UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2017

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: 000-53057

Aerpio Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**EIN 61-1547850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9987 Carver Road **Cincinnati, OH**	**45242**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (513) 985-1920

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "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	☐ (Do not check if a small reporting company)	Small reporting company	☒
Emerging growth company	☒		

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

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

As of August 10, 2017, the registrant had 27,070,038 shares of common stock, $0.0001 par value per share, outstanding.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs and future preclinical and clinical studies;
- our ability to advance any product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization, marketing and manufacturing of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our expectations related to the use of proceeds from private placement offering, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance;
- developments relating to our competitors and our industry, including the impact of government regulation; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Report.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 28,847,937	$ 1,609,694
Short-term investments	50,000	50,000
Accounts receivable	4,264	4,157
Prepaid research and development contracts	311,064	353,434
Other current assets	431,151	209,038
Total current assets	29,644,416	2,226,323
Furniture and equipment, net	129,026	149,595
Deposits	20,960	20,960
Total assets	$ 29,794,402	$ 2,396,878
Liabilities, redeemable convertible preferred stock, and stockholders´ equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,856,817	$ 2,470,970
Convertible notes	—	12,386,647
Total current liabilities	1,856,817	14,857,617
Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock (all classes)	—	73,757,890
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share; 300,000,000 and 17,440,436 shares authorized and 27,070,038 and 1,240,925 shares issued and outstanding at June 30, 2017 and December 31, 2016 respectively.	2,707	124
Additional paid-in capital	125,612,938	—
Accumulated deficit	(97,678,060)	(86,218,753)
Total stockholders' equity (deficit)	27,937,585	(86,218,629)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 29,794,402	$ 2,396,878

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

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Operating expenses:	*(unaudited)*		*(unaudited)*	
Research and development	$ 3,169,115	$ 2,903,564	$ 5,424,699	$ 5,893,122
General and administrative	2,414,747	1,473,869	4,918,748	2,689,754
Total operating expenses	5,583,862	4,377,433	10,343,447	8,582,876
Loss from operations	(5,583,862)	(4,377,433)	(10,343,447)	(8,582,876)
Grant income	11,239	80,954	46,896	89,624
Interest income (expense), net	52,316	(88,783)	(219,459)	(87,706)
Other income, net	—	—	—	997
Total other income (expense)	63,555	(7,829)	(172,563)	2,915
Net loss and comprehensive loss	$ (5,520,307)	$ (4,385,262)	$ (10,516,010)	$ (8,579,961)
Reconciliation to net loss attributable to common stockholders:				
Net loss and comprehensive loss	$ (5,520,307)	$ (4,385,262)	$ (10,516,010)	$ (8,579,961)
Extinguishment of preferred stock	—	224,224	—	224,224
Accretion of preferred stock to redemption value	—	(1,028,121)	(943,297)	(2,043,492)
Net Loss attributable to common stockholders	$ (5,520,307)	$ (5,189,159)	$ (11,459,307)	$ (10,399,229)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (6.30)	$ (0.70)	$ (13.33)
Weighted average number of common shares used in computing net loss per share attributable to common stockholders, basic and diluted	26,895,164	823,097	16,313,324	780,152

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

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders Equity (Deficit)

	Redeemable Convertible Preferred Stock (all classes)		Stockholders' Equity (Deficit)				
			Common Stock				
	Shares	Total	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2016	14,015,016	$ 73,757,890	1,240,925	$ 124	—	$ (86,218,753)	$ (86,218,629)
Adjustment of redeemable convertible preferred stock to redemption value	—	943,297	—	—	—	(943,297)	(943,297)
Conversion of preferred stock	(14,015,016)	(74,701,187)	14,015,016	1,402	74,699,785	—	74,701,187
Conversion of convertible notes and accrued interest	—	—	2,744,059	274	13,447,660	—	13,447,934
Share exchange in connection with Merger	—	—	1,000,000	100	(100)	—	—
Issuance of common stock, net of issuance costs	—	—	8,049,555	805	37,162,585	—	37,163,390
Issuance of common stock upon exercise of stock options	—	—	25,729	3	36,098	—	36,101
Forfeiture of restricted stock	—	—	(5,246)	(1)	1	—	—
Share-based compensation expense	—	—	—	—	266,909	—	266,909
Net loss	—	—	—	—	—	(10,516,010)	(10,516,010)
Balance at June 30, 2017	—	—	27,070,038	$ 2,707	$ 125,612,938	$ (97,678,060)	$ 27,937,585

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

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

	Six months ended June 30, 2017	2016
Operating activities:	*(unaudited)*	
Net loss	$ (10,516,010)	$ (8,579,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	27,117	37,991
Stock-based compensation	266,909	244,765
Amortization of debt issuance costs	75,561	59,277
Interest expense related to convertible note conversion	204,929	89,962
Changes in operating assets and liabilities:		
Accounts receivable	(107)	113,943
Prepaid expenses and current other assets	(179,743)	259,938
Accounts payable and other current liabilities	(130,711)	(71,261)
Net cash used in operating activities	(10,252,055)	(7,845,346)
Investing activities:		
Purchase of furniture and equipment	(6,547)	(113,297)
Net cash used in investing activities	(6,547)	(113,297)
Financing activities:		
Proceeds from exercise of stock options	36,101	18,969
Proceeds from issuances of convertible notes	297,354	4,536,531
Cash paid for debt issuance costs	—	(138,312)
Proceeds from sale of common stock	40,247,775	—
Cash paid in connection with the sale of common stock	(3,084,385)	—
Net cash provided by financing activities	37,496,845	4,417,188
Net increase (decrease) in cash and cash equivalents	27,238,243	(3,541,455)
Cash and cash equivalents at beginning of year	1,609,694	5,144,211
Cash and cash equivalents, six months ended	$ 28,847,937	$ 1,602,756
Non-cash financing activities		
Conversion of preferred stock into common stock	$ 74,701,187	$ —
Conversion of notes and accrued interest into common stock	13,447,934	—
Accretion of preferred stock to redemption value	943,297	2,043,492
Extinguishment of preferred stock	—	(224,224)

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

1. Nature of Organization and Operations

Aerpio Pharmaceuticals, Inc. (the "Company") was incorporated as Zeta Acquisition Corp. II ("Zeta") in the State of Delaware on November 16, 2007. Prior to the Merger, (as defined below), Zeta was a "shell company" (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended).

On March 3, 2017, the Company's Board of Directors, and on March 10, 2017, the Company's pre-Merger (as defined below) stockholders, approved an amended and restated certificate of incorporation, which, among other things, increased authorized capital stock from 100,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, to 300,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

On March 15, 2017, Zeta changed its name to Aerpio Pharmaceuticals, Inc. and its wholly-owned subsidiary, Aerpio Acquisition Corp., a corporation formed in the State of Delaware on March 3, 2017, merged with and into Aerpio Therapeutics, Inc., ("Aerpio"), (the "Merger"), a corporation incorporated on November 17, 2011 in the State of Delaware. Pursuant to the Merger, Aerpio remained as the surviving corporation and became the Company's wholly-owned subsidiary.

At the effective time of the Merger, the shares of the Aerpio's (i) common stock issued and outstanding immediately prior to the closing of the Merger (including restricted common stock, whether vested or unvested, issued under the Aerpio's 2011 Equity Incentive Plan), and (ii) redeemable convertible preferred stock issued and outstanding immediately prior to the closing of the Merger, were converted into shares of the Company's common stock. In addition, immediately prior to the Merger, the outstanding amounts under certain Senior Secured Convertible Promissory Notes issued by Aerpio to its pre-Merger noteholders were converted into shares of Aerpio's preferred stock, which were then converted to shares of Aerpio's common stock and subsequently were converted into shares of the Company's common stock, together with the other shares of the Aerpio's common stock described above. In addition, pursuant to the Merger Agreement options to purchase shares of the Aerpio's common stock issued and outstanding immediately prior to the closing of the Merger were assumed and converted into options to purchase shares of the Company's common stock. All the outstanding capital stock of Aerpio was converted into shares of the Company's common stock on a 2.3336572:1 basis.

As a result of the Merger, the Company acquired the business of Aerpio and will continue the existing business operations of Aerpio as a public reporting company under the name Aerpio Pharmaceuticals, Inc. Immediately after the Merger, on March 15, 2017, Aerpio converted into a Delaware limited liability company (the "Conversion").

