# 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 June 30, 2019**

**or**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-36332**

# ALDEYRA THERAPEUTICS, INC.

**(Exact name of registrant as specified in its charter)**

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

**(781) 761-4904**
**(Registrant's telephone number, including area code)**

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

Securities registered pursuant to 12(b) of the Act:

| Title of Class | Trading Symbol | Name of exchange on which registered |
|---|---|---|
| Common Stock, $0.001 par value per share | ALDX | The Nasdaq Stock Market LLC |

As of August 9, 2019, there were 27,578,247 shares of the registrant's common stock issued and outstanding.

**Aldeyra Therapeutics, Inc.**

**Quarterly Report on Form 10-Q**
**For the Quarter Ended June 30, 2019**

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**Part I – FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements**

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | June 30, 2019 (unaudited) | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,399,564 | $ 3,357,472 |
| Cash equivalent - Reverse Repurchase Agreements | 32,000,000 | 44,000,000 |
| Marketable securities | 30,057,408 | 46,242,220 |
| Prepaid expenses and other current assets | 3,398,930 | 1,169,594 |
| Total current assets | 72,855,902 | 94,769,286 |
| Deferred offering costs | — | 86,644 |
| Debt issuance costs | 492,448 | — |
| Right-of-use assets | 294,173 | — |
| Fixed assets, net | 196,491 | 235,225 |
| Total assets | $ 73,839,014 | $ 95,091,155 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,773,987 | $ 3,051,678 |
| Accrued expenses | 3,403,789 | 5,421,498 |
| Current portion of operating lease liabilities | 211,744 | — |
| Total current liabilities | 6,389,520 | 8,473,176 |
| Operating lease liabilities, long-term | 116,124 | — |
| Total liabilities | 6,505,644 | 8,473,176 |
| Commitments and contingencies (Notes 14 and 15) | | |
| 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 26,986,936 and 26,244,435 shares issued and outstanding, respectively | 26,987 | 26,244 |
| Additional paid-in capital | 234,779,291 | 225,136,127 |
| Accumulated other comprehensive income (loss) | 13,453 | (9,224) |
| Accumulated deficit | (167,486,361) | (138,535,168) |
| Total stockholders’ equity | 67,333,370 | 86,617,979 |
| Total liabilities and stockholders’ equity | $ 73,839,014 | $ 95,091,155 |

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

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development | $ 10,664,858 | $ 6,792,974 | $ 18,513,448 | $ 13,393,080 |
| Acquired in-process research and development | (49,848) | — | 6,547,703 | — |
| General and administrative | 3,116,414 | 2,373,059 | 6,101,452 | 4,264,360 |
| Loss from operations | (13,731,424) | (9,166,033) | (31,162,603) | (17,657,440) |
| Other income (expense): | | | | |
| Interest income | 432,908 | 141,956 | 932,049 | 264,346 |
| Interest expense | (28,649) | (26,358) | (30,612) | (54,402) |
| Total other income (expense), net | 404,259 | 115,598 | 901,437 | 209,944 |
| Loss before income taxes | (13,327,165) | (9,050,435) | (30,261,166) | (17,447,496) |
| Income tax benefit | — | — | 1,309,973 | — |
| Net loss | $ (13,327,165) | $ (9,050,435) | $ (28,951,193) | $ (17,447,496) |
| Net loss per share - basic and diluted | $ (0.49) | $ (0.46) | $ (1.08) | $ (0.88) |
| Weighted average common shares outstanding - basic and diluted | 26,985,454 | 19,761,352 | 26,836,292 | 19,761,352 |

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

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Net loss | $ (13,327,165) | $ (9,050,435) | $ (28,951,193) | $ (17,447,496) |
| Other comprehensive income: | | | | |
| Unrealized gain on marketable securities | 6,641 | 13,826 | 22,677 | 15,272 |
| Total other comprehensive income | $ 6,641 | $ 13,826 | $ 22,677 | $ 15,272 |
| Comprehensive loss | $ (13,320,524) | $ (9,036,609) | $ (28,928,516) | $ (17,432,224) |

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

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)**

| | Stockholders' Equity | | | | | |
|---|---|---|---|---|---|---|
| | Common Voting Stock | | | | | |
| | Shares | Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Income/(Loss), net of tax | Accumulated Deficit | Total Stockholders' Equity |
| Balance, December 31, 2018 | 26,244,435 | $ 26,244 | $225,136,127 | $ (9,224) | $ (138,535,168) | $ 86,617,979 |
| Stock-based compensation | — | — | 3,981,052 | — | — | 3,981,052 |
| Issuance of common stock in connection with Helio Vision, Inc. acquisition | 582,363 | 582 | 4,862,149 | — | — | 4,862,731 |
| Issuance of common stock, net of issuance costs | 83,557 | 84 | 720,879 | — | — | 720,963 |
| Issuance of common stock, employee stock purchase plan | 11,569 | 12 | 79,149 | | | 79,161 |
| Issuance of common stock for vested restricted stock units | 65,012 | 65 | (65) | | | — |
| Other comprehensive income | — | — | — | 22,677 | — | 22,677 |
| Net loss | — | — | — | — | (28,951,193) | (28,951,193) |
| Balance, June 30, 2019 | 26,986,936 | $ 26,987 | $234,779,291 | $ 13,453 | $ (167,486,361) | $ 67,333,370 |
| | | | | | | |
| Balance, December 31, 2017 | 19,137,639 | 19,138 | 139,241,635 | (17,831) | (99,641,923) | 39,601,019 |
| Stock-based compensation | — | — | 1,853,199 | — | — | 1,853,199 |
| Issuance of common stock, net of issuance costs | 1,663,584 | 1,663 | 12,956,940 | — | — | 12,958,603 |
| Issuance of common stock for vested restricted stock units | 40,975 | 41 | (41) | | | — |
| Other comprehensive income | — | — | — | 15,272 | — | 15,272 |
| Net loss | — | — | — | — | (17,447,496) | (17,447,496) |
| Balance, June 30, 2018 | 20,842,198 | $ 20,842 | $154,051,733 | $ (2,559) | $ (117,089,419) | $ 36,980,597 |

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

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)**

| | Stockholders' Equity | | | | | |
|---|---|---|---|---|---|---|
| | Common Voting Stock | | | | | |
| | Shares | Amount | Additional Paid-in Capital | Accumulated Other Comprehensive Income/(Loss), net of tax | Accumulated Deficit | Total Stockholders' Equity |
| Balance, March 31, 2019 | 26,910,355 | $ 26,910 | $ 232,605,244 | $ 6,812 | $ (154,159,196) | $ 78,479,770 |
| Stock-based compensation | — | — | 2,094,963 | — | — | 2,094,963 |
| Issuance of common stock, employee stock purchase plan | 11,569 | 12 | 79,149 | | | 79,161 |
| Issuance of common stock for vested restricted stock units | 65,012 | 65 | (65) | | | — |
| Other comprehensive income | — | — | — | 6,641 | — | 6,641 |
| Net loss | — | — | — | — | (13,327,165) | (13,327,165) |
| Balance, June 30, 2019 | 26,986,936 | $ 26,987 | $ 234,779,291 | $ 13,453 | $ (167,486,361) | $ 67,333,370 |
| | | | | | | |
| Balance, March 31, 2018 | 19,664,921 | $ 19,665 | $ 144,036,909 | $ (16,385) | $ (108,038,986) | $ 36,001,203 |
| Stock-based compensation | — | — | 984,784 | — | — | 984,784 |
| Issuance of common stock, net of issuance costs | 1,136,302 | 1,136 | 9,030,081 | — | — | 9,031,217 |
| Issuance of common stock for vested restricted stock units | 40,975 | 41 | (41) | | | — |
| Other comprehensive income | — | — | — | 13,826 | — | 13,826 |
| Net loss | — | — | — | — | (9,050,433) | (9,050,433) |
| Balance, June 30, 2018 | 20,842,198 | $ 20,842 | $ 154,051,733 | $ (2,559) | $ (117,089,419) | $ 36,980,597 |

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

**ALDEYRA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (28,951,193) | $ (17,447,496) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development | 6,547,703 | — |
| Deferred taxes | (1,309,973) | — |
| Stock-based compensation | 3,981,052 | 1,853,199 |
| Amortization of debt discount – non-cash interest expense | 30,738 | 7,738 |
| Net amortization of premium on debt securities available for sale | (341,758) | 7,163 |
| Depreciation | 48,263 | 29,282 |
| Change in assets and liabilities: | | |
| Prepaid expenses and other current assets | (2,138,104) | (373,938) |
| Accounts payable | (956,174) | (198,838) |
| Accrued expenses | (2,353,411) | 1,922,606 |
| Net cash used in operating activities | $ (25,442,857) | (14,200,284) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Acquisitions of property and equipment | (9,529) | (200,763) |
| Cash acquired in Helio asset acquisition | 562,362 | — |
| Purchases of marketable securities | (21,466,353) | (12,091,149) |
| Sales of marketable securities | 38,000,000 | 17,950,000 |
| Net cash provided by investing activities | 17,086,480 | 5,658,088 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock, net of issuance costs | 720,964 | 13,124,533 |
| Proceeds from employee stock purchase plan | 79,161 | — |
| Debt issuance costs paid in cash | (401,656) | — |
| Net cash provided by financing activities | 398,469 | 13,124,533 |
| NET (DECREASE)/INCREASE IN CASH | (7,957,908) | 4,582,337 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 47,357,472 | 20,023,337 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 39,399,564 | $ 24,605,674 |
| SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES: | | |
| Helio acquisition: | | |
| Assets acquired | $ 75,632 | $ — |
| Liabilities acquired | $ 637,994 | $ — |
| Fair value of securities issued | $ 4,862,731 | $ — |
| Debt issuance costs not yet paid | $ 121,530 | $ — |
| Right-of-use assets acquired through operating leases | $ 386,060 | $ — |
| Cash paid during the period for interest | $ — | $ 46,877 |

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

## 1. NATURE OF BUSINESS

Aldeyra Therapeutics, Inc., together with its wholly-owned subsidiaries (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 consolidated 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 notes for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the Securities and Exchange Commission on March 8, 2019. The financial information as of June 30, 2019, and the three and six months ended June 30, 2019 and 2018 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, 2018 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.

