties or responsibilities with respect to the Company or any successor or acquiring entity, including, without limitation, any requirement that you report to anyone other than the Chief Executive Officer of the ultimate parent entity of the Company (the "Ultimate Parent Company");

(iii) a breach of a material provision of your Offer Letter or other written agreement governing employment with the Company (it being understood that a change in title without your consent shall be a material breach); or

(iv) without your prior consent, a relocation of your principal workplace by more than fifty (50) miles away from the location which you were working immediately prior to the required relocation.

A termination shall not be a Good Reason unless (x) you give the Company written notice of such condition within 90 days after such condition first comes into existence, (y) the Company fails to remedy such condition within 30 days after receiving your written notice, and (z) you have a Separation within 30 days of the expiration of the cure period described in clause (y) provided that the Company has not cured the Good Reason event or condition.

“Involuntary Termination” means your Termination without Cause or Termination for Good Reason.

“Separation” means a “separation from service,” as defined in the regulations under Section 409A of the Code.

“Termination for Good Reason” means a Separation as a result of a termination of your employment by you for Good Reason.”

“Termination without Cause” means a Separation as a result of a termination of your employment by the Company without Cause.”

* * * * *

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Confidentiality, Non-Competition and Work Product Agreement and returning them to me. This offer, if not accepted, will expire at the close of business on July 6, 2018. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States. Your employment is also contingent upon (i) your starting work with the Company on or before July 30, 2018, (ii) your completing an employment application, and (iii) a background and/or reference check to the Company's satisfaction.

Very truly yours,

ALDEYRA THERAPEUTICS, INC.

/s/ Todd C. Brady

By: Todd C. Brady, M.D., Ph. D.
Title: Chief Executive Officer

I have read and accept this employment offer:

/s/ Joshua Reed

Signature of Joshua Reed

Dated: July 5, 2018

July 27, 2018

Stephen Tulipano

Dear Steve:

This letter (the "Agreement") confirms the agreement between you and Aldeyra Therapeutics, Inc. (the "Company") regarding the termination of your employment with the Company.

1. **Termination Date**. Your employment with the Company will terminate on July 27, 2018 (the "Termination Date"). On or prior to the Termination Date, you and the Company shall execute the Consulting Agreement attached hereto as Exhibit A.

2. **Salary and Vacation Pay**. On the Termination Date, the Company will pay you $17,938.52, less all applicable withholdings. This amount represents all of your salary earned through the Termination Date and all of your accrued but unused vacation time or PTO. You acknowledge that the only payments and benefits that you are entitled to receive from the Company in the future are those specified in this Agreement.

3. **Severance Pay**. Subject to you not revoking this Agreement as set forth in Section 16 below and in accordance with your offer letter, dated as of June 13, 2014 (the "Offer Letter"), the Company will on the first payroll date following the Effective Date: (i) commence paying you your current base salary for nine months in accordance with the Company's standard payroll procedures, and (ii) will make a lump sum cash payment to you equal to $124,704 (which represents your target bonus for 2018), each less all applicable withholdings. If you breach any provision of this Agreement, you understand that no additional severance payments will be made.

4. **COBRA Premiums**. You will receive information about your right to continue your group health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") after the Termination Date. In order to continue your coverage, you must file the required election form. Subject to you electing COBRA continuation coverage and you not revoking this Agreement as set forth in Section 16 below, the Company shall pay you an amount equal to the Company share of group health plan monthly premiums until the earlier of (i) 9 months after the Termination Date or (ii) the date you become eligible for substantially equivalent health care coverage in connection with new employment or self-employment. Any such payments shall be reported as wages and subject to tax withholding.