Immediately following the Conversion, the pre-Merger stockholders of Zeta surrendered for cancellation 4,000,000 of the 5,000,000 shares of the outstanding common stock of Zeta, (the "Share Cancellation"). Following the Share Cancellation, on March 15, 2017, the Company closed a private placement offering (the "Offering") of 8,049,555 shares of the Company's common stock, at a purchase price of $5.00 per share, for net proceeds of approximately $37.2 million and the issuance of warrants with a term of three years, to purchase 317,562 shares of the Company's common stock at an exercise price of $5.00 per share.

The Merger was treated as a recapitalization and reverse acquisition for financial reporting purposes. The Company is the legal acquirer of Aerpio in the transaction. However, Aerpio is considered the acquiring company for accounting purposes since (i) former Aerpio stockholders own in excess of 50% of the combined enterprise on a fully diluted basis immediately following the Merger and Offering, and (ii) all members of the Company's executive management and Board of Directors are from Aerpio. In accordance with "reverse merger" or "reverse acquisition" accounting treatment, the unaudited condensed consolidated interim financial statements for the period ended June 30, 2017 include the accounts of the Company and its wholly owned subsidiary, Aerpio Therapeutics, LLC. The comparative historical financial statements for periods ended prior to the date of the Merger are the historical financial statements of Aerpio. Consequently, the assets and liabilities and the historical operations that are reflected in these condensed consolidated financial statements of the company are those of Aerpio, which were recorded at their historical cost basis. Unless otherwise indicated, all share and per share figures reflect the exchange of each 2.3336572 shares of Aerpio capital stock, convertible notes and share based awards, then outstanding, for 1 share of the Company's common stock at the effective time of the Merger.

The Company is a biopharmaceutical company focused on advancing first-in-class treatments for ocular disease. The Company's lead product candidate, AKB-9778, a small molecule activator of the tie-2 pathway, is being developed for the treatment of diabetic retinopathy ("DR"). Tie-2 signaling is essential for regulating blood vessel development and the stability of mature vessels. The Company has completed a Phase 2a clinical trial in diabetic macular edema ("DME"), a swelling of the retina that is a common cause of vision loss in patients with DR and during the second quarter of 2017, initiated a twelve month, double blind Phase 2b clinical trial in patients with DR who have not developed more serious complications such as DME or proliferative diabetic retinopathy.

In addition, the Company has two pipeline programs. AKB-4924 is a drug candidate for the treatment of inflammatory bowel disease and ARP-1536, humanized monoclonal antibody is a drug candidate for ocular disease. Humanized antibodies are antibodies from non-human species whose protein sequences have been modified to increase their similarity to antibodies produced naturally in humans. The Company completed a Phase 1a clinical trial in healthy volunteers for AKB-4924 and APR-1536 is currently in preclinical development. Further development on the pipeline programs is subject to receiving additional funding, which the Company may seek through collaborations with potential strategic and commercial partners.

The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates, and undertaking preclinical and clinical studies. The Company has not generated any revenues to date, nor is there any assurance of any future revenues. The Company's product candidates are subject to long development cycles, and there is no assurance the Company will be able to successfully develop, obtain regulatory approval for, or market its product candidates.

The Company is subject to a number of risks similar to other life science companies in the current stage of its life cycle, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved, and protection of proprietary technology. If the Company does not successfully commercialize any of its products or mitigate any of these other risks, it will be unable to generate revenue or achieve profitability.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Securities and Exchange Commission (SEC) regulations and include all of the information and disclosures required by generally accepted accounting principles in the United States ("U.S. GAAP" or "GAAP") for interim financial reporting, and, in the opinion of management include all adjustments necessary for a fair presentation of the results of operations, financial position and cash flows for each period presented. All adjustments are of a normal and recurring nature. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements of Aerpio Therapeutics Inc. and related footnotes for the year ended December 31, 2016, included in the Company's Registration Statement on Form S-1 filed with the SEC. The results of operations for the interim periods are not necessarily indicative of results of operations for a full year. The Company's condensed consolidated financial statements are stated in U.S. Dollars.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics. All the assets and operations of the Company's sole operating segment are located in the United States of America.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: fair value of the Company's common stock and other equity instruments, accrued expenses, and income taxes.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock and other equity instruments. The Company granted stock options at exercise prices not less than the fair value of its common stock, as determined by the Board of Directors contemporaneously at the date such grants were made. The Board of Directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of common and preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time, and, for periods prior to the Offering, the likelihood of achieving a liquidity event, such as a public offering or sale of the Company.

Historically, the Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time, and, at December 31, 2016, a probability analysis of various liquidity events under differing scenarios, including both a potential public trading scenario and potential sale scenario. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock and other equity instruments at each valuation date.

The Company's results can also be affected by economic, political, legislative, regulatory, and legal actions. Economic conditions, such as recessionary trends, inflation, interest and monetary exchange rates, government fiscal policies, and changes in the prices of research studies, can have a significant effect on operations. While the Company maintains reserves for anticipated liabilities and carries various levels of insurance, the Company could be affected by civil, criminal, regulatory or administrative actions, claims, or proceedings.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits, and funds invested in short-term investments with remaining maturities of three months or less at the time of purchase. The Company may maintain balances with its banks in excess of federally insured limits.

Short-Term Investments

Time deposits with remaining maturities of greater than three months but less than one year at the time of purchase are classified as short-term investments in the accompanying balance sheets.

Grant Income

Grant income is recognized as earned based on contract work performed.

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expense consists of (i) employee-related expenses, including salaries, benefits, travel, and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organizations and consultants; (iii) the cost of acquiring, developing, and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies; and (v) costs associated with preclinical activities and regulatory operations.

The Company enters into consulting, research, and other agreements with commercial firms, researchers, universities, and others for the provision of goods and services.

Under such agreements, the Company may pay for services on a monthly, quarterly, project, or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to the Company by its clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

Patents

Costs incurred in connection with the application for and issuances of patents are expensed as incurred.

Income Taxes

Income taxes are recorded in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification (ASC) Topic 740, *Income Taxes*, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities and for loss and credit carryforwards using enacted tax rates anticipated to be in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that some or all of the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of June 30, 2017, and December 31, 2016, the Company does not have any significant uncertain tax positions. If incurred, the Company would classify interest and penalties on uncertain tax positions as income tax expense.

Net Loss per Share

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by adjusting the weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury stock method. For purposes of this calculation, convertible preferred stock, convertible notes payable, stock options to purchase common stock, warrants, and unvested restricted stock awards are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

For all periods presented, all share and per share amounts have been retrospectively adjusted to reflect the exchange of each 2.3336572 shares of Aerpio capital stock and share based awards then outstanding, for 1 share of the Company's common stock at the effective time of the Merger.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation*. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock, to be recognized in the statements of operations and comprehensive loss based on their fair values. All the Company's stock-based awards are subject only to service-based vesting conditions. The Company estimates the fair value of its stock-based awards using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate, and (d) expected dividends. The fair value of restricted stock awards is determined based on the Company's estimated common stock value.

Due to the lack of a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees, and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options.

Compensation expense related to awards to employees is calculated on a straight-line basis by recognizing the grant date fair value over the associated service period of the award, which is generally the vesting term. Awards to non-employees are adjusted through share-based compensation expense as the award vests to reflect the current fair value of such awards and are expensed using an accelerated attribution model.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash equivalents, short-term investments, accounts receivable, and accounts payable. The Company values cash equivalents using quoted market prices. The valuation technique used to measure the fair value of short-term investments was based on net asset values corroborated with observable market data. The fair value of accounts receivable and accounts payable approximate the carrying value because of their short-term nature.

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly
- Level 3 – Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable

To the extent that a valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no transfers within the fair value hierarchy in the six months ended June 30, 2017 or June 30, 2016. The assets of the Company measured on a recurring basis as of June 30, 2017 and December 31, 2016 basis are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
June 30, 2017				
Assets:				
Cash and cash equivalents	$ 28,847,937	$ —	$ —	$ 28,847,937
Short-term investments	—	50,000	—	50,000
Total assets	$ 28,847,937	$ 50,000	$ —	$ 28,897,937
December 31, 2016				
Assets:				
Cash and cash equivalents	$ 1,609,694	$ —	$ —	$ 1,609,694
Short-term investments	—	50,000	—	50,000
Total assets	$ 1,609,694	$ 50,000	$ —	$ 1,659,694

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents and short-term investments are the only financial instruments that potentially subject the Company to concentrations of credit risk. At June 30, 2017 and December 31, 2016, all the Company's cash was deposited in accounts at two principal financial institutions. The Company maintains its cash and cash equivalents and short-term investments with a high-quality, accredited financial institution and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, if any. Comprehensive loss equaled net loss for all periods presented.