Based on its current operating plan, and not including access to capital under the Company's credit facility or the Open Market Sales Agreement SM (Jefferies Sales Agreement), the Company believes that its cash, cash equivalents, and marketable securities as of June 30, 2019, will be adequate to fund currently anticipated operating expenses through the end of 2020, including the currently planned Phase 3 clinical trial in dry eye disease (the RENEW trial) and the initial part of the currently planned adaptive Phase 3 clinical trial in proliferative vitreoretinopathy (the GUARD trial). The Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all planned research and development activities; commercialize product candidates; or conduct any substantial, additional development requirements requested by the 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, 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 GAAP requires management to make estimates and assumptions, including fair value estimates for investments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's financial statements relate to accruals, including research and development costs, acquired in-process research and development expense, accounting for income taxes and related valuation allowance and accounting for stock-based compensation and related fair value assessments. Although estimates and assumptions 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.

### *In-process research and development*

Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired are deemed to have an alternative future use, provided that the acquired asset did not also include processes or activities that would constitute a "business" as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Acquired in-process research and development payments are immediately expensed in the period in which they are incurred and include upfront payments, as well as transaction fees and subsequent pre-commercial milestone payments. Research and development costs incurred after the acquisition are expensed as incurred.

***Recent Accounting Pronouncements***

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 adopted the provisions of ASU 2016-02 as of January 1, 2019, and the provisions did not have a material impact on the Company's financial statements.

## 3. HELIO VISION ACQUISITION

On January 28, 2019 (the closing date), the Company acquired Helio Vision, Inc. (Helio). As a result of the acquisition, the Company initially issued an aggregate of 1,150,990 shares of common stock to the former securityholders and an advisor of Helio. The founders of Helio were issued 568,627 shares and non-founders were issued 582,363 shares. The Helio founders' shares are subject to vesting based on continued service to the Company over three years from the closing date. The Company will recognize the expense associated with the founders' restricted shares as compensation expense on a straight-line basis as the shares vest over the three-year period. For the three and six months ended June 30, 2019, the Company recorded $0.6 million and $1.0 million, respectively, of research and development expense for the founders' restricted shares. The Company, subject to the conditions of the acquisition agreement, will be obligated to make additional payments to the former securityholders of Helio as follows: (a) $2.5 million of common stock on the date that is 24 months following the closing date (assuming certain technical milestones are met); (b) $10.0 million of common stock following approval by the FDA of a new drug approval application for the prevention and/or treatment of proliferative vitreoretinopathy or a substantially similar label prior to the 10th anniversary of the closing date; and (c) $2.5 million of common stock following FDA approval of a new drug application for an indication (other than proliferative vitreoretinopathy) prior to the 12th anniversary of the closing date (the shares of common stock issuable pursuant to the preceding clauses (a) – (c) are referred to herein as the Milestone Shares), provided that in no event shall the Company be obligated to issue more than an aggregate of 5,248,885 shares of common stock. Additionally, in the event of certain change of control or divestitures by the Company, certain former convertible noteholders of Helio will be entitled to a tax gross-up payment in an amount not to exceed $1.0 million.

The Company determined that liability accounting is not required for the Milestone Shares under FASB ASC (Accounting Standards Council) Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The Company then determined that the Milestone Shares meet the scope exception from derivative under FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), from inception of the Milestone Shares through June 30, 2019. Accordingly, the Milestone Shares are evaluated under FASB ASC Topic 450, *Contingencies* (ASC 450) and the Company will record a liability related to the Milestone Shares if and when the milestones are achieved, and the consideration becomes probable. At that time, the Company will record the cost of the Milestone Shares issued to the founders as compensation expense and to the Helio non-founders as in-process research and development expense if there is no alternative future use. No milestones related to the Milestone Shares are probable of being achieved as of June 30, 2019.

The Company assessed the acquisition of Helio under the FASB ASC Topic 805, *Business Combinations* (ASC 805). Under ASC 805, the Company determined that the acquired assets did not constitute a business since substantially all of the assets acquired were related to ADX-2191 and that the transaction would be accounted for as an asset acquisition. The asset and development program acquired from Helio are at an early stage of development and will require a significant investment of time and capital for development. There is no assurance that the Company will be successful in developing such asset, and a failure to successfully develop such asset could diminish the Company's prospects. Under ASC 805, the asset acquired is considered to have no alternative future uses, since the future economic benefit of the acquired asset at the date of acquisition is highly uncertain. The fair value of the assets was determined using the quoted market price of the Company's common stock on the closing date and was fully expensed as in-process research and development. Additionally, the Company assessed the Helio acquisition under ASC Topic 740, *Income Taxes* (ASC 740). The acquisition resulted in an income tax benefit of $1.3 million and a corresponding increase to acquired in-process research and development expense. The expense resulted from the reduction in the Company's valuation allowance due to the deferred tax liability created as a result of the book and tax basis difference during the quarter ended March 31, 2019. During the quarter ended March 31, 2019, the Company recorded $6.6 million in in-process research and development expense related to the fair value of consideration given which includes transaction costs and the deferred tax impact of the Helio acquisition.

## 4. NET LOSS PER SHARE

As of June 30, 2019 and 2018, 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 and Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Options to purchase common stock | 4,817,497 | 3,402,163 |
| Warrants to purchase common stock | — | 60,000 |
| Restricted stock units | 430,425 | 212,297 |
| Unvested restricted shares | 568,627 | — |
| Total of common stock equivalents | 5,816,549 | 3,674,460 |

## 5. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

Cash, cash equivalents, and marketable securities were comprised of:

| | June 30, 2019 | | | | | |
|---|---|---|---|---|---|---|
| | Carrying Amount | Unrecognized Gain | Unrecognized Loss | Estimated Fair Value | Cash Equivalents | Current Marketable Securities |
| Cash | $ 1,963,104 | $ — | $ — | $ 1,963,104 | $ 1,963,104 | $ — |
| Money market funds | 3,438,880 | — | — | 3,438,880 | 3,438,880 | — |
| Reverse repurchase agreements | 32,000,000 | — | — | 32,000,000 | 32,000,000 | — |
| U.S. government agency securities | 32,041,535 | 13,453 | | 32,054,988 | 1,997,580 | 30,057,408 |
| Available for Sale(1) | 64,041,535 | 13,453 | — | 64,054,988 | 33,997,580 | 30,057,408 |
| Total cash, cash equivalents, and current marketable securities | | | | | $ 39,399,564 | $ 30,057,408 |

| | December 31, 2018 | | | | | |
|---|---|---|---|---|---|---|
| | Carrying Amount | Unrecognized Gain | Unrecognized Loss | Estimated Fair Value | Cash and Cash Equivalents | Current Marketable Securities |
| Cash | $ 2,127,175 | $ — | $ — | $ 2,127,175 | $ 2,127,175 | $ — |
| Money market funds | 1,230,297 | — | — | 1,230,297 | 1,230,297 | — |
| Reverse repurchase agreements | 44,000,000 | — | — | 44,000,000 | 44,000,000 | — |
| U.S. government agency securities | 46,251,444 | — | (9,224) | 46,242,220 | — | 46,242,220 |
| Available for Sale(1) | 90,251,444 | — | (9,224) | 90,242,220 | 44,000,000 | 46,242,220 |
| Total Cash, cash equivalents and current marketable securities | | | | | $ 47,357,472 | $ 46,242,220 |

(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 June 30, 2019.

## 6. FAIR VALUE MEASUREMENTS

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

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

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

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

There were no liabilities measured at fair value at June 30, 2019 or December 31, 2018.

Money market funds included in cash and cash equivalents in the consolidated balance sheets, are recorded at fair value and considered as Level 1 inputs under the fair value hierarchy.

Reverse repurchase agreements and U.S. government agency securities are recorded at fair market values and considered as Level 2 inputs under the fair value hierarchy.

Financial instruments including cash equivalents, clinical trial prepayments to contract research organizations, 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.

## 7. ACCRUED EXPENSES

Accrued expenses were comprised of:

| | June 30, 2019 | December 31, 2018 |
|---|---|---|
| Accrued compensation | $ 1,012,314 | $ 1,172,880 |
| Accrued research and development | 1,604,180 | 3,882,313 |
| Accrued general & administrative | 787,295 | 366,305 |
| Accrued expenses | $ 3,403,789 | $ 5,421,498 |

## 8. CREDIT FACILITY

In March 2019, the Company entered into a Loan and Security Agreement with Hercules Capital, Inc. (Hercules) and the several banks and other financial institutions or entities from time to time parties thereto (collectively, referred to as Lender), providing for a term loan of up to $60.0 million that is secured by a lien covering all of the Company's assets, other than the Company's intellectual property (the "Loan and Security Agreement" or the Hercules Credit Facility). The Loan and Security Agreement provides for an initial term loan advance of up to $5.0 million at the Company's option, commencing on March 25, 2019 through and including April 15, 2019; three additional term loan advances of up to $15.0 million, at the Company's option, each available to the Company upon the occurrence of certain funding conditions prior to September 30, 2019, March 31, 2020 and March 31, 2021, respectively; and a final additional term loan advance of up to $10.0 million prior to December 31, 2021, at the Company's option, subject to approval by the Lender's investment committee. As of June 30, 2019, no amount was outstanding under the Hercules Credit Facility. The Company elected not to draw down capital under the initial term loan advance, which ceased to be available on April 15, 2019. The $15.0 million term loan advance that became available upon the satisfaction of the AC ("ALLEVIATE") Milestone (as defined in the Loan and Security Agreement) is expected to be available until September 30, 2019.