5. **Option**. On July 21, 2014, the Company granted you an option to purchase 67,642 shares of its Common Stock (the "2014 Option") under the Company's 2013 Equity Incentive Plan (the "Plan"). As of the Termination Date, you will be vested in all of the shares that are subject to the 2014 Option. Additionally, you were granted the following options under the Plan: on June 3, 2015, an option to purchase 25,000 shares of its Common Stock (the "2015 Option"); on March 16, 2016, an option to purchase 30,000 shares of its Common Stock

(the "2016 Option"); on March 3, 2017, an option to purchase 220,980 shares of its Common Stock (the "2017 Option"); on March 6, 2018, an option to purchase 125,670 shares of its Common Stock (the "2018 Option" and collectively, with the 2015 Option, the 2016 Option and the 2017 Option, the "Options"). As of the Termination Date, you will be vested in 21,875 of the shares that are subject to the 2015 Option; 18,750 of the shares that are subject to the 2016 Option; 82,868 of the shares that are subject to the 2017 Option; and 18,327 of the shares that are subject to the 2018 Option. Each of the 2014 Option, the 2015 Option, the 2016 Option, the 2017 Option and the 2018 Option will be subject to the terms and conditions applicable to options granted under the Plan, as described in the Plan and the applicable Stock Option Agreement. The Options shall continue to vest pursuant to the terms and conditions of the Consulting Agreement. You acknowledge and agree that you have no rights to the Company's capital stock except as described in this Section 5.

6. **Release of All Claims**. In consideration for receiving the severance benefits described above, to the fullest extent permitted by law, you waive, release and promise never to assert any claims or causes of action, whether or not now known, against the Company or its predecessors, successors or past or present subsidiaries, stockholders, directors, officers, employees, consultants, attorneys, agents, assigns and employee benefit plans (together, the "Releasees") with respect to any matter, including (without limitation) any matter related to your employment with the Company or the termination of that employment, including (without limitation) claims to attorneys' fees or costs, claims of wrongful discharge, constructive discharge, emotional distress, defamation, invasion of privacy, fraud, breach of contract or breach of the covenant of good faith and fair dealing and any claims of discrimination or harassment based on sex, age, race, national origin, disability or any other basis under Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act of 1967, the Older Workers Benefit Protection Act, the Americans with Disabilities Act, Massachusetts G.L.c. 151B and all other state and federal laws and regulations relating to employment. However, this release covers only those claims that arose prior to the execution of this Agreement. Execution of this Agreement does not bar any claim that arises hereafter, including (without limitation) a claim for breach of this Agreement and does not bar any claim for indemnification as set forth in the Indemnification Agreement between you and the Company (the "Indemnification Agreement").

7. **Exception.** This Agreement does not (i) prohibit or restrict you from communicating, providing relevant information to or otherwise cooperating with the EEOC or any other governmental authority with responsibility for the administration of fair employment practices laws regarding a possible violation of such laws or responding to any inquiry from such authority, including an inquiry about the existence of this Agreement or its underlying facts, (ii) preclude the Employee from benefiting from class-wide injunctive relief awarded in any fair employment practices case brought by any governmental agency, provided such relief does not result in Employee's receipt of any monetary benefit or substantial equivalent thereof or (iii) responding to any inquiry or investigation by any governmental agency or subdivision.

8. **Consideration Period.** IN SIGNING THIS AGREEMENT, YOU ACKNOWLEDGE THAT: (A) YOU HAVE READ AND UNDERSTAND THIS AGREEMENT AND YOU ARE HEREBY ADVISED IN WRITING TO CONSULT WITH AN ATTORNEY PRIOR TO SIGNING THIS AGREEMENT, (B) YOU HAVE SIGNED

THIS AGREEMENT VOLUNTARILY AND UNDERSTANDS THAT IT CONTAINS A FULL AND FINAL RELEASE OF ALL CLAIMS, AS SET FORTH IN SECTION 6 AGAINST THE RELEASEES AS OF THE EFFECTIVE DATE OF THIS AGREEMENT, INCLUDING ALL RIGHTS AND CLAIMS YOU HAVE OR MAY HAVE UNDER ADEA; (C) YOU ARE NOT WAIVING ANY RIGHTS OR CLAIMS UNDER ADEA THAT ARISE AFTER THE EFFECTIVE DATE OF THIS AGREEMENT; (D) YOU HAVE BEEN OFFERED AT LEAST TWENTY-ONE (21) CALENDAR DAYS TO CONSIDER THE MATTERS MEMORIALIZED IN THIS AGREEMENT, AND (E) YOU WILL, BY EXECUTING THIS RELEASE AGREEMENT, RECEIVE CONSIDERATION

9. **No Admission**. Nothing contained in this Agreement will constitute or be treated as an admission by you or the Company of liability, any wrongdoing or any violation of law.