Furniture and Equipment

Furniture and equipment is stated at cost, less accumulated depreciation. Furniture and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to seven years. Such costs are periodically reviewed for recoverability when impairment indicators are present. Such indicators include, among other factors, operating losses, unused capacity, market value declines, and technological obsolescence. Recorded values of asset groups of property, plant, and equipment that are not expected to be recovered through undiscounted future net cash flows are written down to current fair value, which generally is determined from estimated discounted future net cash flows (assets held for use) or net realizable value (assets held for sale).

Research and Development Costs

Research and development costs are expensed as incurred.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In March 2016, the FASB issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting." This ASU is intended to simplify accounting for share-based payments and requires that excess tax benefits for share-based payments be recorded as a reduction of income tax expense and reflected within operating cash flows rather than being recorded within equity and reflected within financing cash flows. The ASU also provides an option for companies to recognize forfeitures as they occur rather than estimating the number of awards expected to be forfeited. The Company adopted this ASU on January 1, 2017 and is applying the new guidance related to excess tax benefits on a prospective basis. The Company has also elected to account for forfeitures of share-based payments as they occur. The effect of adoption was not material to the condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. This ASU will require lessees to recognize almost all leases on the balance sheet as a right-of-use asset and a lease liability. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as finance leases or operating leases. This update is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted. The Company is currently assessing the effect that adoption of the new standard will have on its condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15—Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The amendments in ASU 2016-15 address eight specific cash flow issues and apply to all entities that are required to present a statement of cash flows under FASB Accounting Standards Codification (FASB ASC) 230, Statement of Cash Flows. The amendments in ASU 2016-15 are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption during an interim period. The Company has not yet adopted this update and is currently evaluating the impact of ASU No. 2016-15 on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issue Task Force)*, or ASU 2016-18. This new standard addresses the diversity that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments in ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within the year of adoption, with early adoption permitted. We do not expect that the adoption of ASU 20116-18 will have a material impact on our condensed consolidated financial statements.

3. Related-Party Arrangements

Aerpio was initially capitalized in December 2011 in a spinout transaction from Akebia Therapeutics, Inc. (Akebia) to enable more rapid development of its compounds. In connection with the spinout of Aerpio from Akebia, the companies entered into shared services agreements. Under the terms of the shared services agreements, Akebia and Aerpio obtained from and provided to each other certain services, as outlined below. These agreements were expired at December 31, 2016.

Below is a summary of the activities included in the statements of operations and comprehensive loss:

Activity	Financial Statement Caption	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Akebia related employee costs	Research and development operating expenses	$ —	$ —	$ —	$ 12,923
Facility-related reimbursement	Other income, net	—	—	—	997

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses are as follows:

	June 30, 2017	December 31, 2016
Accounts payable	$ 782,169	$ 1,135,608
Professional fees	302,106	200,468
Accrued bonus	256,889	—
Accrued interest	—	483,442
Accrued vacation	106,686	52,835
Accrued project costs	354,995	541,158
Other	53,972	57,459
Total accounts payable and accrued expenses	$ 1,856,817	$ 2,470,970

5. Notes Payable to Investors

In March 2016, Aerpio entered into a senior secured convertible note financing (the “Convertible Notes” or the “Convertible Note Financing”) totaling approximately $9,000,000, with certain preferred investors of Aerpio. All preferred investors were invited to participate in the Convertible Notes Financing. At June 30, 2017 and December 31, 2016 the unamortized debt issuance costs related to Convertible Note financings was $0 and $75,561. In connection with the Convertible Note Financing, Aerpio’s Articles of Incorporation were amended such that any Aerpio preferred stockholder that did not participate in the Aerpio Convertible Note Financing would have their respective shares of Aerpio preferred stock automatically converted into Aerpio common stock using a 3-to-1 conversion ratio and such preferred stockholders would lose the right to representation on the Aerpio Board of Directors and other preferred rights.

The Convertible Note Financing had two separate closings of approximately $4,500,000 each on April 14, 2016 and July 15, 2016. Certain Aerpio preferred stockholders chose not to participate in the Aerpio Convertible Note Financing and their respective Aerpio preferred stock was converted into shares of Aerpio common stock in April 2016 in accordance with the terms of the Articles of Incorporation. Aerpio treated this as an extinguishment of its preferred stock. The Convertible Notes accrued interest at 8% per annum, compounded annually. The Company incurred $138,312 of costs in association with the issuance of the Convertible Notes that were amortized over the expected life of the Convertible Notes, from the date of execution through October 31, 2016. The Convertible Notes were also subject to mandatory prepayment upon the occurrence of certain events, such as a liquidation, dissolution, or the sale of Aerpio. In addition, and prior to maturity, the Convertible Notes were automatically convertible into shares of Aerpio capital stock upon the occurrence of a sale of Aerpio's capital stock in a single transaction resulting in gross proceeds to Aerpio of $30,000,000 (hereinafter referred to as an "Investor Sale"). The type and class of Aerpio capital stock of to be issued to the holder of each Convertible Note upon conversion would have been identical to the type and class of Aerpio capital stock issued in the Investor Sale. The holder of each Convertible Note was entitled to a number of shares of Aerpio capital determined by dividing (i) the outstanding principal amount of the Convertible Note plus any unpaid accrued interest by (ii) an amount equal to the price per share of Aerpio capital stock paid by the purchasers of such shares in connection with the Investor Sale. The Convertible Notes were secured by a first priority perfected security interest in all of the Aerpio's assets.

In October 2016 and February 2017, Aerpio executed an additional senior secured Convertible Note financings (the "Additional Convertible Notes" or the "Additional Convertible Note Financings") totaling approximately $3,500,000 and $300,000 respectively, with certain preferred investors of Aerpio. The terms of the Additional Convertible Notes are identical to the Convertible Notes and are treated as extensions of the original Convertible Note Financing. The Company incurred $125,935 of costs associated with these transactions, which were amortized to the maturity date of March 31, 2017. In connection with the Additional Convertible Note Financings, the Convertible Notes were amended and their respective maturity dates were extended from October 31, 2016 to March 31, 2017. The amendments are accounted for as a modification for accounting purposes.

In connection with the Merger (Note 1) the Convertible Notes and accrued interest were converted into the Company's common stock.

6. Common Stock

As of June 30, 2017, and December 31, 2016, the Company had 300,000,000 and 17,440,436 shares, respectively, of authorized common stock with par value of $0.0001 per share. On March 15, 2017, in connection with the Merger, (Note 1) all the outstanding redeemable convertible preferred stock, was converted into 14,015,016 shares of the Company's common stock and the Convertible Notes, both principal and accrued interest, were converted into 2,744,059 shares of the Company's common stock.

The common stock has the following characteristics.

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings.

Dividends

The holders of common stock are entitled to receive dividends, if and when declared by the Board of Directors. Since the Company's inception, no dividends have been declared or paid to the holders of common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's assets.

Lock-up Agreements and Other Restrictions

In connection with the Merger, each of the Company's executive officers, directors, stockholders holding substantially all of the shares of common stock issued in exchange for shares held in Aerpio immediately prior to the Merger, certain other stockholders, and certain key employees, (the "Restricted Holders"), holding at the closing date of the Merger (the "Closing Date") an aggregate of approximately 18.9 million shares of common stock, entered into lock-up agreements,(the "Lock-Up Agreements"), whereby they are restricted for a period of nine months after the Merger, or the Restricted Period, from certain sales or dispositions (including pledge) of all (or 80% in the case of the holders of 915,000 shares) of the Company's common stock held by (or issuable to) them, (such restrictions together referred to as the "Lock-Up"). The foregoing restrictions will not apply to the resale of shares of common stock by any Restricted Holder in any registered secondary offering of equity securities by the Company (and, if such offering is underwritten, with the written consent of the lead or managing underwriter), or to certain other transfers customarily excepted.

In addition, each Restricted Holder and any stockholders holding or beneficially owning 1% or more of our common stock after giving effect to the Merger, agreed, for a period of 12 months following the Closing Date, that it will not, directly or indirectly, effect or agree to effect any short sale (as defined in Rule 200 under Regulation SHO of the Exchange Act), whether or not against the box, establish any "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) with respect to the common stock, borrow or pre-borrow any shares of common stock, or grant any other right (including, without limitation, any put or call option) with respect to the common stock or with respect to any security that includes, relates to or derives any significant part of its value from the common stock or otherwise seek to hedge its position in the common stock.

