Aldeyra Therapeutics, Inc.
Form 10-Q
May 15, 2018
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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 March 31, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	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 May 15, 2018, there were 20,109,394 shares of the registrant s common stock issued and outstanding.

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Aldeyra Therapeutics, Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended March 31, 2018

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Part I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

ALDEYRA THERAPEUTICS, INC.

BALANCE SHEETS

	March 31, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,963,541	$ 20,023,337
Marketable securities	17,974,600	22,923,462
Prepaid expenses and other current assets	1,666,898	1,018,967
Total current assets	40,605,039	43,965,766
Deferred offering costs		165,930
Fixed assets, net	170,862	43,262
Total assets	$ 40,775,901	$ 44,174,958
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,618,889	$ 1,000,963
Accrued expenses	1,815,428	2,236,465
Current portion of credit facility	232,639	116,319
Total current liabilities	3,666,956	3,353,747
Credit facility, net of current portion and debt discount	1,107,741	1,220,192
Total liabilities	4,774,697	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 19,664,921 and 19,137,639 shares issued and outstanding, respectively	19,665	19,138
Additional paid-in capital	144,036,909	139,241,635
Accumulated other comprehensive loss	(16,385)	(17,831)
Accumulated deficit	(108,038,985)	(99,641,923)

Total stockholders equity	36,001,204	39,601,019
Total liabilities and stockholders equity	$ 40,775,901	$ 44,174,958

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS (Unaudited)

	Three Months ended March 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 6,600,106	$ 3,369,023
General and administrative	1,891,303	1,726,878
Loss from operations	(8,491,409)	(5,095,901)
Other income (expense):		
Interest income	122,390	31,617
Interest expense	(28,044)	(26,837)
Total other income, net	94,346	4,780
Net loss	$ (8,397,063)	$ (5,091,121)
Net loss per share - basic and diluted	$ (0.43)	$ (0.37)
Weighted average common shares outstanding - basic and diluted	19,366,790	13,797,312

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

	Three Months ended March 31,	
	2018	**2017**
Net loss	$ (8,397,063)	$ (5,091,121)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	1,446	(4,876)
Total other comprehensive income (loss)	$ 1,446	$ (4,876)
Comprehensive loss	$ (8,395,617)	$ (5,095,997)

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

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ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS (Unaudited)

	Three months ended March 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,397,063)	$ (5,091,121)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	868,415	858,096
Amortization of debt discount non-cash interest expense	3,869	5,196
Net amortization of premium on debt securities available for sale	9,822	79,775
Depreciation	11,406	9,660
Change in assets and liabilities:		
Prepaid expenses and other current assets	(647,931)	(42,001)
Accounts payable	617,926	419,481
Accrued expenses	(421,037)	(425,929)
Net cash used in operating activities	(7,954,593)	(4,186,843)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(139,006)	(11,592)
Purchases of marketable securities	(4,009,513)	(3,151,867)
Sales of marketable securities	8,950,000	4,055,000
Net cash provided by investing activities	4,801,481	891,541
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	4,093,316	10,583,091
Net cash provided by financing activities	4,093,316	10,583,091
NET CHANGE IN CASH AND CASH EQUIVALENTS	940,204	7,287,789
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	20,023,337	12,015,061
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 20,963,541	$ 19,302,850
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 22,682	$ 20,162

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

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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 raising capital and research and development activities.

2. BASIS OF PRESENTATION

The accompanying interim unaudited condensed financial statements and related disclosures are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company s financial statements and related footnotes for the year ended December 31, 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 March 31, 2018, the three months ended March 31, 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℠ Sales agreement (Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), as sales agent, pursuant to which the Company may offer and sell, 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 may sell 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 issued, the time period during which sales are 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 provides that Cantor will be 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 has no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitations and offers under the Sales Agreement. From January 1, 2018 through March 31, 2018, the Company sold an aggregate of 527,000 shares of common stock and received $4.1 million after deducting commissions related to the Sales Agreement. From April 1, 2018 through May 15, 2018, the Company sold an aggregate of 444,000 shares of its common stock and received $3.2 million after deducting commissions related to the Sales Agreement.