The term loan bears interest at an annual rate equal to the greater of (i) 9.10% and (ii) the prime rate (as reported in the Wall Street Journal or any successor publication thereto) plus 3.10%. The Loan and Security Agreement provides for interest-only payments for twenty-four months, with an option to extend the interest-only period to thirty-six months based upon the achievement of certain milestones and repayment of the aggregate outstanding principal balance of the term loan in monthly installments starting upon expiration of the interest only period and continuing through October 1, 2023 (the Maturity Date). In addition, the Company incurred a commitment charge of $25,000, transaction costs of $123,186, and a fee of $375,000 upon closing and is required to pay a fee of 6.95% multiplied by the aggregate amount of advances under the Loan and Security Agreement at maturity. The fees and transaction costs are captured as an asset on the balance sheet and are amortized to interest expense through the Maturity Date. At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus all fees and other amounts due under the Loan and Security Agreement, including a prepayment charge equal to the following percentage of the principal amount being prepaid: 3% if the term loan is prepaid during the first 24 months following the initial closing and 1.5% if the term loan is prepaid any time thereafter but prior to 36 months.

The Loan and Security Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company. In addition, the Company granted the Lender the right to purchase up to an aggregate of $2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in financings upon the same terms and conditions afforded to such other investors.

## 9. STOCKHOLDERS' EQUITY

In December 2018, the Company entered into the Jefferies Sales Agreement with Jefferies LLC (Jefferies), as sales agent, pursuant to which the Company may offer and sell, from time to time through Jefferies, shares of the Company's common stock, par value $0.001 per share, providing for aggregate sales proceeds of up to $50,000,000. Under the Jefferies Sales Agreement, Jefferies may sell such shares of common stock in privately negotiated transactions with our consent; as block transactions; or by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or sales made into any other existing trading market for the Company's common stock, 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 Jefferies Sales Agreement provides that Jefferies will be entitled to a commission rate of up to 3.0% of the aggregate gross proceeds from the sale of shares. The Company has no obligation to sell any shares under the Jefferies Sales Agreement, and may at any time suspend solicitations and offers under the Jefferies Sales Agreement. From January 1, 2019 through June 30, 2019, the Company sold, at a volume-weighted average price of $10.73, an aggregate of 83,557 shares of common stock and received $0.7 million after deducting commissions related to the Jefferies Sales Agreement and other offering costs.

## 10. 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, 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. Aldeyra has undergone three ownership changes through the year ended December 31, 2018. However, the Company's management believes that there is sufficient "Built-In-Gain" to offset the Section 382 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 incur 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. Accordingly, in the provision for income taxes, the Company recognizes interest accrued related to unrecognized tax benefits and penalties; however, management is currently unaware of any uncertain tax positions.

## 11. STOCK INCENTIVE PLAN

The Company's equity incentive plans are described below. The plans provided 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 and generally prescribed a contractual term of ten years.

The Company approved the 2010 Employee, Director and Consultant Equity Incentive Plan (2010 Plan) in September 2010. 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 June 30, 2019, 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 was amended in June 2016 and June 2018. On January 1 of each year the aggregate number of common shares that may be issued under the 2013 Plan shall automatically increase by such a number of shares equal to the lower of (a) 6% of the total number of shares of common stock outstanding on the last calendar day of the prior fiscal year, or (b) a number of shares of common stock determined by the Company's board of directors. As of June 30, 2019, options to purchase 4,404,367 shares of common stock at a weighted average exercise price of $7.13 per share and 430,425 shares of common stock underlying restricted stock units (RSUs) remained outstanding under the 2013 Plan. As of June 30, 2019, there were 380,644 shares of common stock available for grant under the 2013 Plan.

In connection with the Helio acquisition, the Helio founders were issued 568,627 shares of Aldeyra common stock pursuant to the acquisition agreement. Such shares were not issued from the 2013 Plan. This common stock is subject to vesting conditions based on continuous service to Aldeyra over three years. The Company will recognize the expense associated with the Helio founders' restricted shares as compensation expense on a straight-line basis as the shares vest over the three-year period. Note 3 contains additional details on the Helio acquisition.

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 associated with the two equity incentive plans are as follows:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development expenses | $ 649,530 | $ 386,590 | $ 1,272,190 | $ 738,402 |
| General and administrative expenses | 845,359 | 598,194 | 1,699,957 | 1,114,797 |
| Total stock-based compensation expense | $ 1,494,889 | $ 984,784 | $ 2,972,147 | $ 1,853,199 |

***Stock Options***

The table below summarizes activity relating to stock options under the incentive plans for the six months ended June 30, 2019:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Contractual Term | Aggregate Intrinsic Value(a) |
|---|---|---|---|---|
| Outstanding at December 31, 2018 | 3,383,047 | $ 6.17 | | |
| Granted | 1,289,819 | 7.92 | | |
| Forfeitures | (20,531) | 7.11 | | |
| Outstanding at June 30, 2019 | 4,652,335 | $ 6.65 | 7.75 | $ 3,087,867 |
| Exercisable at June 30, 2019 | 2,384,324 | $ 5.66 | 6.56 | $ 2,813,930 |

(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 June 30, 2019 of $6.00 and the price of the underlying options.

(b) The table above does not include 165,162 of unvested stock options awarded to a former employee which were modified to vest only upon a Change in Control event as defined, under the Company's equity incentive plans. As of June 30, 2019, the Company has not recognized any expense related to these options as the event was not considered probable. These options will expire in the third quarter of 2019 unless a Change in Control event occurs.

As of June 30, 2019, unamortized stock-based compensation for all stock options was $11,381,334 and will be recognized over a weighted average period of 2.87 years.

***Restricted Stock Units***

The table below summarizes activity relating to RSUs for the six months ended June 30, 2019:

| | Number of Shares |
|---|---|
| Outstanding at December 31, 2018 | 212,297 |
| Granted | 283,140 |
| Vested/released | (65,012) |
| Outstanding at June 30, 2019 | 430,425 |

The weighted-average fair value of RSUs granted was $8.05 per share for the six months ended June 30, 2019. As of June 30, 2019, the outstanding RSUs had unamortized stock-based compensation of $2.9 million with a weighted-average remaining recognition period of 3.25 years and an aggregate intrinsic value of $2.6 million.

***Employee Stock Purchase Plan***

At June 30, 2019, the Company had 631,216 shares available for issuance under the 2016 Employee Stock Purchase Plan (2016 ESPP). A summary of the weighted-average grant-date fair value, and total stock-based compensation expense recognized related to the 2016 ESPP are as follows:

| | Six Months ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Weighted-average grant-date fair value per share | $ 2.98 | $ 2.63 |
| Total stock-based compensation expense | $ 61,225 | $ 37,877 |

## 12. STOCK PURCHASE WARRANTS

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 were exercisable beginning on May 1, 2015 for cash or on a cashless basis at a per share price of $10.00. The unexercised warrants, representing warrants to purchase up to 40,300 shares of common stock expired on May 1, 2019 pursuant to their terms and as of June 30, 2019, none of these warrants were outstanding.

## 13. LEASES

The Company currently leases an office used to conduct business. The exercise of lease renewal options is at our discretion and the renewal to extend the lease terms are not included in our Right-Of-Use (ROU) assets and lease liabilities as they are not reasonably certain of exercise. We regularly evaluate the renewal options and when they are reasonably certain of exercise, we include the renewal period in our lease term. As our lease does not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

As of June 30, 2019, the Company recognized a ROU asset with a corresponding operating lease liability of $0.3 million based on the present value of the minimum rental payments as a result of adoption of ASC Topic 842, *Leases*. The weighted average discount rate used for leases as of June 30, 2019 is 9.1%. The weighted average lease term as of June 30, 2019 is 1.5 years. The operating lease expense for the three and six months ended June 30, 2019 was $53,310 and $106,175, respectively. Maturities and balance sheet presentation of our lease liabilities for all operating leases as of June 30, 2019 is as follows:

| | |
|---|---|
| 2019 | $ 114,550 |
| 2020 | 237,671 |
| Total Lease Payments | 352,221 |
| Less effect of discounting: | (24,353) |
| Present value of lease liabilities | $ 327,868 |
| Current operating lease liabilities | $ 211,744 |
| Operating lease liabilities, long-term | 116,124 |
| Total | $ 327,868 |

The Company's gross future minimum payments under all non-cancelable operating leases as of December 31, 2018, are:

| | Total | 2019 | 2020 | 2020 | 2021 |
|---|---|---|---|---|---|
| Operating lease obligations | $ 465,991 | $ 228,320 | $ 237,671 | $ — | $ — |

## 14. LEGAL PROCEEDINGS

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

## 15. COMMITMENTS AND CONTINGENCIES

Other than as set forth in Notes 3 and 8, there have been no material changes to the Company's commitments and contingencies from the information provided in Note 12, Commitments and Contingencies, of the Notes to the Financial Statements, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 which was filed with the SEC on March 8, 2019.

## 16. SUBSEQUENT EVENTS

In August 2019, the Company announced results from Part 1 of the two-part adaptive Phase 3 RESET trial in Sjögren-Larsson Syndrome. Prior to initiating subsequent clinical testing, Aldeyra plans to discuss the RESET Part 1 results with regulatory authorities.