Anti-dilution protection

Investors in the Offering have anti-dilution protection with respect to the shares of the Company's common stock sold in the Offering such that if within six (6) months after the initial closing of the Offering the Company issues additional shares of common stock or common stock equivalents (subject to certain exceptions), for consideration per share less than the Offering Price, or the Lower Price, each such investor will be entitled to receive from the Company additional shares of common stock in an amount such that, when added to the number of shares of common stock initially purchased by such investor and still held of record and beneficially owned by such investor at the time of the dilutive issuance, or the Held Shares, will equal the number of shares of common stock that such investor's Offering subscription amount for the Held Shares would have purchased at the Lower Price. Either (i) holders of a majority of the then-held Held Shares or (ii) a representative of the holders of the then-held Held Shares, which representative shall be appointed by three (3) investors who then hold the largest number of Held Shares, may waive the anti-dilution rights of all Offering investors with respect to a particular issuance by the Company. These anti-dilution rights were determined not to be a freestanding financial instrument and do not meet the definition of a derivative. Accordingly, the anti-dilution rights are embedded into the shares of the Company's common stock and do not require separate accounting at June 30, 2017.

Warrants to Purchase Common Stock

At June 30, 2017, the Company had warrants outstanding for the purchase of 317,562 shares of the Company's common stock at an exercise price of $5.00 per share. The warrants have a three-year term and expire on March 15, 2020. The Warrants were issued in connection with the Offering. At the expiration date of the warrant, if the fair value of the Company's common stock exceeds the exercise price, the warrant will be automatically exercised and the exercise price will be fulfilled through the net share settlement provisions. The number of shares and the exercise price shall be adjusted for standard ant-dilution events such as stock splits, combinations, reorganizations, or issue shares as part of a stock dividend. Upon a change of control, the warrant holder will have the right to receive securities, cash or other properties it would have been entitled to receive had the warrant been exercised. The Warrants are equity classified instruments and do not contain contingent exercise provisions, or other features, that would preclude the Company from concluding that the Warrants are indexed solely to the Company's stock.

7. Preferred Stock

At June 30, 2017, the Company had 10,000,000 shares of preferred stock, par value $0.0001 per share, in authorized capital. No preferred stock was issued and outstanding at June 30, 2017. In connection with the Merger (Note 1), all the Aerpio redeemable convertible preferred stock issued and outstanding prior to the Merger was converted into shares of the Company's common stock.

At December 31, 2016, Aerpio's redeemable convertible preferred stock consisted of the following:

- Series A redeemable convertible preferred stock: 1,326,147 shares authorized and 1,239,338 shares issued and outstanding;
- Series A1 redeemable convertible preferred stock: 8,368,247 shares authorized and 8,289,663 shares issued and outstanding; and

- Series A2 redeemable convertible preferred stock: 4,660,573 shares authorized and 4,486,015 shares issued and outstanding.

All share and per share amounts are on an as converted basis to reflect the effect of the Merger. The rights, preferences, and privileges of the redeemable convertible preferred stock issued and outstanding prior to the Merger were as follows:

Voting

The holders of redeemable convertible preferred stock were entitled to the number of votes equal to the number of whole shares of Aerpio common stock into which the shares of redeemable convertible preferred stock were convertible. Except as provided by law or otherwise, the holders of redeemable convertible preferred stock voted together with the holders of Aerpio common stock as a single class. Certain significant actions required approval by at least 50% of the holders of redeemable convertible preferred stock voting as a single class on an as converted basis. Such significant actions include significant asset transfers, acquisitions, liquidation, amendments to the certificate of incorporation, new indebtedness, repurchase of common stock, changes in the authorized numbers of directors constituting the Board of Directors, and the declaration of dividends.

The holders of shares of redeemable convertible preferred stock were entitled to elect six members of Aerpio's Board of Directors, which was subject to reduction to not less than four directors under certain circumstances. The holders of Aerpio common stock (including any holders of all shares of redeemable convertible preferred stock on an as converted basis) were entitled to elect two members of Aerpio's Board of Directors, which was subject to reduction to one director under certain circumstances.

Dividends

Dividends were payable, if permitted by law, in accordance with redeemable convertible preferred stock terms or when and if declared by Aerpio Board of Directors. Prior to the issuance of Series A2 Preferred Stock, dividends on Series A Preferred Stock and Series A1 Preferred Stock were cumulative and accrued daily at a rate of 6% per annum whether or not declared. As part of the Series A2 Preferred Stock issuance, the dividend provisions for Series A Preferred Stock and Series A1 Preferred Stock were retrospectively amended to be noncumulative with the cumulative provision to begin after the Series A2 Preferred Stock issuance date at a rate of 6% per annum. This amendment did not significantly affect the nature of the Series A Preferred Stock and Series A1 Preferred Stock or their fair value. Accordingly, the amendment was treated as a modification for accounting purposes.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of Aerpio, or upon the occurrence of a Deemed Liquidation Event, as defined, at the election of more than 50% of the holders of Series A2 Preferred Stock and Series A1 Preferred Stock, those holders were entitled to be paid, in preference to the holders of Series A Preferred Stock and Aerpio common stock, out of the assets of Aerpio available for distribution at $4.90 per share for Series A2 Preferred Stock and $3.97 per share for Series A1 Preferred Stock, plus any accrued but unpaid dividends. After the holders of Series A1 Preferred Stock and Series A2 Preferred Stock are satisfied, the holders of Series A Preferred Stock were paid at $4.27 per share, plus any accrued but unpaid dividends before any payment was made to the holders of Aerpio's common stock.

In the event the assets of Aerpio available for distribution to stockholders were insufficient to pay the full amount to which the holder was entitled, the holders of Series A2 Preferred Stock and Series A1 Preferred Stock would share ratably any assets available for distribution in proportion to their relative original investment amounts. Any remaining assets of Aerpio would be distributed ratably among the holders of Series A Preferred Stock based upon aggregate applicable dividends accrued on Series A Preferred Stock not previously paid.

After the payment of all preferential amounts required to be paid to the holders of redeemable convertible preferred stock, the remaining assets available for distribution would be distributed among the holders of redeemable convertible preferred stock and Aerpio common stock based on the pro rata number of shares held by each holder, treating such securities as if they had been converted to Aerpio common stock immediately prior to such dissolution, liquidation, or winding-up of Aerpio.

Conversion

Each share of redeemable convertible preferred stock was convertible at the option of the holder, at any time and from time to time, into fully paid and non-assessable shares of Aerpio common stock. The initial conversion ratio was one share of redeemable convertible preferred stock for one share of Aerpio's common stock. The applicable conversion rate was subject to adjustments upon the occurrence of certain events.

Each share of redeemable convertible preferred stock was automatically convertible into fully paid and non-assessable shares of Aerpio common stock at the then-applicable conversion ratio, as defined, upon either: (i) the closing of the sale of shares of Aerpio's common stock to the public in an underwritten public offering at a price of $14.70 resulting in at least $40,000,000 of gross proceeds, or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of more than 50% of the then outstanding shares of redeemable convertible preferred stock on an as-converted basis.

Aerpio evaluated each series of its redeemable convertible preferred stock and determined that each individual series is considered an equity host under ASC Topic 815, Derivatives and Hedging. In making this determination, Aerpio's analysis followed the whole instrument approach, which compares an individual feature against the entire redeemable convertible preferred stock instrument that includes that feature. Aerpio's analysis was based on a consideration of the economic characteristics and risks of each series of redeemable convertible preferred stock. More specifically, Aerpio evaluated all the stated and implied substantive terms and features, including: (i) whether the redeemable convertible preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of redeemable convertible preferred stock were entitled to dividends, (iv) the voting rights of the redeemable convertible preferred stock, and (v) the existence and nature of any conversion rights. Aerpio concluded that as the redeemable convertible preferred stock represents an equity host, the conversion feature included in all series of redeemable convertible preferred stock is clearly and closely related to the associated host instrument. Accordingly, the conversion feature of all series of redeemable convertible preferred stock was not considered an embedded derivative that required bifurcation.

Aerpio accounted for potentially beneficial conversion features under ASC Topic 470-20, Debt with Conversion and Other Options. At the time of each of the issuances of redeemable convertible preferred stock, Aerpio's common stock into which each series of the redeemable convertible preferred stock was convertible had an estimated fair value less than the effective conversion prices of the redeemable convertible preferred stock. Therefore, there was no beneficial conversion element on the respective commitment dates.