The Company believes that its cash, cash equivalents and marketable securities as of March 31, 2018, together with the proceeds from the Sales Agreement through May 15, 2018 and the amounts available under the credit facility (Note 7), will be adequate to fund operations into the first quarter of 2020 based on its current business plan. The

Company will need to raise additional capital to implement its business plan. However, these amounts will not be sufficient for the Company to commercialize its product candidates or conduct any substantial, additional development requirements requested by the U.S. Food and Drug Administration (FDA). Additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to secure additional capital, or meet financial covenants that could be implemented under the Company s term loans in certain circumstances, it will be required to significantly decrease the amount of planned expenditures, and may be required to cease operations.

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

Use of estimates

The preparation of financial statements in conformity with 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

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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 August 2016, the FASB issued Accounting Standards Update (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. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. ASU 2016-15 may be adopted retrospectively or prospectively if it is impractical to apply the amendments retrospectively. The Company 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. The Company is currently evaluating the impact this standard might have on its financial statements.

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 and is effective for fiscal years beginning after December 15, 2017. 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. ASU 2014-09 is effective for fiscal years beginning after December 15, 2017. 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.

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3. NET LOSS PER SHARE

As of March 31, 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 March 31,	
	2018	2017
Options to purchase common stock	3,066,856	2,238,121
Warrants to purchase common stock	60,000	1,384,608
Restricted stock units	253,272	163,902
Total of common stock equivalents	3,380,128	3,786,631

4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

At March 31, 2018, cash, cash equivalents and marketable securities were comprised of:

	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$ 1,345,392	$	$	$ 1,345,392	$ 1,345,392	$
Money market funds	2,618,149			2,618,149	2,618,149	
Reverse repurchase agreements	17,000,000			17,000,000	17,000,000	
U.S. government agency securities	17,990,985	183	(16,568)	17,974,600		17,974,600
Available for Sale(1)	34,990,985	183	(16,568)	34,974,600	17,000,000	17,974,600
Total cash, cash equivalents and current marketable securities					$ 20,963,541	$ 17,974,600

(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 March 31, 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.

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There were no liabilities measured at fair value at March 31, 2018 or December 31, 2017. The following table presents information about the Company s assets measured at fair value at March 31, 2018 and December 31, 2017:

	March 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (a)	$ 2,618,149	$	$	$ 2,618,149
Reverse repurchase agreements (b)		17,000,000		17,000,000
U.S. government agency securities (b)		17,974,600		17,974,600
Total assets at fair value	$ 2,618,149	$ 34,974,600	$	$ 37,592,749

	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) U.S. 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 rates currently available to the Company. Marketable securities are carried at fair value.

6. ACCRUED EXPENSES

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

	March 31, 2018	December 31, 2017
Accrued compensation	$ 435,448	$ 788,570

Accrued research and development	1,063,004	1,327,103
Accrued general & administrative	316,976	120,792
Accrued expenses	$ 1,815,428	$ 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 March 31, 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, we amended our 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.

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The Credit Facility is collateralized by 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. These discounts are 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 March 31, 2018 and December 31, 2017, the Credit Facility is shown net of a remaining debt discount of $55,500 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 has 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 such 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 March 31, 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 March 31, 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. On January 1 of each year the aggregate number of common shares that may be issued under the 2013 Plan shall

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automatically increase by such a number of shares equal to the least of (a) 7% of the total number of common shares outstanding on the last calendar day of the prior fiscal year, (b) subject to adjustment for certain corporate transactions, 1,000,000 common shares, or (c) a number of common shares determined by the Company s board of directors. As of March 31, 2018, options to purchase 2,629,772 shares of common stock at a weighted average exercise price of $6.54 per share and 219,071 shares of common stock underlying restricted stock units (RSU s) remained outstanding under the 2013 Plan. As of March 31, 2018, there were 863,713 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 March 31,	
	2018	2017
Research and development expenses	$ 351,812	$ 262,964
General and administrative expenses	516,603	595,132
Total stock-based compensation expense	$ 868,415	$ 858,096

Stock Options

The table below summarizes activity relating to stock options under the incentive plans for the three months ended March 31, 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	819,999	8.50		
Cancelled				
Forfeited				
Exercised				
Outstanding at March 31, 2018	3,066,856	$ 5.84	8.20	$ 6,037,040
Exercisable at March 31, 2018	1,296,368	$ 4.62	6.84	$ 3,866,261

(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 March 31, 2018 of $7.50 and the price of the underlying options.