10. **Other Agreements**. At all times in the future, you will remain bound by your Proprietary Information and Inventions Agreement with the Company that you signed, a copy of which is attached as Exhibit B. You and the Company will also remain bound by the Indemnification Agreement. Except as expressly provided in this Agreement and the Consulting Agreement, this Agreement renders null and void all prior agreements between you and the Company and constitutes the entire agreement between you and the Company regarding the subject matter of this Agreement. This Agreement may be modified only in a written document signed by you and a duly authorized officer of the Company.

11. **Company Property**. You represent that you have returned to the Company all property that belongs to the Company, including (without limitation) copies of documents that belong to the Company and files stored on your computer(s) that contain information belonging to the Company.

12. **Confidentiality of Agreement**. You agree that you will not disclose to others the existence or terms of this Agreement, except that you may disclose such information to your spouse, attorney or tax adviser if such individuals agree that they will not disclose to others the existence or terms of this Agreement.

13. **No Disparagement**. You agree that you will never make any negative or disparaging statements (orally or in writing) about the Company or its stockholders, directors, officers, employees, products, services or business practices, except as required by law.

14. **Severability**. If any term of this Agreement is held to be invalid, void or unenforceable, the remainder of this Agreement will remain in full force and effect and will in no way be affected, and the parties will use their best efforts to find an alternate way to achieve the same result.

15. **Choice of Law**. This Agreement will be construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts (other than its choice-of-law provisions).

16. **Revocation Period.** You may revoke this Agreement in writing at any time during a period of seven (7) calendar days after the execution of this Agreement by the Employee (the "Revocation Period"). This Agreement shall become effective upon the expiration of the Revocation Period (the "Effective Date"); provided that the Employee has not revoked this Agreement before such time.

17. **Execution**. This Agreement may be executed in counterparts, each of which will be considered an original, but all of which together will constitute one agreement. Execution of a facsimile copy will have the same force and effect as execution of an original, and a facsimile signature will be deemed an original and valid signature.

Please indicate your agreement with the above terms by signing below.

Very truly yours,

Aldeyra Therapeutics, Inc.

By: /s/ Todd Brady
CEO

I agree to the terms of this Agreement, and I am voluntarily signing this release of all claims. I acknowledge that I have read and understand this Agreement, and I understand that I cannot pursue any of the claims and rights that I have waived in this Agreement at any time in the future.

/s/ Stephen Tulipano
Signature of Stephen Tulipano

Dated: July 27, 2018

EXHIBIT B

PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

CONSULTING AGREEMENT

This Consulting Agreement (the ***Agreement***), effective as of the date of the last signature (the ***Effective Date***), is entered into by Stephen Tulipano and **ALDEYRA THERAPEUTICS, INC.**, a Delaware corporation with a place of business at 131 Hartwell Avenue, Suite 320, Lexington, MA 02421, USA (***Company***). Consultant and Company agree as follows:

1. Services and Payment.

A. ENGAGEMENT. **COMPANY HEREBY ENGAGES CONSULTANT TO PROVIDE THE SERVICES ASSIGNED BY COMPANY FROM TIME TO TIME (THE *SERVICES*), AND CONSULTANT ACCEPTS SUCH ENGAGEMENT. THE COMPANY AND CONSULTANT HEREBY AGREE THAT PROVISION OF THE SERVICES SHALL CONSTITUTE CONTINUOUS "SERVICE" FOR PURPOSES OF THE OPTIONS (AS DEFINED ON SCHEDULE A). CONSULTANT AGREES TO USE BEST EFFORTS TO UNDERTAKE AND PROMPTLY COMPLETE THE SERVICES IN ACCORDANCE WITH THE DESCRIPTIONS AND SCHEDULES SPECIFIED THEREFOR. CONSULTANT WILL REPORT TO JOSHUA REED, THE CHIEF FINANCIAL OFFICER OF THE COMPANY.**