In March 2016, in connection with the Convertible Note Financing described more fully in Note 5, Aerpio's Articles of Incorporation were amended such that any preferred stockholder that did not participate in the Convertible Note Financing would have their respective shares of redeemable convertible preferred stock automatically converted into Aerpio common stock using a 3-to-1 conversion ratio and such preferred stockholders would lose the right to representation on Aerpio's Board of Directors and other preferred rights. The amendment did not represent an increase in value to the preferred stockholders and was treated as a modification to the redeemable convertible preferred stock for accounting purposes. Certain shares of redeemable convertible preferred stock held by preferred stockholders that elected to not participate in the Convertible Note Financing were converted to shares in Aerpio's common stock.

Redemption

The redeemable convertible preferred stock was redeemable on or after July 31, 2017, upon a request by more than 50% of the holders of redeemable convertible preferred stock then outstanding, payable in three annual installments commencing not more than 60 days following receipt by notice at a price equal to the greater of (i) the applicable original purchase price and dividends accrued but unpaid (Applicable Accrued Value), which is equal to its liquidation preference, or (ii) the redeemable convertible preferred stock fair value per share. Due to this redemption option, the redeemable convertible preferred stock was recorded in the mezzanine equity and subject to subsequent measurement under the guidance provided under ASC 480-10-S99. In accordance with that guidance, Aerpio elected to recognize changes in redemption value immediately as they occur through adjustments to the carrying amounts of the instruments at the end of each reporting period. As of December 31, 2016, the redemption values of all series of redeemable convertible preferred stock were equal to their respective Applicable Accrued Value. The fair values of redeemable convertible preferred stock were based upon a hybrid of the probability-weighted expected returns method and an option pricing model (OPM), which is a nonrecurring Level 3 fair value measurement within the fair value hierarchy. Under this hybrid model, share value is based on the probability weighted value of Aerpio in a potential public trading scenario, in which the redeemable convertible preferred stock converted to Aerpio common stock, and a second scenario in which equity value is allocated using the OPM. For the public trading scenario, Aerpio used the guideline public company method under the market approach.

8. Stock-Based Compensation

Pursuant to the Merger (Note 1), the Company assumed each option to purchase Aerpio common stock that remained outstanding under the Aerpio Therapeutics, Inc. 2011 Equity Incentive Plan (the "Plan"), whether vested or unvested, and converted it into an option to purchase such number of shares of the Company's common stock equal to the number of shares of Aerpio common stock subject to the option immediately prior to the Merger, divided by the applicable Merger exchange rate of 2.3336572, with any fraction rounded down to the nearest whole number. The exercise price per share of each assumed option is equal to the exercise price of the Aerpio option prior to the assumption, multiplied by the applicable Merger exchange rate of 2.3336572, rounded up to the nearest whole cent. The terms of the 2011 Plan continue to govern the options covering an aggregate of 898,692 shares of the Company's common stock at June 30, 2017 and December 31, 2016, subject to awards assumed by the Company, except that all references in the 2011 Plan to Aerpio, will now be the Company. In addition, each unvested share of Aerpio restricted common stock issued under the 2011 Plan that was outstanding immediately prior to the effective time of the Merger, was converted by virtue of the Merger into restricted common stock of the Company, equal to the number of shares of Aerpio common stock subject to the unvested shares of Aerpio restricted common stock immediately prior to the Merger divided by the applicable Merger exchange rate of 2.3336572, with any fraction rounded down to the nearest whole number.

In March 2017, the Company's Board of Directors adopted, and the stockholders approved, the 2017 Stock Option and Incentive Plan (the "2017 Plan"), that became effective in April 2017. The 2017 Plan provides for the issuance of incentive awards up to 4,600,000 shares of common stock to officers, employees, consultants and directors, less the number of shares subject to issued and outstanding awards under the 2011 Plan that were assumed in the Merger. The 2017 Plan also provides that the number of shares reserved for issuance thereunder will be increased annually on the first day of each year beginning in 2018 by four percent (4%) of the shares of our common stock outstanding on the last day of the immediately preceding year or such smaller increase as determined by our board of directors. No awards were granted under the 2017 Plan as of June 30, 2017.

Stock Options

The options granted generally vest over 48 months. For employees with less than one year's service, options vest in installments of 25% at the one-year anniversary and thereafter in 36 equal monthly installments beginning in the 13th month after the initial Vesting Commencement Date (as defined), subject to the employee's continuous service with the Company. Options granted to other employees vest in 48 equal monthly installments after the initial Vesting Commencement Date, subject to the employee's continuous service with the Company. The options generally expire ten years after the date of grant. The fair value of the options at the date of grant is recognized as an expense over the requisite service period. No option awards were granted in the six months ended June 30, 2017 and one option award was granted for 50,228 shares in the six months ended June 30, 2016.

The following table summarizes the stock option activity during the six-months ended June 30, 2017:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2017	927,592	$ 1.70	7.48	$ 1,030,217
Granted	—	—		
Exercised	(25,729)	1.40		
Expired/cancelled	(2,901)	2.11		
Outstanding, June 30, 2017	898,962	$ 1.70	6.87	$ 2,963,449
Expected to vest, June 30, 2017	231,733	$ 1.80	7.91	742,130
Options exercisable, June 30, 2017	667,229	$ 1.67	6.50	$ 2,221,319

Aggregate intrinsic value represents the estimated fair value of the Company's common stock at the end of the period in excess of the weighted average exercise price multiplied by the number of options outstanding or exercisable.

Compensation expense for stock options was $38,954 and $42,225 for the three months ended June 30, 2017 and 2016, respectively and $120,075 and $85,041 for the six months ended June 30, 2017 and 2016 respectively. As of June 30, 2017, there was $226,405 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.0 years.

Restricted Stock

Shares of restricted stock generally have similar vesting terms as stock options. A summary of the Company's restricted stock activity and related information during the six months ended June 30, 2017 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Nonvested, January 1, 2017	241,096	$ 1.91
Granted	—	—
Vested	(67,126)	$ 1.77
Forfeited	(5,246)	$ 2.20
Nonvested, June 30, 2017	168,724	$ 1.94

The Company recognized compensation expense for restricted stock of $72,570 and $77,325 for the three months ended June 30, 2017 and 2016, respectively, and $146,834 and 159,724 for the six months ended June 30, 2017 and 2016 respectively. As of June 30, 2017, there was $288,016 of unrecognized compensation cost related to these restricted stock grants, which is expected to be recognized over a weighted average period of 1.2 years.

Compensation Expense Summary

The Company has recognized the following compensation cost related to employee and non-employee stock-based compensation activity:

	Three Months Ended June 30		Six Months Ended June 30	
	2017	2016	2017	2016
Research and development	$ 73,033	$ 74,944	$ 188,335	$ 156,677
General and administrative	38,491	44,606	78,574	88,088
Total	$ 111,524	$ 119,550	$ 266,909	$ 244,765

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option pricing models require the input of various subjective assumptions, including the option's expected life, expected dividend yield, price volatility and risk free interest rate of the underlying stock. Accordingly, the weighted-average fair value of the options granted during the three and six months ended June 30, 2016 was $1.22. The calculation was based on the following assumptions.

	Three Months Ended June 30, 2016	Six Months Ended June 30, 2016
Expected term (years)	6.00	6.00
Risk-free interest rate	1.39%	1.39%
Expected volatility	78.00%	78.00%
Expected dividend yield	0.00%	0.00%

9. Income Taxes

The Company did not record a current or deferred income tax expense of benefit for the six months ended June 30, 2017 and 2016, due to the Company's net losses and increases in its deferred tax asset valuation allowance.

10. Net Loss per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented:

	Three Months Ended June 30		Six Months Ended June 30	
	2017	2016	2017	2016
Net loss and comprehensive loss	$ (5,520,307)	$ (4,385,262)	$ (10,516,010)	$ (8,579,961)
Extinguishment of preferred stock	—	224,224	—	224,224
Accretion of preferred stock to redemption value	—	(1,028,121)	(943,297)	(2,043,492)
Net loss attributable to common stockholders	$ (5,520,307)	$ (5,189,159)	$ (11,459,307)	$ (10,399,229)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (6.30)	$ (0.70)	$ (13.33)
Weighted average common shares used in computing net loss per share attributable to common stockholders, basic and diluted	26,895,164	823,097	16,313,324	780,152

The following weighted average common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	June 30	
	2017	2016
Convertible preferred stock (if converted)	—	14,141,112
Notes and accrued interest (if converted)	—	944,048
Options to purchase common stock	898,962	927,592
Unvested restricted stock	168,724	344,574
Warrants to purchase common stock	317,562	—

11. Commitments and Contingencies

The Company contracts with various organizations to conduct research and development activities. In addition, the Company is a party to a lease covering 7,580 square feet of space in Cincinnati, Ohio that expires in June 2018. Total rent expense for all operating leases was $51,153 and $59,924 for the three months ended June 30, 2017 and 2016, and $102,442 and $108,104 the six months ended June 30, 2017 and 2016 respectively. The lease agreement contains free rent, escalating rent payments and reimbursement for tenant improvements that amounted to $0 and $46,390 in the three and six months ended June 30, 2016, respectively. Rent expense is recorded on the straight-line basis over the initial term with the differences between rent expense and rent payments recorded as deferred rent. As of June 30, 2017, the Company had deferred rent of $46,372, which is included in accrued expenses in the accompanying condensed consolidated balance sheet. As of June 30, 2017, non-cancelable future minimum lease payments under the existing operating lease were $105,735. As of June 30, 2017, future payments related to operating leases activities are presented in the table below.