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

### Cautionary Note Regarding Forward-Looking Statements

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

- the timing of enrollment, commencement and completion of our clinical trials;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- delay in or failure to obtain regulatory approval of our product candidates;
- the ability to maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving our product candidates;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- uncertainty as to our ability to commercialize (alone or with others) our product candidates following regulatory approval, if any;
- 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 limited sales and marketing infrastructure;
- our ability to establish and maintain development partnerships;
- our ability to successfully integrate acquisitions into our business;
- 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, 2018, which was filed with the SEC on March 8, 2019 (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 our results will lead to the consequences that we expect. Accordingly, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

**Overview**

Aldeyra Therapeutics, including its wholly-owned subsidiaries (we, us or the Company) is a biotechnology company devoted to developing and commercializing 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 (DED), allergic conjunctivitis (AC), and Sjögren-Larsson Syndrome (SLS). We have additional product candidates in development for proliferative vitreoretinopathy and other retinal diseases, post-transplant lymphoproliferative disease, autoimmune disease, metabolic disease, and cancer. We currently intend to commercialize our products directly or through collaborations. None of our product candidates have been approved for sale in the United States or elsewhere.

Our lead product candidate reproxalap is a RASP (reactive aldehyde species) inhibitor that has been shown to diminish ocular inflammation and has demonstrated statistically significant and clinically relevant improvements across an aggregate of four Phase 2 clinical trials in DED and AC, and one Phase 3 clinical trial in AC, when administered topically to the eye as an ophthalmic solution. Administered to the skin as a topical dermatologic formulation in a Phase 2 clinical trial and in Part 1 of a Phase 3 clinical trial, reproxalap demonstrated statistically significant improvements in ichthyosis (a severe skin disorder) caused by SLS, a rare RASP-mediated disease with no approved therapy. We have discovered and are developing additional RASP inhibitors for the treatment of retinal disease and autoimmune disease.

As we continue to execute on our strategy of expanding our product candidate pipeline, we intend to license or acquire new immune-modulating approaches with novel therapeutic potential. In January 2019, we acquired Helio Vision, Inc. (Helio) and thereby obtained rights to ADX-2191, an intravitreal DHFR inhibitor (methotrexate) for the prevention of proliferative vitreoretinopathy, a serious sight-threatening retinal disease with no approved treatment. In addition, in December 2016, we in-licensed the clinical-stage product candidate ADX-1612 (investigated in oncology under the name ganetespib) and ADX-1615 (an oral pro-drug of ADX-1612), both of which are chaperome inhibitors and represent a mechanistically differentiated approach for the potential treatment of a number of inflammatory diseases.

In the future, we may enter into additional partnerships that facilitate the development and commercialization of our product candidates. All of our development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, funding, and other factors that could delay the initiation, completion, or reporting of clinical trials.

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 debt facilities.

In December 2018, we entered into an Open Market Sale Agreement SM (Jefferies Sales Agreement) with Jefferies LLC (Jefferies), as sales agent, pursuant to which we could offer and sell, from time to time through Jefferies, shares of our common stock, par value $0.001 per share, providing for aggregate sales proceeds of up to $50,000,000. Under the Jefferies Sales Agreement, Jefferies may sell such shares of common stock in privately negotiated transactions with our consent; as block transactions; or by any other method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or sales made into any other existing trading market for our common stock, with us 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 Jefferies Sales Agreement provides that Jefferies will be entitled to a commission rate of up to 3.0% of the aggregate gross proceeds from each sale of shares. We have no obligation to sell any shares under the Sales Agreement, and may at any time suspend solicitations and offers under the Jefferies Sales Agreement. From January 1, 2019 through June 30, 2019, we sold, at a volume-weighted average price of $10.73, an aggregate of 83,557 shares of common stock and received $0.7 million after deducting commissions related to the Jefferies Sales Agreement and other offering costs.

On January 28, 2019 (the closing date), we acquired Helio. As a result of the acquisition, we initially issued an aggregate of 1,150,990 shares of common stock to the former securityholders and an advisor of Helio. The founders of Helio were issued 568,627 shares and non-founders were issued 582,363 shares. The Helio founders' shares are subject to vesting based on continued service to us over three years from the closing date. We will recognize the expense associated with the founders' restricted shares as compensation expense on a straight-line basis as the shares vest over the three-year period. We, subject to the conditions of the acquisition agreement, will be obligated to make additional payments to the former securityholders of Helio as follows: (a) $2.5 million of common stock on the date that is 24 months following the closing date (assuming certain technical milestones are met); (b) $10.0 million of common stock following approval by the U.S. Food and Drug Administration (FDA) of a new drug application for the prevention and/or treatment of proliferative vitreoretinopathy or a substantially similar label prior to the 10th anniversary of the closing date; and (c) $2.5 million of common stock following FDA approval of a new drug application for an indication (other than proliferative vitreoretinopathy) prior to the 12th anniversary of the closing date, provided that in no event shall we be obligated to issue more than 5,248,885 shares of common stock. Additionally, in the event of certain change of control or divestitures by us, certain former convertible noteholders of Helio will be entitled to a tax gross-up payment in an amount not to exceed $1.0 million.

In March 2019, we entered into the Hercules Credit Facility, which provides for a term loan of up to $60 million. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. The credit facility is described in Note 8 to the notes to the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q. We are under no obligation to draw down any capital from the facility.

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

- per patient trial costs;
- the number of sites included in clinical trials;
- the countries in which clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the design of clinical trials;
- the cost of drug manufacturing;
- the number of patients that participate in clinical trials;

- the number of doses that patients receive;
- the cost of vehicle or active comparative agents used in clinical 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 of our product candidates; and
- the efficacy and safety profile of our product candidates.

Included in Research and Development are expenses associated with asset acquisitions. Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired are deemed to have an alternative future use. Acquired in-process research and development payments are immediately expensed and include upfront payments, as well as transaction fees and subsequent milestone payments. Development costs incurred after the asset acquisition are expensed as incurred.

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 six months ended June 30, 2019 and 2018. Other general and administrative expenses include professional fees for auditing, tax, and legal services including patent related costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums, and fees associated with investor relations.

*Total other income (expense)*

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts and interest expense incurred on our outstanding debt.

*Comprehensive loss*

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. For the six months ended June 30, 2019, comprehensive loss is equal to our net loss of $28.9 million and an unrealized gain on marketable securities of approximately $23.0 thousand. For the six months ended June 30, 2018, comprehensive loss is equal to our net loss of $17.4 million and an unrealized gain on marketable securities of approximately $15.0 thousand.

**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 materially from these estimates under different assumptions or conditions. While our significant accounting policies are more fully described in the notes to our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q and our audited financials in our Annual Report on Form 10-K for the year ended December 31, 2018, not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are critical accounting policies.

Other than the policy below, there have been no additional 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 on Form 10-K for the year ended December 31, 2018, which was filed with the Securities and Exchange Commission on March 8, 2019.

***In-process research and development***

Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired are deemed to have an alternative future use, provided that the acquired assets did not also include processes or activities that would constitute a "business" as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Acquired in-process research and development payments are immediately expensed in the period in which they are incurred and include upfront payments, as well as transaction fees and subsequent pre-clinical milestone payments. Research and development costs incurred after the acquisition are expensed as incurred.

**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 June 30, 2019 compared to three months ended June 30, 2018***

*Research and development expenses.* Research and development expenses were $10.7 million for the three months ended June 30, 2019, compared to $6.8 million for the three months ended June 30, 2018. The increase of $3.9 million is primarily related to the increases in our external research and development expenditures, including clinical, manufacturing, and pre-clinical activities; and non-cash compensation costs related to a portion of the upfront consideration paid to the founders of Helio, which is subject to vesting based on continuous service.

*General and administrative expenses.* General and administrative expenses were $3.1 million for the three months ended June 30, 2019, compared to $2.4 million for the three months ended June 30, 2018. The increase of $0.7 million is primarily related to an increase in personnel costs, including stock-based compensation.

*Other income (expense).* Total other income (expense), net was $0.4 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively. For the three months ended June 30, 2019 and 2018, other income (expense) primarily consisted of interest income, which was partially offset by interest expense related to our credit facility.

***Six months ended June 30, 2019 compared to six months ended June 30, 2018***

*Research and development expenses.* Research and development expenses were $18.5 million for the six months ended June 30, 2019, compared to $13.4 million for the six months ended June 30, 2018. The increase of $5.1 million is primarily related to the increases in our external research and development expenditures, including clinical, manufacturing, and pre-clinical activities; and non-cash compensation costs related to a portion of the upfront consideration paid to the founders of Helio, which is subject to vesting based on continuous service.

*General and administrative expenses.* General and administrative expenses were $6.1 million for the six months ended June 30, 2019, compared to $4.3 million for the six months ended June 30, 2018. The increase of $1.8 million is primarily related to an increase in personnel costs, including stock-based compensation.

*Acquired in-process research and development expenses.* Acquired in-process research and development expenses were $6.5 million for the six months ended June 30, 2019. We did not have acquired in-process research and development expense for the six months ended June 30, 2018. The increase of $6.5 million is related to the in-process research and development expenses associated with the January 2019 acquisition of Helio. We determined that the assets acquired from Helio did not constitute a business since substantially all of the assets acquired were related to ADX-2191, and that the transaction would be accounted for as an asset acquisition. As the asset and development program acquired from Helio are at an early stage of development and determining the future economic benefit of the acquired assets at the date of acquisition is highly uncertain, the fair value of the assets was fully expensed as in-process research and development. During the three months ended March 31, 2019, we recorded $6.6 million of acquired in-process research and development expense related to the fair value of consideration given, which includes transaction costs.

*Other income (expense).* Total other income (expense), net was $0.9 million and $0.2 million for the six months ended June 30, 2019 and 2018, respectively. For the six months ended June 30, 2019 and 2018, 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. 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 June 30, 2019, we had total stockholders' equity of approximately $67.3 million, and cash, cash equivalents, and marketable securities of $69.5 million. During the three and six months ended June 30, 2019, we had a net loss of approximately $13.3 million and $29.0 million, respectively. We expect to generate operating losses for the foreseeable future.