B. FEES AND EXPENSES. **AS THE ONLY CONSIDERATION DUE CONSULTANT REGARDING THE SUBJECT MATTER OF THIS AGREEMENT, CONSULTANT WILL CONTINUE TO VEST IN THE OPTIONS. SUBJECT TO REASONABLE DOCUMENTATION, COMPANY SHALL REIMBURSE CONSULTANT FOR ITS OUT-OF-POCKET EXPENSES REASONABLY INCURRED IN PROVIDING THE SERVICES; *PROVIDED*, THAT INDIVIDUAL EXPENSES IN EXCESS OF $250 MUST BE APPROVED IN ADVANCE IN WRITING BY COMPANY. PROMPTLY AFTER EXECUTION OF THIS AGREEMENT, CONSULTANT SHALL DELIVER TO COMPANY A PROPERLY COMPLETED AND DULY EXECUTED DEPARTMENT OF THE TREASURY IRS FORM W-9 OR, IF CONSULTANT IS A NON-U.S. PERSON, A DEPARTMENT OF THE TREASURY IRS FORM W-8BEN (OR OTHER APPROPRIATE FORM W-8).**

2. Intellectual Property.

a. Inventions Assignment. Company owns all right, title and interest (including patent rights, copyright rights, trade secret rights, trademark rights, *sui generis* database rights and all other intellectual and industrial property rights of any sort throughout the world) relating to any and all inventions (whether or not patentable), technologies, works of authorship, software, designs, know-how, ideas, data and other information and work products that are made, conceived, reduced to practice or obtained, in whole or in part, by Consultant, and that arise out of the Services or that are based on or otherwise reflect any Proprietary Information (as defined below) (collectively, ***Inventions***). Consultant will promptly provide and fully disclose all Inventions to Company. All Inventions are works made for hire to the extent allowed by law and, in addition, Consultant agrees to make and does hereby make all assignments necessary to accomplish the foregoing ownership. Consultant shall assist Company, at Company's expense, to further evidence, confirm, record and perfect such assignments, and to perfect, obtain, maintain, enforce, and defend any rights assigned. Consultant hereby irrevocably designates and appoints Company and its officers as its agents and attorneys-in-fact (coupled with an interest), with full power of substitution, to act for and in Consultant's behalf to execute and file any document and to do all other lawfully permitted acts to further the foregoing with the same legal force and effect as if executed by Consultant.

b. Confidentiality. Consultant agrees that all Inventions and all other financial, business, legal and technical information (including, without limitation, the identity of and information relating to customers, prospects, vendors, affiliates and employees) that Consultant develops, learns or obtains in connection with the Services, or that are received by or for Company in confidence, constitute ***Proprietary Information.*** Consultant will hold in strict confidence, and exercise all reasonable precautions to prevent unauthorized access to, and not disclose or, except in performing the Services, use any Proprietary Information. However, Proprietary Information will not include information that Consultant can document is or becomes readily publicly available without restriction through no fault of Consultant. Upon termination and at Company's request at any other time, Consultant will promptly return to Company all materials and copies containing or embodying Proprietary Information, except that Consultant may keep its personal copy of its compensation records and this Agreement. Consultant also recognizes and agrees that Consultant has no expectation of privacy with respect to Company's telecommunications, networking or information processing systems (including, without limitation, stored computer files, email messages and voice messages) and that Consultant's activity, and any files or messages, on or using any of those systems may be monitored at any time without notice.