	2017	2018	2019 and Thereafter	Total
Operating leases	$ 52,757	$ 52,978	$ —	$ 105,735

The Company contracts with various organizations to conduct research and development activities, including clinical trial organizations to manage clinical trial activities. The scope of the services under these research and development contracts can be modified and the contracts cancelled by the Company upon written notice. In the event of a cancellation, the Company would only be liable for the cost and expenses incurred to date.

12. Employee Stock Purchase Plan

In March 2017, the Board of Directors adopted and the stockholders approved, the Employee Stock Purchase Plan (the "ESPP"), that became effective in April 2017. The ESPP provides for the issuance of up to 300,000 shares of the Company's common stock for the purchases made under the ESPP. The ESPP also provides that the number of shares reserved for issuance thereunder will be increased annually on the first day of each year beginning in 2018 by one percent (1%) of the shares of the Company's common stock outstanding on the last day of the immediately preceding year or such smaller increase as determined by the Company's Board of Directors. The Board of Directors has not yet determined the timing for the offering periods under the ESPP.

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

The following discussion of the financial condition and results of operations of Aerpio Pharmaceuticals, Inc. should be read in conjunction with the financial statements and the notes to those statements included in this Quarterly Report on Form 10Q for the period ended June 30, 2017. Some of the information contained in this discussion and analysis including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risk, uncertainties and assumptions. You should read the "Risk Factors" section of this Quarterly Report on Form 10Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Operating Overview

We are a biopharmaceutical company focused on advancing first-in-class treatments for ocular disease. Our lead product candidate, AKB-9778, a small molecule activator of the tie-2 pathway, is being developed for the treatment of diabetic retinopathy ("DR"). Tie-2 signaling is essential for regulating blood vessel development and the stability of mature vessels. We completed a Phase 2a clinical trial in diabetic macular edema ("DME"), a swelling of the retina that is a common cause of vision loss in patients with DR. In June 2017, we initiated a twelve month, double blind Phase 2b clinical trial, which we refer to as TIME-2b, in patients with DR who have not developed more serious complications such as DME or proliferative diabetic retinopathy.

The TIME-2b study is a double-masked, placebo-controlled multi-center trial that will enroll 150 patients randomized 1:1:1 to receive either AKB-9778 15 mg subcutaneously once daily, AKB-9778 15 mg twice daily or placebo for a 12-month period. The primary endpoint of the TIME-2b study is the percentage of patients who improve by at least 2 steps in diabetic retinopathy Severity Score (DRSS) in the study eye.

We recently completed a single-center study of the safety and efficacy of AKB-9778 with concomitant PRN anti-vascular endothelial growth factor ("anti-VEGF") therapy in patients with retinal vein occlusion and a history of persistent macular edema on anti-VEGF monotherapy. We believe the results from this study suggest that activation of Tie2 by AKB-9778 may be beneficial in patients with chronic retinal vein occlusion. However, these results are considered exploratory, given that this was an open-label, non-controlled study without a placebo or active control arm.

In addition, we have two pipeline programs. AKB-4924 is a drug candidate for the treatment of inflammatory bowel disease and ARP-1536, humanized monoclonal antibody is a drug candidate for ocular disease. Humanized antibodies are antibodies from non-human species whose protein sequences have been modified to increase their similarity to antibodies produced naturally in humans. We completed a Phase 1a clinical trial in healthy volunteers for AKB-4924 and APR-1536 is currently in preclinical development. Further development on the pipeline programs is subject to receiving additional funding, which we may seek through collaborations with potential strategic and commercial partners.

Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical and clinical studies. We have not generated any revenues to date, nor is there any assurance of future revenues. Our product candidates are subject to long development cycles, and there is no assurance we will be able to successfully develop, obtain regulatory approval for, or market our product candidates. As of June 30, 2017, we had an accumulated deficit of $97.6 million and anticipate incurring additional losses for the next several years.

Our primary source of liquidity to date has been through the private placement offering of our common stock (the "Offering") in March 2017 and the historical sales of redeemable convertible preferred stock, common stock and proceeds from convertible debt. The aggregate net proceeds from the Offering in March 2017 were $37.2 million. In 2016, we raised a total of $12.5 million through the issuance of secured convertible notes. In 2017, we raised a total of $0.3 million through the issuance of secured convertible notes. In 2014, we raised a total of $22.0 million ($21.8 million net of offering costs) through the issuance of redeemable convertible preferred stock. Based on our current plans, we expect that our existing cash and cash equivalents, will enable us to conduct our planned operations into the first quarter of fiscal 2019. We will need to raise additional funds to further advance our clinical research programs, commence additional clinical trials, and commercialize our products, if approved. While we continue to pursue financing alternatives, which may include equity financing, business development arrangements, licensing arrangements and business combination transactions, financing may not be available to us in the necessary time frame, in the amounts that we need, on terms that are acceptable to us or at all. If we are unable to raise the necessary funds when needed or reduce spending on currently planned activities, we may not be able to continue the development of our product candidates or we could be required to delay, scale back, or eliminate some or all of our development programs and other operations and will materially harm our business and financial position.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our research and development efforts, primarily in connection with our ongoing TIME-2b clinical trial;
- add personnel to support our clinical development program; and
- operate as a public company.

We are subject to a number of risks similar to other life science companies in the current stage of our life cycle, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, competitors developing new technological innovations, and protection of proprietary technology. If we do not successfully mitigate any of these risks, we will be unable to generate revenue or achieve profitability. The accompanying financial statements have been prepared assuming our company will continue as a going concern, which contemplates the realization of assets and payments of liabilities in the ordinary course of business. We had cash and cash equivalents and short-term investments of $28.9 million at June 30, 2017. We believe our existing cash and cash equivalents and short-term investments, will be sufficient to fund currently planned operations into the first quarter of fiscal year 2019.

Basis of Presentation

The unaudited interim financial statements of the Company for the three months ended June 30, 2017 and 2016, and the six months ended June 30, 2017 and 2016 contained herein, include a summary of our significant accounting policies and should be read in conjunction with the discussion below.

Other Recent Developments

Listing on the OTCQB Market

Shares of our common stock were approved for trading and began trading on August 8, 2017 on the OTCQB marketplace under the symbol “ARPO.”

Merger

On March 15, 2017, our wholly-owned subsidiary, Aerpio Acquisition Corp., a corporation formed in the State of Delaware, or the Acquisition Sub, merged with and into Aerpio Therapeutics, Inc., (“Aerpio”) a corporation incorporated on November 17, 2011 under the laws of the State of Delaware. Pursuant to this transaction, or the Merger, Aerpio was the surviving corporation and became our wholly-owned subsidiary. We changed our name from Zeta Acquisition Corp II to Aerpio Pharmaceuticals, Inc. All the outstanding stock of Aerpio was converted into shares of our common stock.

At the effective time of the Merger, the legal existence of Acquisition Sub ceased and each 2.3336572 shares of Aerpio common and preferred stock that was issued and outstanding immediately prior to the effective time of the Merger, including share based awards, whether vested or unvested issued under the Aerpio Therapeutics, Inc. 2011 Equity Incentive Plan (the “2011 Plan”), was automatically exchanged for one share of our common stock. In addition, immediately prior to the Merger, the outstanding amounts under certain senior secured convertible notes issued by Aerpio to its pre-Merger noteholders were converted into Aerpio common stock, which were converted in the Merger into shares of our common stock at the same ratio. We issued an aggregate of 18,000,000 shares of our common stock upon such exchange of the outstanding shares of Aerpio common stock. In addition, at the effective time of the Merger, we assumed Aerpio’s 2011 Equity Incentive Plan. At the effective time of the Merger, we assumed the outstanding options under the 2011 Plan and converted them into options to purchase 927,592 shares of our common stock. As a result of the Merger, we acquired the business of Aerpio and will continue the existing business operations of Aerpio as a public reporting company under the name Aerpio Pharmaceuticals, Inc. Immediately after the Merger, Aerpio was converted into a Delaware limited liability company (the “Conversion”).