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

In December 2018, we entered into an Open Market Sale Agreement SM (Jefferies Sales Agreement) with Jefferies LLC (Jefferies), as sales agent, pursuant to which we could offer and sell, from time to time through Jefferies, shares of our common stock, par value $0.001 per share, providing for aggregate sales proceeds of up to $50,000,000. Under the Jefferies Sales Agreement, Jefferies may sell such shares of common stock in privately negotiated transactions with our consent; as block transactions; or by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or sales made into any other existing trading market for our common stock, with us 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 Jefferies Sales Agreement provides that Jefferies will be entitled to a commission rate of up to 3.0% of the aggregate gross proceeds from each sale of shares. We have no obligation to sell any shares under the Sales Agreement and may at any time suspend solicitations and offers under the Jefferies Sales Agreement. From January 1, 2019 through June 30, 2019, we sold, at a volume-weighted average price of $10.73, an aggregate of 83,557 shares of common stock and received $0.7 million after deducting commissions related to the Jefferies Sales Agreement and other offering costs.

In March 2019, we entered into the Hercules Credit Facility, pursuant to which a term loan of up to an aggregate principal amount of $60.0 million may be made available to us. The Loan Agreement provides for an initial term loan advance of up to $5.0 million at our option, commencing on March 25, 2019 through and including April 15, 2019; three additional term loan advances of up to $15.0 million, at our option, each available to us upon the occurrence of certain funding conditions prior to September 30, 2019, March 31, 2020, and March 31, 2021, respectively; and a final additional term loan advance of up to $10.0 million prior to December 31, 2020, at our option, subject to approval by Lender's investment committee. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. As of June 30, 2019, no amount was outstanding under the Hercules Credit Facility. We elected not to draw down capital under the initial term loan advance, which ceased to be available on April 15, 2019. The $15.0 million term loan advance that became available upon the satisfaction of the AC (ALLEVIATE) Milestone (as defined in the Loan Agreement) is expected to be available until September 30, 2019.

Based on our current operating plan, and not including access to capital under our credit facility or the Jefferies Sales Agreement, we believe that our cash, cash equivalents, and marketable securities as of June 30, 2019, will be adequate to fund our currently anticipated operating expenses through the end of 2020, including the currently planned Phase 3 clinical trial in dry eye disease (the RENEW trial) and the initial part of the currently planned adaptive Phase 3 clinical trial in proliferative vitreoretinopathy (the GUARD trial). We will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of our planned research and development activities; commercialize our product candidates; or conduct any substantial, additional development requirements requested by the FDA. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued clinical development of reproxalap and our other product candidates. Subsequent trials initiated at a later date will cost considerably more, depending on the results of our prior clinical trials, and feedback from the FDA or other third parties. Accordingly, we will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the progress, costs, results of, and timing of our clinical development program for reproxalap and our other product candidates, including our current and planned clinical trials;
- the need for, and the progress, costs, and results of any additional clinical trials of reproxalap or our other product candidates that we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of reproxalap and our other product candidates;

- the outcome, costs, and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing reproxalap and our other product candidates for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development, and scientific personnel;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecuting, defending, and enforcing of any patents or other intellectual property rights;
- the timing and costs associated with establishing sales and marketing infrastructure;
- market acceptance of reproxalap and our other product candidates;
- the costs of acquiring, licensing, or investing in additional businesses, products, product candidates, and technologies; and
- our need to remediate any material weaknesses and implement additional internal systems and infrastructure, including financial and reporting systems.

We may need or desire to obtain additional capital to finance our operations through debt, equity, or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant additional liens on certain of our assets that may limit our flexibility. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are unable to obtain additional financing, we may be required to reduce the scope of our future activities which could harm our business, financial condition, and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

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

The following table summarizes our cash flows for the six months ended June 30, 2019 and 2018:

| | Six Months ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Net cash used in operating activities | $ (25,442,857) | $ (14,200,284) |
| Net cash provided by investing activities | 17,086,480 | 5,658,088 |
| Net cash provided by financing activities | 398,469 | 13,124,533 |
| Net increase (decrease) in cash and cash equivalents | $ (7,957,908) | $ 4,582,337 |

*Operating Activities*. Net cash used in operating activities was $25.4 million for the six months ended June 30, 2019, compared to net cash used in operating activities of $14.2 million for the same period in 2018. The primary use of cash was to fund our operations. The increase in the amount of cash used in operating activities for the six months ended June 30, 2019 as compared to 2018 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 $17.1 million for the six months ended June 30, 2019, and $5.7 million provided by investing activities for the six months ended June 30, 2018. The primary source of net cash provided by investing activities was the sales and purchase of marketable securities, and cash acquired from the Helio asset acquisition of $0.5 million for the six months ended June 30, 2019. The primary source of net cash provided by investing activities was sales and purchase of marketable securities, and cost of leasehold improvements, furniture, fixtures, and computers and related equipment acquired for the six months ended June 30, 2018.

*Financing Activities*. Net cash provided by financing activities was $0.4 million for the six months ended June 30, 2019, compared to $13.1 million for the six months ended June 30, 2018. The net cash provided by financing activities for the six months ended June 30, 2019 was primarily related to our Sales Agreement with Jefferies, under which we sold an aggregate of 83,557 shares of our common stock, resulting in $0.7 million in proceeds after deducting commissions and other offering costs. The net cash provided by financing activities for the six months ended June 30, 2018 was related to our prior Controlled Equity Offering SM Sales Agreement with Cantor Fitzgerald & Co., as sales agent.

**Off-Balance Sheet Arrangements**

Through June 30, 2019, 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**

Other than as set forth below, there have been no material changes since December 31, 2018 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, 2018, other than payments made or received in the ordinary course of business.

In March 2019, we entered into the Hercules Credit Facility, pursuant to which a term loan of up to an aggregate principal amount of $60.0 million may be made available to the Company. The Loan Agreement provides for an initial term loan advance of up to $5.0 million at the Company's option, through and including April 15, 2019; three additional term loan advances of up to $15.0 million, at the Company's option, each available to the Company upon the occurrence of certain funding conditions prior to September 30, 2019, March 31, 2020 and March 31, 2021, respectively; and a final additional term loan advance of up to $10.0 million prior to December 31, 2020, at the Company's option, subject to approval by Lender's investment committee. The term loan bears interest at an annual rate equal to the greater of (i) 9.10% and (ii) the prime rate (as reported in the Wall Street Journal or any successor publication thereto) plus 3.10%. As of June 30, 2019, no amount was outstanding under the Hercules Credit Facility.

**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 Hercules 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 Hercules Credit Facility accrues interest from its date of issue at a variable annual interest rate equal to the greater of (i) 9.10% and (ii) the prime rate (as reported in the Wall Street Journal or any successor publication thereto) plus 3.10%. We have not utilized the Hercules Credit Facility as of the date of this filing.

**Effects of inflation**

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

**Item 4. Controls and Procedures.**

**Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

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

**Changes in Internal Control over Financial Reporting**

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

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

*Our business is subject to numerous risks. You should carefully consider the risks described below together with the other information set forth in this quarterly report on Form 10-Q, 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 and the Development and Commercialization of our Product Candidates**

***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 six months ended June 30, 2019 and 2018 was approximately $29.0 million and $17.4 million, respectively. As of June 30, 2019, we had total stockholders' equity of $67.3 million and an accumulated deficit of $167.5 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, 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 RASP, 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 necessary clinical trials;
- we may not be able to provide evidence of safety and efficacy;
- we may not be able to timely or adequately finalize the design or formulation of any product candidate or demonstrate that a formulation of our product candidate will be stable for commercially reasonable time periods;
- the safety and efficacy results of our later phase or larger clinical trials may not confirm the results of our earlier trials;
- there may be variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;

- the results of our clinical trials may not meet the endpoints, or level of statistical or clinical significance required by the FDA, or comparable foreign regulatory bodies, for marketing approval;
- the initial parts of adaptive clinical trials are not designed to be pivotal or definitive, as such we may need to revise the design or endpoints to achieve success in later parts of the trial or potentially abandon the trial;
- 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 may demonstrate greater response rates or improvements from vehicle or in the non-treatment arm then was expected when designing and powering our clinical trials;
- patients in clinical trials for our product candidates may suffer adverse effects or die for reasons that may or may not be related to our product candidates;
- if approved for certain diseases, our 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;
- we may be adversely affected by 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.***

We have 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, in a cost- effective manner;
- obtain required regulatory approvals for our product candidates;
- manage our spending as costs and expenses increase due to the performance and completion of clinical trials, attempting to obtain regulatory approvals, manufacturing and commercialization;
- secure substantial additional funding;
- develop and maintain successful strategic relationships;
- build and maintain a strong intellectual property portfolio;
- build and maintain appropriate clinical, regulatory, quality, manufacturing, compliance, sales, distribution, and marketing capabilities on our own or through third parties;
- price our product candidates, if approved, at expected levels and obtain and maintain sufficient insurance and reimbursement from insurers and other programs; and
- gain broad market acceptance for our product candidates.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business, or continue our operations.