c. Restrictions. As additional protection for the Proprietary Information, Consultant agrees that during the period over which it is (or is supposed to be) providing Services (i) and for 1 year thereafter, Consultant will not encourage or solicit any employee, contractor or consultant of Company to leave Company for any reason, or service or solicit the business or patronage of any of Company's customers, suppliers or prospects for the benefit of Consultant or any other person, or divert, entice or otherwise take away from Company the business or patronage of any customer, supplier or prospect, (ii) Consultant will not (in any capacity) engage in any activity that is in any way competitive with the business or demonstrably anticipated business of Company and (iii) Consultant will not (in any capacity) assist any other person or organization in competing or preparing to compete with any business or demonstrably anticipated business of Company. Consultant understands that the restrictions set forth in this Section 2(c) are intended to protect Company's interest in its proprietary information and established relationships and goodwill with employees and business partners, and Consultant agrees that such restrictions are reasonable and appropriate for this purpose.

d. Moral Rights. To the extent allowed by law, Section 2(a) and any license to Company hereunder includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as moral rights, artist's rights, *droit moral* or the like. To the extent any of the foregoing is ineffective under applicable law, Consultant hereby provides any and all ratification and consents necessary to accomplish the purposes of the foregoing to the extent possible. Consultant will confirm any such ratification and consents from time to time as requested by Company. Consultant will obtain the foregoing ratification, consents and authorizations, for Company's exclusive benefit, from each person who provides any Services hereunder.

e. License. If any part of the Services or Inventions is based on, incorporates or is an improvement or derivative of, or cannot be reasonably and fully made, used, reproduced, modified, distributed or otherwise exploited, without using or violating any technology or intellectual property right owned by Consultant (or any third party) and not assigned hereunder (***Licensed Rights***), then Consultant hereby grants and agrees to grant to Company and its affiliates, successors and assigns a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, sublicensable right and license to exploit and exercise all such Licensed Rights in support of Company's exercise or exploitation of the Services, Inventions or other work performed hereunder (including any modifications, improvements and derivatives). Consultant agrees not to use or disclose any Licensed Rights for which it is not fully authorized to grant the foregoing license.

3. WARRANTY. Consultant represents and warrants that: (a) the Services will be performed in a professional and workmanlike manner; (b) none of the Services or any part of this Agreement is or will be inconsistent with any obligation Consultant may have to others; (c) all work under this Agreement shall be Consultant's original work and none of the Services or Inventions or any development, use, production, distribution or exploitation thereof will infringe, misappropriate or violate any intellectual property or other right of any person or entity (including, without limitation, Consultant itself); (d) Consultant has the full right to provide Company with the assignments and rights provided for herein; and (e) Consultant will not disclose to Company or use for its benefit any trade secret or proprietary or confidential information of any third party.

4. Term and Termination. **THIS AGREEMENT COMMENCES ON THE EFFECTIVE DATE AND WILL REMAIN IN EFFECT UNTIL JULY 30, 2019 (THE "INITIAL TERMINATION DATE"), OR LONGER IF MUTUALLY AGREED BY THE PARTIES IN WRITING. IF COMPANY BREACHES A MATERIAL PROVISION OF THIS AGREEMENT, CONSULTANT MAY TERMINATE THIS AGREEMENT UPON 30 DAYS WRITTEN NOTICE, UNLESS THE BREACH IS CURED WITHIN THAT PERIOD. COMPANY MAY TERMINATE THIS AGREEMENT AT ANY TIME, WITH OR WITHOUT CAUSE, UPON WRITTEN NOTICE. IF PRIOR TO THE INITIAL TERMINATION, (I) THE COMPANY TERMINATES WITHOUT CAUSE OR (II) THE COMPANY IS SUBJECT TO A CHANGE IN CONTROL (AS DEFINED IN SCHEDULE A), CONSULTANT SHALL VEST IN SUCH NUMBER OF SHARES SUBJECT TO THE OPTIONS WHICH HE WOULD HAVE VESTED THROUGH THE INITIAL TERMINATION DATE. SECTIONS 2 THROUGH 5 (INCLUSIVE) OF THIS AGREEMENT, AND ANY REMEDIES FOR BREACH OF THIS AGREEMENT, SHALL SURVIVE ANY TERMINATION OR EXPIRATION.**