The Merger was treated as a recapitalization and reverse acquisition for financial reporting purposes. We are the legal acquirer of Aerpio in the transaction. However, Aerpio is considered the acquiring company for accounting purposes since (i) former Aerpio stockholders own in excess of 50% of the combined enterprise on a fully diluted basis immediately following the Merger and Offering, and (ii) all members of the Company’s executive management and Board of Directors are from Aerpio. In accordance with the “reverse merger” or “reverse acquisition” accounting treatment, the unaudited condensed consolidated interim financial statements for the period ended June 30, 2017 include the accounts of the Company and its wholly owned subsidiary, Aerpio Therapeutics, LLC. The comparative historical financial statements for periods ended prior to the date of the Merger are the historical financial statements of Aerpio.

The following discussion highlights Aerpio's results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described, and provides information that management believes is relevant for an assessment and understanding of the unaudited condensed consolidated statements of financial condition and results of operations presented herein. The following discussion and analysis are based on the Company's unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, which we have prepared in accordance with United States generally accepted accounting principles. You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

Share Cancellation

Following the Merger and Conversion, and immediately prior to the closing of the Offering, an aggregate of 4,000,000 of the 5,000,000 shares of our common stock that were held by the pre-Merger stockholders of Zeta Acquisition Corp. II were surrendered for cancellation (the "Share Cancellation").

Offering

Following the Merger, the Conversion and the Share Cancellation, we sold to accredited investors approximately $40.2 million of our shares of common stock, or 8,049,555 shares, at a price of $5.00 per share, (net proceeds of $37.2 million after deducting placement agent fees and expenses of the offering). In connection with the Offering, we issued warrants to purchase 317,562 shares of our common stock at $5.00 per share to the placement agents for the Offering. The warrants are exercisable for three years. The Offering closed on March 15, 2017.

Components of Statements of Operations

Operating Expenses

Research and Development. Research and development expenses consist primarily of compensation and related costs for personnel, including stock-based compensation, employee benefits and travel. These costs also consist of third-party service providers for our potential product development activities, third-party consulting services, laboratory supplies, research materials, medical equipment, computer equipment, and related depreciation and amortization. We expense research and development expenses as incurred. As we continue to invest in basic research and clinical development of our product candidates, we expect research and development expenses to increase in absolute dollars.

General and Administrative. Our general and administrative expenses consist primarily of compensation and related costs for personnel, including stock-based compensation, employee benefits and travel, for our finance, human resources and other administrative personnel. In addition, general and administrative expenses include third-party consulting, legal, patent, audit, accounting services, and facilities costs. We expect general and administrative expenses to increase in absolute dollars following the consummation of the Merger due to additional legal, accounting, insurance, investor relations and other costs associated with being a public company, as well as other costs associated with growing our business.

Interest Income (Expense), Net

Interest income consists primarily of interest income received on our cash and cash equivalents. Interest expense consists primarily of interest and amortization of debt issuance costs related to our secured convertible promissory notes issued in 2016 and 2017. The secured convertible notes have converted into shares of our common stock in connection with the Merger and Offering.

Grant Income

Grant income is recognized as earned based on contract work performed.

Results of Operations

The following tables set forth our results of operations for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 3,169,115	$ 2,903,564	$ 5,424,699	$ 5,893,122
General and administrative	2,414,747	1,473,869	4,918,748	2,689,754
Total operating expenses	5,583,862	4,377,433	10,343,447	8,582,876
Operating loss	(5,583,862)	(4,377,433)	(10,343,447)	(8,582,876)
Grant income	11,239	80,954	46,896	89,624
Interest income (expense), net	52,316	(88,783)	(219,459)	(87,706)
Other income, net	—	—	—	997
Total other income (expense), net	63,555	(7,829)	(172,563)	2,915
Net loss and comprehensive loss	$(5,520,307)	$(4,385,262)	$(10,516,010)	$(8,579,961)

Comparison of the Three Months Ended June 30, 2017 and 2016

Operating Expenses

	Three Months Ended June 30,	
	2017	2016
Operating expenses:		
Research and development	$ 3,169,115	$ 2,903,564
General and administrative	2,414,747	1,473,869
Total operating expenses	$ 5,583,862	$ 4,377,433

Research and Development

Research and development expenses for the three months ended June 30, 2017 increased $0.3 million, or 9.1%, compared to the three months ended June 30, 2016. This increase was the result of increased expenses associated with our lead program AKB-9778 as we prepared to initiate the double-blind Phase 2b DR clinical trial, offset by a decrease in spending on our pipeline programs – AKP4924 and ARP 1536.

The $0.8 million increase in spending in our lead program, AKB-9778, for the three months ended June 30, 2017 from the corresponding period in 2016 is primarily attributed to expenses associated with initiating the Phase 2 DR clinical trial including the cost of drug product of approximately $2.0 million offset by a decrease in pre-clinical and DME Phase 2a study expenses incurred in the prior period of $1.2 million.

The $0.5 million decrease in spending on our pipeline programs, for the three months ended June 30, 2017 from the corresponding period in 2016 is primarily due to our decision to focus on the lead program while pursuing alternative strategies to fund further development activities for one or both the pipeline programs. During the 2016 period, healthy volunteers were enrolled in the AKB-4924 Phase 1a and ARP-1536 cell line development expenses were incurred.

General and Administrative.

General and administrative expenses in the three months ended June 30, 2017, increased $0.9 million, or 63.8%, compared to the three months ended June 30, 2016. This increase was primarily attributable to personnel and related expenses, including costs to recruit additional resources as well as professional services, including legal, accounting, insurance and other professional service expenses associated with the Merger, related transactions and operating as a public reporting company.

Other Income (Expense), Net

	Three Months Ended June 30, 2017	2016
Other income (expense):		
Grant income	$ 11,239	$ 80,954
Interest income (expense), net	52,316	(88,783)
Total other income (expense), net	$ 63,555	$ (7,829)

Grant income

Grant income is recognized as earned based on contract work performed. Grant income amounts can vary greatly from period to period depending on the funding and needs of the party for whom we perform the requested services.

Interest income (expense), Net

Interest income in the three months ended June 30, 2017 reflects interest earned during the period on cash balances invested in short term money market instruments. The net proceeds received in the Offering on March 15, 2017, less cash used in operations during the quarter, were available for investment. The interest expense in the corresponding three-month period in 2016, was primarily related to the senior secured convertible notes issued in April 2016, offset in part by a small amount of interest income earned on invested cash balances. We completed three note financings in fiscal 2016 totaling an aggregate principal amount of approximately $12.5 million and one note financing in the first quarter of fiscal 2017, totaling an aggregate principal amount of approximately $0.3 million. The financings were funded in four tranches', beginning with one in April 2016 for $4.5 million, one in July 2016 for $4.5 million, one in October 2016 for $3.5 million and one in January 2017 for $0.3 million. The notes accrued interest at the rate of eight percent (8%) per annum, compounded annually. The principal and accrued interest on the secured convertible notes was converted into common stock on March 15, 2017, in connection with the Merger.

Comparison of the Six Months Ended June 30, 2017 and 2016

Operating Expenses

	Six Months Ended June 30, 2017	2016
Operating expenses:		
Research and development	$ 5,424,699	$ 5,893,122
General and administrative	4,918,748	2,689,754
Total operating expenses	$ 10,343,447	$ 8,582,876

Research and Development

Research and development expenses for the six months ended June 30, 2017 decreased $0.5 million, or 7.9%, compared to the six months ended June 30, 2016. This decrease resulted from decreased expenses associated with our pipeline programs – AKB 4924 and ARP 1536, offset by an increase in spending on our lead program AKB-9778, as we prepared to initiate the double-blind Phase 2b DR clinical trial in June 2017.

The $0.7 million increase in spending in our lead program, AKB-9778, for the six months ended June 30, 2017 from the corresponding period in 2016 is primarily attributed to expenses associated with initiating the Phase 2 DR clinical trial including the cost of drug product of approximately $2.9 million offset by a decrease in pre-clinical and Phase 2a expenses incurred in the prior period of $2.2 million.