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

Drug development has inherent risk. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Drug development is a long, expensive, and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, as product candidates proceed through development, the trial designs may often be different and may need to evolve and change from phase to phase or within the same phase or same trial, in the case of an adaptive trial design; 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. For instance, in June 2019, we discontinued our noninfectious anterior uveitis program following the announcement of results from the SOLACE Trial. 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 designing adaptive trials or using new endpoints or methodologies, the regulatory pathways for approval are not well defined, and, as a result, there is greater risk that our clinical trials will not result in our desired outcomes or require additional trials.***

Our clinical focus is on the development of new products for inflammation and an inborn error of metabolism. Our Phase 3 vehicle-controlled clinical program in noninfectious anterior uveitis and our Phase 3 clinical program in SLS represent the first such clinical trials performed. In June 2019, we announced that statistical significance was not achieved for the primary or secondary endpoints in our SOLACE Trial in noninfectious anterior uveitis, due to high rates of disease resolution in vehicle-treated patients. We are performing adaptive trials in SLS (RESET), dry eye disease (RENEW), and proliferative vitreoretinopathy (GUARD), and may do so with other indications in the future. In an adaptive trial, the initial parts of the trial are not designed to be pivotal or definitive. Rather, the initial parts of adaptive trials are expected to provide data to guide subsequent parts of the trial, which could require design changes, including but not limited to, different endpoints. In addition, following the initial parts of adaptive trials, we may, among other things, determine to continue to the subsequent parts of the trial, conclude the trial based on its success or failure in such initial parts, or to discuss the trial results and regulatory pathway with regulatory authorities prior to determining next steps with respect to the trail and development program. For example, in August 2019, we announced that statistically significant improvement from baseline was observed in Part 1 of the Phase 3 RESET trial in SLS. However, due to the novel nature of reproxalap, the limited population of SLS patients, and the uncertain regulatory pathway in SLS, plans for subsequent clinical testing will not be determined until meetings with regulatory authorities are complete. Further, we have proposed to the FDA a novel assessment methodology for our Phase 3 clinical program in allergic conjunctivitis, which may not be acceptable to the FDA. As such, 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 regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and require more time and 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.

***To preserve trial integrity, clinical data from the initial parts of adaptive clinical trials may not be disclosed.***

Adaptive clinical trials are often performed such that the initial parts of the trial are used to determine sample size and endpoints for subsequent, possibly pivotal parts of the trial. Results from the initial parts of adaptive trials are therefore not designed to be pivotal or definitive, and, in some cases, detailed trial data may not be disclosed so as not to positively or negatively bias investigators or patients involved in subsequent parts of the trial.

We are performing adaptive trials in SLS (RESET), dry eye disease (RENEW), and proliferative vitreoretinopathy (GUARD). For the reasons stated above, detailed results from RESET Part 1 and RENEW Part 1, and from the initial part of GUARD, may not be disclosed until the completion of subsequent parts of the trials, or until the entire adaptive trial has completed. Further, the initial parts of adaptive trials may be performed in part to assess biomarkers or surrogate markers that may require substantial time to generate, analyze, and interpret. Thus, disclosure of clinical results from the initial parts of adaptive trials may also be delayed due to the time required for biomarker or surrogate marker assessment.

***Because some of 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.***

Some of 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. Following discussions with the FDA and experts in the field, we may determine that it is not cost effective for us to develop one or more of our product in certain indications and we may decide to cease development in that area or seek a strategic partner.

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

While the primary day-to-day complaint of SLS patients and their caregivers are symptoms associated with severe skin disease (ichthyosis), 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. Additionally, in August 2019, we announced that Part 1 of our Phase 3 RESET trial in SLS demonstrated statistically significant activity of reproxalap in reducing the severity of ichthyosis relative to baseline in drug-treated patients. Given the expected low systemic exposure of reproxalap when administered topically to the skin, it is not possible to anticipate the effect of reproxalap on the non-dermatologic conditions of SLS. Lack of effect in neurologic and ocular manifestations of SLS may negatively impact the potential market for reproxalap in SLS, and may also negatively impact reimbursement, pricing, and commercial acceptance of reproxalap, if approved.

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive and time-consuming, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indication, 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 uncertain and not 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;
- patients in our clinical trials may demonstrate greater response rates or improvements from vehicle or standard of care than was expected when designing and powering our clinical trials, such as was observed in the SOLACE Trial;
- lack of availability of, or difficulty recruiting, a sufficient number of patients to adequately power our clinical trials;

- 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 for us to develop or commercialize, or may fail to achieve market acceptance or adequate pricing or reimbursement;
- our inability to secure strategic partners which may be necessary for advancement of a product candidate into clinical development or commercialization; or
- our prioritization of other product candidates for advancement.

The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including but not limited to:

- such authorities may disagree with the design or implementation of our or any of our future development partners' clinical trials, including the endpoints of our clinical trials; such authorities may require clinical data in addition to clinical trial programs we expect, or may require changes to the designs and endpoints of subsequent clinical trials;
- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials if conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the design of such trials;
- changes in the leadership or operation of such authorities, which may result in, among other things, the implementation of new standards, or changes to the interpretation or enforcement of existing regulatory standards and requirements;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies; or
- the approval policies, standards or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our future development partners from commercializing our product candidates. Moreover, we cannot predict healthcare reform initiatives, including potential reductions in federal funding or insurance coverage, that may be adopted in the future and whether or not any such reforms would have an adverse effect on our business and our ability to obtain regulatory approval for our current or future product candidates. There are evolving legal requirements and other statutory and regulatory regimes that will continue to affect our business.

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

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

- the FDA, or an institutional review board, or IRB, failing to grant permission to proceed or placing a clinical trial on hold;
- subjects failing to enroll or remain in our clinical trials at the rate we expect;

- subjects choosing an alternative treatment for the indication for which we are developing reproxalap or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe, serious or unexpected drug-related adverse effects, whether drug-related or otherwise;
- a facility manufacturing reproxalap, any of our other product candidates or any of their components being ordered by the FDA or other government or regulatory authorities, to temporarily or permanently shut down due to violations of current Good Manufacturing Practices, or cGMP, or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- inability to timely manufacture sufficient quantities of the applicable product candidate for a clinical trial or expiration of materials intended for use in a clinical trial;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, current Good Clinical Practice or regulatory requirements, or other third parties not performing data collection or analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or the finding of regulatory violations by the FDA or IRB, that require us or others to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold in part or on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of reproxalap or our other product candidates or if we need to perform more, larger, or longer clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we or our partners may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, the FDA or other regulatory authorities, the IRB, other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for a product candidate may be harmed and our ability to generate product revenues, if any, will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of reproxalap or other product candidates could be significantly reduced.

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

As part of our business strategy, we have and continue to evaluate the development and commercialization of product candidates for the treatment of orphan and other rare diseases. 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. For instance, in rare diseases such as SLS, lack of availability of, or difficulty recruiting a sufficient number of, patients may make it difficult or cost-prohibitive to sufficiently power our clinical trials, which may not enable us to continue development and seek regulatory approval for the applicable product candidate. Further, if our products are approved by regulatory agencies, we may not be able to identify sufficient number of patients to generate significant revenues.

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

Unacceptable adverse events caused by any of our product candidates that we or others advance into clinical trials could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale.

We have not yet completed testing of any of our product candidates in humans for the treatment of the indications for which we intend to seek approval, and we currently do not know the full extent of adverse events that will be observed in subjects that receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, which may be larger or longer than those previously conducted, we may not be able to obtain regulatory approval or commercialize such product candidate.

***Final marketing approval for reproxalap or our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.***

After the completion of our clinical trials, assuming the results of the trials are successful, and the submission of an NDA, we cannot predict whether or when we will obtain regulatory approval to commercialize reproxalap or our other product candidates and we cannot, therefore, predict the timing of any future revenue. We cannot commercialize reproxalap or our other product candidates until the appropriate regulatory authorities have reviewed and approved the applicable applications. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for reproxalap or our other product candidates. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review. If marketing approval for reproxalap or our other product candidates is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

***Even if we obtain marketing approval for reproxalap or any other product candidate, it could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any are approved.***

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance, or other potential additional clinical trials. Following approval, if any, of reproxalap or any other product candidate, such candidate will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping, and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements, including those relating to quality control, quality assurance, and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated seriousness, severity, or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for reproxalap or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy (REMS) plan as part of a NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry.

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

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

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, is also generally necessary for commercial success. In addition, we may not be able to price our products at the expected level or at levels that make successful commercialization viable. The pricing of our products will be subject to numerous factors, many of which are outside of our control, including the pricing of similar products. The degree of market acceptance of our product candidates will depend on a number of factors, including but not limited to:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient populations and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulations by health care providers and their patients;
- the prevalence, seriousness and severity of any adverse effects;
- new procedures or methods of treatment that may be more effective in treating conditions for which our products are intended to treat;
- the safety of product candidates seen in a broader patient group, including their use outside the approved indications;
- pricing and cost-effectiveness, including the cost of treatment in relation to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient and timely third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts;
- unfavorable publicity; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

Further, our ability to successfully commercialize ADX-2191, if approved, depends on a number of additional factors, including but not limited to, the level of enforcement by the FDA to ensure that compounded copies of commercially available FDA-approved products manufactured by compounding pharmacies, including compounded copies of ADX-2191, that may be in violation of the federal Drug Quality and Security Act (DQSA) and other relevant provisions of the United States Federal Food, Drug, and Cosmetic Act, are not produced and dispensed to patients.

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.

Additionally, if any of our competitors' products are approved and are unable to gain market acceptance for any reason, there could be a market perception that products like reproxalap are not able to adequately meet an unmet medical need. If we are unable to demonstrate to physicians, hospitals, third-party payors and patients that our products are better alternatives, we may not be able to gain market acceptance for our products at the levels we anticipate and our business may be materially harmed as a result.

***If the market opportunities for reproxalap and our product candidates are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.***

We focus our research and product development on treatments for immune-mediated diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected.

Any of these factors may negatively affect our ability to generate revenues from sales of our product and our ability to achieve and maintain profitability, and as a consequence, our business may suffer.

***Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.***

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. The reimbursement levels may be significantly less than the currently anticipated pricing of our product candidates. As a result of negative trends in the general economy in the United States or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost effectiveness data for the use of the applicable product candidate to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Further, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only in limited levels, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the United States healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. More recently, the current presidential administration and many members of the United States Congress have attempted to repeal and replace the Patient Protection and Affordable Care Act (PPACA), but they have been unsuccessful in doing so as of the date of the filing of this report. We cannot predict the ultimate form or timing of any repeal or replacement of PPACA or the effect such repeal or replacement would have on our business. Regardless of the impact of repeal or replacement of PPACA on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments, or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers, and other third-party payers for our current and future product candidates, if any, for which we are able to obtain regulatory approval. Some of these changes and proposed changes could result in reduced reimbursement rates for such product candidates, if approved, which would adversely affect our business strategy, operations, and financial results.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for use of newly approved drugs, which in turn could lower drug pricing. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals as well as country, regional, or local healthcare budget limitations.

***If we fail to develop and commercialize other product candidates, we may be unable to grow our business.***

As part of our growth strategy, we plan to evaluate the development and commercialization of other therapies related to immune-mediated diseases. We will evaluate internal opportunities from our compound libraries, and also may choose to continue to in-license or acquire other product candidates, as well as commercial products, to treat patients suffering from immune-mediated disorders with high unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials, and approval by the FDA and/or applicable foreign regulatory authorities. In-licensed product candidates may have been unsuccessfully developed by others in indications similar to those that we may pursue. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, adequately priced, successfully commercialized, or widely accepted in the marketplace or be more effective than other commercially available alternatives.

***Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.***

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

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

The FDA designates orphan drug designation status to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Drugs that receive an orphan drug designation do not require prescription drug user fees at the time of marketing application, may qualify the drug development sponsor for certain tax credits, and can be marketed without generic competition for seven years. In April 2017, we announced that the FDA granted reproxalap orphan drug designation for the treatment of congenital ichthyosis, a severe skin disease characteristic of SLS. In April 2018, ADX-2191 received orphan drug designation from the FDA for the prevention of proliferative vitreoretinopathy. In addition, it may be difficult or not possible to obtain from the FDA orphan drug designation or a designation that facilitates and expedites development and review of certain new drugs, including breakthrough therapy designation, fast track designation or any other expedited status that we may apply for in the future, for reproxalap or our other product candidates. We cannot guarantee that we will be able to receive breakthrough therapy or fast-track designation from the FDA for reproxalap or our other product candidates. If we are unable to secure, breakthrough therapy designation or fast-track designation for reproxalap or our other product candidates, our regulatory and commercial prospects may be negatively impacted.

***We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of reproxalap and our other product candidates.***

As of June 30, 2019, we had only 20 full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis, manufacturing, financial reporting and accounting, and human resources, as well as for certain functions required of publicly traded companies. We may have limited control over third parties and we cannot guarantee that any third party will perform its obligations in an effective and timely manner.

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

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

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We are dependent on third parties to conduct the clinical trials for reproxalap and for our other product candidates and, therefore, the timing of the initiation and completion of these trials is controlled by such third parties and may occur on substantially different timing from our estimates. Specifically, we use CROs to conduct our clinical trials and we also rely on medical institutions, clinical investigators, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

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

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

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

clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-initiated clinical trials could have a material adverse effect on our prospects and the perception of our product candidates. As a result, our lack of control over the conduct and timing of, and communications with the FDA regarding, investigator-sponsored trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates.

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

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

We also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. We do not have any control over the process or timing of the acquisition of raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of that clinical trial, product candidate testing, and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

***We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.***

The process of manufacturing our products is complex, highly regulated, and subject to several risks, including:

- The manufacturing of compounds is extremely susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures, and numerous other factors.
- We and our contract manufacturers must comply with the FDA's cGMP regulations and guidelines. We and our contract manufacturers may encounter difficulties in achieving quality control and quality assurance, and may experience shortages in qualified personnel. We and our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or any delay, interruption, or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies, the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions, and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to account for inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

***We may not be successful in establishing and maintaining development or other strategic partnerships, which could adversely affect our ability to develop and commercialize product candidates.***

We have in the past, and may in the future, choose to enter into development or other strategic partnerships, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish other development partnerships or other alternative arrangements for any of our product candidates or programs because our research and development pipeline may be insufficient, our product candidates or programs may be deemed to be at too early a stage of development for collaborative effort, and/or third parties may not view our product candidates or programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are below expectations. Any delay in entering into development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce competitiveness, if approved.

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

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

***We may not realize the benefits of our current or future strategic alliances.***

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

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

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

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. Other parties may discover and patent treatment approaches and compositions that are similar to or different from ours. Competition in drug development is intense. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

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

***We may not be successful in executing our sales and marketing strategy for the commercialization of our product candidates. We have no sales, marketing, or distribution capabilities and expect to invest significant financial and management resources to develop these capabilities. If we are unable to establish sales, distribution and marketing capabilities or enter into agreements with third parties to market, sell and distribute our product candidates, we may be unable to generate any revenues.***

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. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. 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.

If we are unable to successfully implement our commercialization plans and drive adoption by patients of our approved product candidates, if any, through our sales, marketing and commercialization efforts, then we will not be able to generate significant revenue, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

***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 five individuals and certain other employees: Todd C. Brady, M.D., Ph.D., our President and Chief Executive Officer; Joshua Reed, M.B.A., our Chief Financial Officer; David J. Clark, M.D., our Chief Medical Officer; David B. McMullin, M.B.A., our Chief Commercial Officer, and Stephen G. Machatha, Ph.D., our Senior Vice President, Technical Operations. Our current management team has only been working together for a relatively short period of time. Our future performance will depend significantly on our ability to successfully integrate our management team, and on those officers' ability to develop and maintain an effective working relationship. Our failure to integrate these recently hired executive officers with other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. In addition, we rely on the services of a number of key consultants, including IP, pharmacokinetic, chemistry, toxicology, and drug development consultants. The loss of such individuals or the services of future members of our management team could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business.

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

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

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

***In order to commercialize our product candidate, we will need to substantially grow the size of our organization. We may encounter difficulties in managing our growth and expanding our operations successfully.***

Because, as of June 30, 2019, we only had 20 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 towards potential commercialization, increase the number of ongoing product development programs and advance our future product candidates through preclinical studies and clinical trials, we will need to expand our financial, development, regulatory, manufacturing, marketing, and sales capabilities, or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train, and integrate additional management, clinical and regulatory, financial, administrative and sales, and marketing personnel. We may not be able to accomplish these tasks, and our failure to so accomplish could prevent us from successfully growing our company.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory and 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. 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. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of reproxalap or any future product candidates. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- additional studies, including clinical studies;
- recall, replacement, or discontinuance of one or more of our products;
- the payment of additional taxes; or
- additional record keeping.

Each of these requirements would likely entail substantial time and cost and could adversely harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for any future products would harm our business, financial condition and results of operations. 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 such 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.

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.

In addition, a federal court in Texas ruled in December 2018 that the PPACA is unconstitutional. That decision currently is being appealed and may result in an opinion by appellate courts, including potentially the Supreme Court of the United States, on the constitutionality of the PPACA as revised. We cannot predict the ultimate content, timing, or effect of any such reform activities, litigation, or court decisions on our operations. Additionally, the pricing and reimbursement of pharmaceutical products continues to receive significant attention from U.S. policymakers, the Trump Administration, and others. For example, on January 31, 2019, the Department of Health and Human Services issued a proposed rule that removes from existing anti-kickback statute safe harbor protection certain reductions in price paid by pharmaceutical manufacturers to Medicare Part D plan sponsors, Medicaid MCOs, and those entities' pharmacy benefit managers (PBMs) and adds two new safe harbors that protect certain point-of-sale price reductions by pharmaceutical manufacturers as well as certain service fee payments from pharmaceutical manufacturer to PBMs. At this time, we cannot predict the impact of this increased scrutiny would have on our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.***

We intend to market our product candidates internationally. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

***To the extent that we enter markets outside the United States, our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.***

There are significant regulatory and legal barriers in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We will be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States would be subject to political, economic and social uncertainties including, among others:

- changes and limits in import and export controls;
- increases in custom duties and tariffs;
- changes in currency exchange rates;
- economic and political instability, such as Brexit in the United Kingdom;
- changes in government regulations and laws;
- absence in some jurisdictions of effective laws to protect our intellectual property rights; and
- currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

The current presidential administration has expressed antipathy towards existing trade agreements such as the North American Free Trade Agreement, greater restrictions on free trade generally and significant increases on tariffs on goods imported into the United States, particularly from China and Mexico. Changes in United States social, political, regulatory and economic conditions or in laws and policies governing foreign trade, manufacturing, development and investment, and any negative sentiments towards the United States as a result of such changes, could adversely affect our business.

Any changes related to these and other factors could adversely affect any business operations that we conduct outside the United States**.**

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

We face an inherent risk of product liability as a result of the clinical testing of reproxalap and our other product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if reproxalap or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for reproxalap or our other product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to continue to develop or commercialize reproxalap or our other product candidates; and
- a decline in our stock price.

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

***We are subject to litigation risks.***

From time to time, we may become involved in various litigation matters and claims, including regulatory proceedings, administrative proceedings, governmental investigations, and contract disputes, as they relate to our services and business. We may face potential claims or liability for, among other things, breach of contract, defamation, libel, fraud or negligence. We may also face employment-related litigation, including claims of age discrimination, sexual harassment, gender discrimination, immigration violations, or other local, state, and federal labor law violations. Because of the uncertain nature of litigation and insurance coverage decisions, the outcome of such actions and proceedings cannot be predicted with certainty and an unfavorable resolution of one or more of them could have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our securities. In addition, legal fees and costs associated with prosecuting and defending litigation matters could have a material adverse effect on our business, financial condition, results of operation and the trading price of our securities.