5. General Provisions.

A. RELATIONSHIP. **NOTWITHSTANDING ANY PROVISION HEREOF, FOR ALL PURPOSES OF THIS AGREEMENT EACH PARTY SHALL BE AND ACT AS AN INDEPENDENT CONTRACTOR AND NOT AS PARTNER, JOINT VENTURER, EMPLOYER, EMPLOYEE OR AGENT OF THE OTHER AND SHALL NOT BIND NOR ATTEMPT TO BIND THE OTHER TO ANY CONTRACT. CONSULTANT IS AN INDEPENDENT CONTRACTOR AND IS SOLELY RESPONSIBLE FOR ALL TAXES, WITHHOLDINGS, AND OTHER STATUTORY OR CONTRACTUAL OBLIGATIONS OF ANY SORT, INCLUDING, BUT NOT LIMITED TO, WORKERS' COMPENSATION INSURANCE. CONSULTANT AGREES TO DEFEND, INDEMNIFY AND HOLD COMPANY HARMLESS FROM ANY AND ALL CLAIMS, DAMAGES, LIABILITIES, LOSSES, ATTORNEYS' FEES AND EXPENSES ON ACCOUNT OF (A) AN ALLEGED FAILURE BY CONSULTANT TO SATISFY ANY SUCH OBLIGATIONS OR ANY OTHER OBLIGATION (UNDER THIS AGREEMENT OR OTHERWISE) OR (B) ANY OTHER ACTION OR INACTION OF CONSULTANT. IF CONSULTANT IS A CORPORATION OR OTHER ENTITY, IT WILL ENSURE THAT ITS EMPLOYEES AND AGENTS ARE BOUND IN WRITING TO CONSULTANT'S OBLIGATIONS UNDER THIS AGREEMENT.**

b. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflicts of law provisions. Exclusive jurisdiction and venue for any action arising under this Agreement is in the federal and state courts located in Massachusetts, and both parties hereby consent to such jurisdiction and venue for this purpose. In any action or proceeding to enforce this Agreement, the prevailing party will be entitled to recover from the other party its costs and expenses (including reasonable attorneys' fees) incurred in connection with such action or proceeding and enforcing any judgment or order obtained.

c. Remedies. Consultant acknowledges and agrees that in the event of any breach or threatened breach of Section 2 or 3, Company will suffer irreparable damage for which it will have no adequate remedy at law. Accordingly, Company shall be entitled to injunctive and other equitable remedies to prevent or restrain, temporarily or permanently, such breach or threatened breach, without the necessity of proving actual damages or posting any bond or surety, in addition to any other remedy that Company may have at law or in equity.

D. NOTICE. **ANY NOTICE REQUIRED OR PERMITTED TO BE GIVEN HEREUNDER WILL BE EFFECTIVE UPON RECEIPT AND SHALL BE GIVEN IN WRITING, IN ENGLISH AND DELIVERED IN PERSON, VIA ESTABLISHED EXPRESS COURIER SERVICE (WITH CONFIRMATION OF RECEIPT), CONFIRMED FACSIMILE OR REGISTERED OR CERTIFIED MAIL, POSTAGE PREPAID, RETURN RECEIPT REQUESTED, TO THE PARTIES AT THEIR RESPECTIVE ADDRESSES GIVEN HEREIN OR AT SUCH OTHER ADDRESS DESIGNATED BY WRITTEN NOTICE.**

E. ASSIGNMENT. **THIS AGREEMENT AND THE PERFORMANCE CONTEMPLATED HEREUNDER ARE PERSONAL TO CONSULTANT AND CONSULTANT SHALL NOT HAVE THE RIGHT OR ABILITY TO SUBCONTRACT, DELEGATE, ASSIGN OR OTHERWISE TRANSFER ANY RIGHTS OR OBLIGATIONS UNDER THIS AGREEMENT WITHOUT THE PRIOR WRITTEN CONSENT OF COMPANY. ANY ATTEMPT TO DO OTHERWISE SHALL BE VOID AND OF NO EFFECT. COMPANY MAY TRANSFER THIS AGREEMENT WITHOUT THE CONSENT OF CONSULTANT. THIS AGREEMENT WILL BE BINDING UPON, AND INURE TO THE BENEFIT OF, THE SUCCESSORS, REPRESENTATIVES AND PERMITTED ASSIGNS OF THE PARTIES.**