As of March 31, 2018, unamortized stock-based compensation for all stock options was $7,743,412 and will be recognized over a weighted average period of 3.17 years.

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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 three months ended March 31, 2018:

	Number of Shares
Outstanding at December 31, 2017	157,128
Granted	96,144
Vested/released	
Outstanding at March 31, 2018	253,272

The weighted-average fair value of RSUs granted was $8.60 per share for the quarter ended March 31, 2018. As of March 31, 2018, the outstanding restricted stock units had unamortized stock-based compensation of $1,405,641 with a weighted-average remaining recognition period of 3.45 years and an aggregate intrinsic value of $1.9 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 initial issuance of up to a total of 223,263 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. As of March 31, 2017, there was no activity under the 2016 ESPP. At March 31, 2018, the Company had 191,778 shares available for issuance under the 2016 ESPP. Total expense under the Plan for the quarter ended March 31, 2018 was $14,510.

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 in January 2018.

In connection with the Initial Public Offering, the Company issued the underwriters of the offering warrants to purchase up to 60,000 shares of common stock. The warrants are exercisable beginning on May 1, 2015 for cash or on a cashless basis at a per share price of $10.00. The warrants will expire on May 1, 2019 and were outstanding at March 31, 2018.

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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

From April 1, 2018 through May 15, 2018, we sold an aggregate of 444,000 shares of our common stock and received $3.2 million after deducting commissions related to the Sales Agreement with Cantor.

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

Cautionary Note Regarding Forward-Looking Statements

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

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

our ability to attract or retain key personnel;

our ability to establish and maintain development partnerships;

our expectations regarding federal, state and foreign regulatory requirements;

regulatory developments in the United States and foreign countries;

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

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

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

We encourage you to read Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors, as well as our unaudited financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read our Annual Report on Form 10-K for the year ended December 31, 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.

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Overview

Aldeyra Therapeutics (we, us or the Company) 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. We intend to commercialize our products directly and through collaborations that expand global reach.

Our program in dry eye disease has begun Phase 2b clinical testing. Our programs in noninfectious anterior uveitis and allergic conjunctivitis have begun Phase 3 clinical testing, and our program Sjögren-Larsson Syndrome is expected to begin Phase 3 clinical testing in the second quarter of 2018. Our systemic inflammation programs are expected to begin clinical testing in 2019. A novel product candidate is in pre-clinical development for retinal disease. All of our development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, completion, or reporting of clinical trials.

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

In 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 may offer and sell, 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 may sell 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 issued, the time period during which sales are 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 provides that Cantor will be 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 have no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitations and offers under the Sales Agreement. From January 1, 2018 through March 31, 2018, we sold an aggregate of 527,000 shares of common stock and received $4.1 million after deducting commissions related to the Sales Agreement. From April 1, 2018 through May 15, 2018, we sold an aggregate of 444,000 shares of our common stock and received $3.2 million after deducting commissions related to the Sales Agreement.

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.

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;

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- 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 months ended March 31, 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 March 31, 2018, comprehensive loss is equal to our net loss of $8.4 million and an unrealized gain on marketable securities of $1,446. For March 31, 2017, comprehensive loss is equal to our net loss of $5.1 million and an unrealized loss on marketable securities of $4,876.

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.

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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 March 31, 2018 compared to three months ended March 31, 2017

Research and development expenses. Research and development expenses were $6.6 million for the three months ended March 31, 2018, compared to $3.4 million for the three months ended March 31, 2017. The increase of $3.2 million is primarily related to the increases in our external research and development expenditures, including clinical, manufacturing and pre-clinical activities.

General and administrative expenses. General and administrative expenses were $1.9 million for the three months ended March 31, 2018, compared to $1.7 million for the three months ended March 31, 2017. The increase of $0.2 million is primarily related to an increase in personnel costs, including stock-based compensation, and legal costs.