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

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

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

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

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

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

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

From time to time, we have entered into, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. For example, in January 2019 we acquired Helio Vision, Inc. and obtained the rights to ADX-2191, an intravitreal DHFR inhibitor (methotrexate) for the prevention of proliferative vitreoretinopathy. These initiatives may include acquiring businesses, technologies, or products, or entering into a business combination with another company. Any acquisitions we undertake or have recently completed will likely be accompanied by business risks which may include, among other things:

- the effect of the acquisition on our financial and strategic position and reputation;
- the failure of an acquisition to result in expected benefits, which may include benefits relating to new product candidates, human resources, costs savings, operating efficiencies, goodwill and other synergies;
- the difficulty, cost and management effort required to integrate the acquired businesses, including costs and delays in implementing common systems and procedures and costs and delays caused by communication difficulties;
- the assumption of certain known or unknown liabilities of the acquired business, including litigation-related liabilities;
- the reduction of our cash available for operations and other uses, the increase in amortization expense related to identifiable assets acquired, potentially dilutive issuances of equity securities or the incurrence of debt;
- the possibility that we will pay more than the value we derive from the acquisition;
- the impairment of relationships with our partners, consultants or suppliers or those of the acquired business; and
- the potential loss of key employees of the acquired business.

These factors could harm our business, results of operations or financial condition.

In addition to the risks commonly encountered in the acquisition of a business or assets as described above, we may also experience risks relating to the challenges and costs of closing a transaction. The risks described above may be exacerbated as a result of managing multiple acquisitions at once.

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

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

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

***Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.***

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition, and increase our costs and expenses. We rely on third-party manufacturers to produce reproxalap and our other product candidates. Our ability to obtain clinical supplies of reproxalap or our other product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

We are exposed to the risk of employee and others, fraud or other misconduct. Misconduct by employees, consultants, or agents could include intentional failures to comply with FDA regulations, provide accurate information to regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Our current and former employees, consultants or sub-contractors may also become subject to allegations of sexual harassment, racial and gender discrimination or other similar misconduct, which, regardless of the ultimate outcome, may result in adverse publicity that could significantly harm our company’s brand, reputation and operations. Employee misconduct could also involve improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

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

**Risks Relating to Our Intellectual Property**

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and the use of our product candidates or proprietary technologies as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. While we have issued composition-of-matter patents in the United States and other countries for reproxalap, we cannot be certain that the claims in our patent applications covering composition-of-matter of our other product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute. In addition, there are possibly treatment compositions and methods that we have not conceived of or attempted to patent, and other parties may discover and patent approaches and compositions that are similar to or different from ours.

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

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

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

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of reproxalap or our other product candidates. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing reproxalap or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of patent infringement against us, others may hold proprietary rights that could prevent reproxalap or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market reproxalap or our other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing reproxalap or our other product candidates, which could harm our business, financial condition, and operating results.

Any such claims against us could also be deemed to constitute an event of default under our loan and security agreement with Hercules Capital, Inc. (Hercules). In the case of a continuing event of default under the loan, Hercules, could, among other remedies, elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. In the event we do not or are not able to repay the obligations at the time a default occurred, Hercules may elect to commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to Hercules under the loan.

***Our issued patents could be found invalid or unenforceable if challenged in court.***

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

***We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.***

We are a party to technology licenses, including the in-license agreement for ADX-1612 and an in-license agreement for ADX-2191, and we may enter into additional licenses in the future. Such licenses do, and may in the future, impose commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we could lose valuable rights under our collaboration agreements and our ability to develop product candidates could be impaired. Additionally, should such a license agreement be terminated for any reason, there may be a limited number of replacement licensors, and a significant amount of time may be required to transition to a replacement licensor.

Our rights to develop and commercialize ADX-1612 and ADX-2191 are each subject in part to the terms and conditions of a third party license, pursuant to which we have acquired exclusive rights to ADX-1612 and ADX-2191 and other intellectual property. Our rights with respect to the intellectual property to develop and commercialize ADX-1612 and ADX-2191 may terminate, in whole or in part, if we fail to meet certain milestones contained in each of our license agreements relating to the development and commercialization of ADX-1612 and ADX-2191. We may also lose our rights to develop and commercialize either of ADX-1612 or ADX-2191 if we fail to pay required milestones or royalties. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may be extinguished, which may have an adverse effect on our business and results of operations.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, consultants, or agents have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.***

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants and our employees were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that our company or an employee, consultant, or agent inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

***If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent terms and obtaining data exclusivity for our product candidate, our business may be materially harmed.***

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources, and could adversely impact our financial condition or results of operations.

***Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming, and inherently uncertain. In addition, Congress may pass patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available or weakening the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents, or to enforce our existing patents and patents we might obtain in the future.

***We may not be able to protect our intellectual property rights throughout the world.***

While we have issued composition-of-matter patents covering reproxalap and certain of our other product candidates in the United States and other countries, filing, prosecuting, and defending patents on reproxalap and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

**Risks Related to Our Financial Position and Need for Capital**

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

We will require substantial future capital in order to complete the remaining clinical development for reproxalap and our other product candidates, and to potentially commercialize these product candidates, if approved. We expect our spending levels to increase in connection with our clinical trials of reproxalap and our other product candidates, as well as other corporate activities. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our planned clinical trials of reproxalap or any our other product candidates which we are pursuing or may choose to pursue in the future;
- the need for, and the progress, costs and results of, any additional clinical trials of reproxalap and our other product candidates we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of reproxalap and our other product candidates;
- the costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for reproxalap and our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales and marketing capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing collaborations, license agreements, and other partnerships on terms favorable to us;
- costs associated with any other product candidates that we may develop, in-license or acquire, including potential milestone or royalty payments;
- the effect of competing technological and market developments;
- our ability to establish and maintain partnering arrangements for development; and
- the costs associated with being a public company.

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

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through collaboration agreements and public or private financings, including debt financings. The state of the global economy and market instability has made the business climate volatile and more costly. Uncertain economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Additional funding may not be available to us on acceptable terms, or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders or be excessively dilutive. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we will be unable to complete the planned clinical trials for reproxalap and our other product candidates and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners that may require us to relinquish rights to our product candidates or other technologies, or otherwise agree to terms unfavorable to us.

***The terms of our secured debt facility require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

In March 2019, we entered into a credit facility with Hercules Capital that is secured by a lien covering all of our assets, other than our intellectual property. The loan agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, and maintain insurance coverage. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Hercules Credit Facility or any future debt facility, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. The lender could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the loan agreement. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and certain other tax assets (tax attributes) to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs or credits could have a material adverse effect on our results of operations and cash flows. We have undergone three ownership changes through the year ended December 31, 2018. However, our management believes that we had sufficient "Built-In-Gain" to offset the Section 382 limitation generated by such ownership changes. Any future ownership changes may cause our existing tax attributes to have additional limitations. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. However, subject to annual limitations, NOLs generated in years 2018 and beyond will have an indefinite carryforward period and will not expire. Future changes in federal and state tax laws pertaining to NOLs carryforwards may also cause limitations or restrictions from us claiming such NOLs. If the NOLs carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

**Risks Related to Our Common Stock**

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

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

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

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

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

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

***Our quarterly operating results may fluctuate significantly.***

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

- variations in the level of expenses related to our clinical trial and development programs;
- addition or termination of clinical trials or development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting reproxalap and our other product candidates;

- our execution of any collaborative, licensing, or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- nature and terms of stock-based compensation grants; and
- derivative instruments recorded at fair value.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

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

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

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

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

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

As of June 30, 2019, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 32% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and business affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

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

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding nonbinding advisory votes on executive compensation, and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2019, although circumstances could cause us to lose that status earlier, including: if we become a large accelerated filer; if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31; or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on emerging growth company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

***We qualify as an emerging growth company, smaller reporting company and a non-accelerated filer under Rule 12b-2 of the Securities Exchange Act of 1934. As a result, we are not required by Section 404 of the Sarbanes-Oxley Act to have our independent registered public accounting firm attest to the effectiveness of our internal controls over financial reporting.***

Our management is required by Section 404 of the Sarbanes-Oxley Act to make a formal assessment of the effectiveness of our internal controls over financial reporting. Our independent registered public accounting firm, however, is not required to attest to the effectiveness of our internal controls over financial reporting until such time as we are no longer either an emerging growth company or a non-accelerated filer as defined by Rule 12b-2 of the Securities Exchange Act of 1934. This lack of attestation by our independent registered accounting firm may increase the risk that we fail to detect and remedy any weakness of deficiencies in our internal control over financial reporting. Additionally, at such time as we are subject to the auditor attestation requirements, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. If we are unable to establish and maintain effective internal controls it could have a material adverse effect on our business, financial condition, results of operations or cash flows.

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

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

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

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

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

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

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

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

***We could be subject to securities class action litigation.***

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

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

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

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Exhibit Number | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of Registrant, (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference). |
| 3.2 | Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K as filed on May 7, 2014, and incorporated herein by reference). |
| 31.1 | Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of the Principal Financial and Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2019 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Balance Sheets as of June 30, 2019 and December 31, 2018; (ii) Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2019 and 2018; (iii) Statements of Cash Flows for the three months ended June 30, 2019 and 2018; and (iv) Notes to Financial Statements. |

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

**SIGNATURES**

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

Aldeyra Therapeutics, Inc.

August 9, 2019 /s/ Todd C. Brady, M.D., Ph.D.

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

Aldeyra Therapeutics, Inc.

August 9, 2019 /s/ Joshua Reed

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

**Exhibit 31.1**

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

I, Todd C. Brady, certify that:

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

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

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

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

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

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

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

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

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

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

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

August 9, 2019

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

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

**Exhibit 31.2**

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

I, Joshua Reed, certify that:

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

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

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

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

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

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

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

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

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

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

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

August 9, 2019

/s/ Joshua Reed

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

**Exhibit 32.1**

**CERTIFICATION**

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

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

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 9, 2019 /s/ Todd C. Brady, M.D., Ph.D.

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

August 9, 2019 /s/ Joshua Reed

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

*A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.*