f. Miscellaneous. This Agreement (including any applicable Statements of Work) constitutes the entire agreement, and supersedes all prior negotiations, understandings or agreements (oral or written), between the parties concerning the subject matter of this Agreement (and all past dealing or industry custom). Headings are for convenience of reference only and shall in no way affect interpretation of the Agreement. This Agreement may be executed in one or more counterparts, each of which is an original, but taken together constituting one and the same instrument. Execution of a facsimile copy (including PDF) shall have the same force and effect as execution of an original, and a facsimile signature shall be deemed an original and valid signature. No change, consent or waiver to this Agreement will be effective unless in writing and signed by the party against which enforcement is sought. The failure of a party to enforce its rights under this Agreement at any time for any period will not be construed as a waiver of such rights. Unless expressly provided otherwise, each right and remedy in this Agreement is in addition to any other right or remedy, at law or in equity, and the exercise of one right or remedy will not be deemed a waiver of any other right or remedy. In the event that any provision of this Agreement is determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement will otherwise remain in full force and effect and enforceable.

IN WITNESS WHEREOF, intending to be legally bound, the parties have executed this Agreement as an instrument under seal as of the Effective Date.

CONSULTANT

By: /s/ Todd Brady
Name: Todd Brady
Title: Chief Executive Officer

ALDEYRA THERAPEUTICS, INC.

By: /s/ Stephen Tulipano
Name: Stephen Tulipano
Title: Consultant

ALDEYRA THERAPEUTICS™

SCHEDULE A

During the term of this agreement, Consultant shall continue to vest in the following options to purchase Common Stock of the Company (collectively, the "Options"):

Grant Date	Original Type of Grant	Exercise Price	Shares originally subject to Option	Vested as of July 27, 2018	Unvested as of July 27, 2018	Vesting Schedule
03/16/2016	NSO	$ 4.59	19,975	16,850	3,125	(1)
03/03/2017	NSO	$ 5.10	220,980	82,867	138,113	(2)
03/06/2018	NSO	$ 8.60	125,670	15,708	109,962	(3)
06/03/2015	ISO	$ 7.85	10,751	7,626	3,125	(4)
03/16/2016	ISO	$ 4.59	10,025	1,900	8,125	(5)

(1) Option vests with respect to 416 shares on the monthly anniversary of the grant date.
(2) Option vests with respect to 4,604 shares on the monthly anniversary of the grant date.
(3) Option vests with respect to 2,618 shares on the monthly anniversary of the grant date.
(4) Option vests with respect to 224 shares on the monthly anniversary of the grant date.
(5) Option vests with respect to 209 shares on the monthly anniversary of the grant date.

For purposes of this Agreement, "Change in Control" shall mean any of the following has occurred:

1. Any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities;

2. The consummation of the sale or disposition by the Company of all or substantially all of the Company's assets;

3. The consummation of a merger or consolidation of the Company with or into any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or

4. Individuals who are members of the Board of Directors of the Company (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board of Directors of the Company over a period of 12 months; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In addition, if a Change in Control constitutes a payment event with respect to any award which provides for

a deferral of compensation and is subject to Section 409A of the Internal Revenue Code of 1986, as amended ("Code Section 409A"), then notwithstanding anything to the contrary contained herein or applicable option agreement the transaction with respect to such award must also constitute a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Code Section 409A.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd C. Brady, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aldeyra Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 14, 2018

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER AND PRINCIPAL ACCOUNTING OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua Reed, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aldeyra Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 14, 2018

/s/ Joshua Reed

Joshua Reed
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Aldeyra Therapeutics, Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 14, 2018

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

Todd C. Brady, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

November 14, 2018

/s/ Joshua Reed

Joshua Reed
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.