Other income (expense). Total other income (expense), net was $94,346 and $4,780 for the three months ended March 31, 2018 and 2017, respectively. For the three months ending March 31, 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 March 31, 2018, we had total stockholders equity of approximately $36.0 million, and cash, cash equivalents, and marketable securities of $38.9 million. During the three months ended March 31, 2018, we had a net loss of approximately $8.4 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 March 31, 2018 and December 31, 2017, $1.4 million was outstanding under the Credit Facility. At March 31, 2018 and December 31, 2017, the Credit Facility is shown net of a remaining debt discount of $55,500 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 February 2017, we closed an underwritten public offering in which we sold, 2,555,555 shares of our common stock, including 333,333 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $10.6 million after deducting underwriting discounts and commissions and the other offering expenses payable by us.

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 may offer and sell, 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 may sell 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 issued, the time period during which sales are 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 provides that Cantor will be 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 have no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitations and offers under the Sales Agreement. From January 1, 2018 through March 31, 2018, we sold an aggregate of 527,000 shares of our common stock and received $4.1 million after deducting commissions related to the Sales Agreement. From April 1, 2018 through May 15, 2018, we sold an aggregate of 444,000 shares of our common stock and received $3.2 million after deducting commissions related to the Sales Agreement.

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In September 2017, we closed an underwritten public offering in which we sold an aggregate of 3,967,500 shares of common stock, including 517,500 shares sold in connection with the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately $26.9 million, after deducting underwriting discounts, commissions, and other offering expenses payable by us.

We believe that our cash, cash equivalents, and marketable securities as of March 31, 2018, together with the proceeds of the sales of common stock under the Sales Agreement through May 15, 2018 and the amounts available under the Credit Facility, will be adequate to fund operations into the first quarter of 2020 based on our current business plan. However, these amounts will not be sufficient for us to commercialize our product candidates or conduct any substantial, additional development requirements requested by the FDA. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued clinical development of 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.

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The following table summarizes our cash flows for the three months ended March 31, 2018 and 2017:

	Three Months ended March 31,	
	2018	2017
Net cash used in operating activities	$ (7,954,593)	$ (4,186,843)
Net cash provided by/(used in) investing activities	4,801,481	891,541
Net cash provided by/(used in) financing activities	4,093,316	10,583,091
Net increase (decrease) in cash and cash equivalents	$ 940,204	$ 7,287,788

Operating Activities. Net cash used in operating activities was $8.0 million for the three months ended March 31, 2018, compared to net cash used in operating activities of $4.2 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 three months ended March 31, 2018 as compared to 2017 was due to an increase in research and development expenses, including clinical, manufacturing, and preclinical activities.

Investing Activities. Net cash provided by investing activities was $4.8 million for the three months ended March 31, 2018, and $0.9 million used in investing activities for the three months ended March 31, 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 three months ended March 31, 2018. The primary source of cash for investing activities for the three months ended March 31, 2018 was from the sale of marketable securities. The net primary use of cash for the three months ended March 31, 2017 was for the purchase of marketable securities and computers and related equipment.

Financing Activities. Net cash provided by financing activities was $4.1 million for the three months ended March 31, 2018, compared to $10.6 million for the three months ended March 31, 2017. The net cash provided by financing activities for the three months ended March 31, 2018 was related to our Sales Agreement with Cantor, under which we sold an aggregate of 527,000 shares of our common stock, resulting in $4.1 million in proceeds after deducting commissions. The net cash provided by financing activities for the three months ended March 31, 2017 was related to our February 2017 underwritten public offering.

Off-Balance Sheet Arrangements

Through March 31, 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

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.

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.

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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 March 31, 2017. 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.

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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 March 31, 2018 and 2017 was approximately $8.5 million and $5.1 million, respectively. As of March 31, 2018, we had total stockholders equity of $36.0 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;

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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.

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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 need to 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 planned 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 program in allergic conjunctivitis. Thus, the 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.

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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;

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- 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;

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- 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.

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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.

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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;

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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 or Breakthrough Therapy 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. 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 or Breakthrough Therapy Designation for reproxalap or our other product candidates, our regulatory and commercial prospects may be negatively impacted.

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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 March 31, 2018, we had only 14 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.

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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.

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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.

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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 three individuals and certain other employees: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; Stephen J. Tulipano, our Chief Financial Officer; and David J. Clark, M.D., our Chief Medical Officer. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, 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 March 31, 2018, we only had 14 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.

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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.

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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