The $1.2 million decrease in spending on our pipeline programs, for the six months ended June 30, 2017 from the corresponding period in 2016 is primarily due to our decision to focus on the lead program while pursuing alternative strategies to fund further development activities for one or both the pipeline programs. During the 2016 period, healthy volunteers were enrolled in the AKB-4924 Phase 1a and ARP-1536 cell line development expenses were incurred.

General and Administrative

General and administrative expenses in the six months ended June 30, 2017, increased $2.2 million, or 83.7%, compared to the six months ended June 30, 2016. This increase was primarily attributable to personnel and related expenses, including costs to recruit additional resources as well as professional services including, legal, accounting, insurance and other professional service expenses associated with the Merger, related transactions and operating as a public reporting company.

Other (Expense) Income, Net

	Six Months Ended June 30, 2017	2016
Other (expense) income:		
Grant income	$ 46,896	$ 89,624
Interest expense, net	(219,459)	(87,706)
Other income, net	—	997
Total other (expense) income, net	$ (172,563)	$ 2,915

Grant income

Grant income is recognized as earned based on contract work performed. Grant income amounts can vary greatly from period to period depending on the funding and needs of the party for whom we perform the requested services.

Interest expense, Net

Interest expense in the six months ended June 30, 2017, was primarily related to the senior secured convertible notes issued in 2016 and 2017, offset by interest income earned during the period on cash balances invested in short term money market instruments. The net proceeds received in the Offering on March 15, 2017, less cash used in operations during the period, were available for investment. The interest expense in the corresponding six-month period in 2016, was primarily related to the senior secured convertible notes issued in April 2016, offset in part by a small amount of interest income earned on invested cash balances. We completed three note financings in fiscal 2016 totaling an aggregate principal amount of approximately $12.5 million and one note financing in the first quarter of fiscal 2017, totaling an aggregate principal amount of approximately $0.3 million. The convertible note financings were funded in four tranches', beginning with one in April 2016 for $4.5 million, one in July 2016 for $4.5 million, one in October 2016 for $3.5 million and one in January 2017 for $0.3 million. The notes had interest at the rate of eight percent (8%) per annum, compounded annually. The principal and accrued interest on the secured convertible notes was converted into common stock on March 15, 2017, in connection with the Merger.

Other income

Other income represents amounts received from Akebia for services rendered under the shared services agreements. The agreements expired in 2016.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and negative cash flows from operations. For the three months ended June 30, 2017 and 2016, we had net losses of $5.5 million and $4.4 million, respectively. At June 30, 2017 and December 31, 2016, we had an accumulated deficit of $97.7 million and $86.2 million, respectively.

At June 30, 2017, we had cash and cash equivalents and short-term investments of $28.9 million. To date, we have financed our operations principally through the Offering, private placements of our redeemable convertible preferred stock, common stock and issuances of secured convertible promissory notes. Based on our current plans**,** we expect that our existing cash and cash equivalents, will enable us to conduct our planned operations into the first quarter of fiscal 2019.

We could potentially use our available financial resources sooner than we currently expect, and we may incur additional indebtedness to meet future financing needs. We continuously evaluate our needs for additional capital and consider opportunities on an ongoing basis, including capital from many different sources including equity capital, strategic alliances, business development debt, collaborations and business combinations. Adequate additional funding may not be available to us on acceptable terms or at all. In addition, although we anticipate being able to obtain additional financing through non-dilutive means, we may be unable to do so. Our failure to raise capital as and when needed could have significant negative consequences for our business, financial condition and results of operations. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth in the section titled "Risk Factors."

The following table summarizes our cash flows for the periods presented:

	Six Months Ended June 30,	
	2017	2016
Net cash used in operating activities	$ (10,252,055)	$ (7,845,346)
Net cash used in investing activities	(6,547)	(113,297)
Net cash provided by financing activities	37,496,845	4,417,188
Net increase (decrease) in cash and cash equivalents	$ 27,238,243	$ (3,541,455)

Operating Activities

We have historically experienced negative cash outflows as we developed AKB-9778, ARP-1536 and AKB-4924. Our net cash used in operating activities primarily results from our net loss adjusted for non-cash expenses and changes in working capital components. Our primary uses of cash from operating activities are amounts due to contract research organizations for the conduct of our clinical programs and employee-related expenditures for research and development, and general and administrative activities. Our cash flows from operating activities will continue to be affected principally by increased spending to advance of our product candidates in the clinic, personnel to support those activities and other operating and general administrative activities.

For the six months ended June 30, 2017, operating activities used approximately $10.2 million in cash, primarily as a result of our net loss of $10.5 million, and approximately $0.3 million from changes in working capital offset by approximately $0.6 million in non-cash charges that consisted of stock compensation expense, non-cash interest expense, amortization of debt issuance costs and depreciation expense. For the six months ended June 30, 2016, operating activities used approximately $7.8 million in cash, primarily as a result of our net loss of $8.6 million, offset by approximately $0.6 million net change in our working capital, and $0.4 million of non-cash charges consisting of stock compensation expense, non-cash interest expense, amortization of debt issuance costs and depreciation expense.

Investing Activities

Cash used in investing activities for both six month periods ended June 30, 2017 and 2016 was due to capital expenditures to support our operations. In addition, in the six months ended June 30, 2016, we acquired approximately $0.1 million of laboratory equipment to support internal drug development capabilities

Financing Activities

During the six months ended June 30, 2017, we received net proceeds of $37.2 million from the sale of common stock at $5.00 per share, issued in the Offering and $0.3 million in January from an extension to the Aerpio senior secured convertible notes.

On March 31, 2016, Aerpio entered into a senior secured convertible note financing with certain preferred stock investors of Aerpio. The secured convertible notes accrued interest at 8% per annum, compounded annually. Each of the secured convertible notes were also subject to mandatory prepayment and were also convertible into preferred stock of Aerpio upon the occurrence of certain events, as described in the Note Agreements.

We received proceeds from the first tranche in April 2016 and subsequent tranches in July 2016, October 2016 and January 2017. The outstanding principal and accrued interest under the secured convertible notes was converted into shares of Aerpio common stock immediately prior to the effective time of the Merger, and exchanged for shares of our common stock pursuant to the Merger.

Contractual Obligations and Commitments

There have been no material changes outside the ordinary course of business during the period covered by this Report from the contractual obligations and commitments as of December 31, 2016 described in our Current Report on Form 8-K filed on March 17, 2017.

Off-Balance Sheet Arrangements

As of June 30, 2017 and 2016, we did not have any off-balance sheet arrangements as defined by applicable SEC regulations.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates.

We believe that the assumptions and estimates have the greatest potential impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates. For further information on all our significant accounting policies, see the notes to our financial statements.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at the time. We confirm the accuracy of estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include expenses for:

- Clinical Research Organizations (CROs) in connection with clinical studies;
- Investigative sites in connection with clinical studies;
- Vendors in connection with preclinical development activities; and
- Vendors related to product manufacturing, development and distribution of clinical materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under these contracts can be modified and some of the agreements may be cancelled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

Stock-Based Compensation

We issue stock-based awards generally in the form of stock options and restricted stock. We account for our stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock and modifications to existing stock awards to be recognized in the statements of operations and comprehensive loss based on their fair values. Described below is the methodology we have utilized in measuring stock-based compensation expense.

We estimate the fair value of our options to purchase shares of common stock to employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to our company, including stage of product development and life science industry focus. We are a development stage company in an early stage of product development with no revenues and the representative group of companies has certain similar characteristics. We believe the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of our company. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees and non-employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock, similar to our peer group. The grant date fair value of restricted stock award grants is based on the estimated value of our common stock at the date of grant.

Our stock-based awards are subject to service-based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Awards to non-employees are adjusted through share-based compensation expense as the award vests to reflect the current fair value of such awards and are expensed using an accelerated attribution model.

During the three months ended June 30, 2017 and 2016, and the six months ended June 30, 2017 and 2016 stock-based compensation expense was approximately $0.1 million, $0.1 million, $0.3 million and $0.2 million, respectively. As of June 30, 2017, we had $0.2 million of total unrecognized stock-based compensation costs for stock options, which we expect to recognize over a weighted-average period of 2.0 years. As of June 30, 2017, we had $0.3 million of total unrecognized stock-based compensation costs for restricted stock awards, which we expect to recognize over a weighted-average period of 1.2 years.

Common Stock Valuations.

The fair value of the common stock was determined by our board of directors, which intended all stock options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. As a privately held company, the valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation* of *Privately-Held-Company Equity Securities Issued as Compensation*, or AICPA Practice Aid. The assumptions we used in the valuation model were based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant. including the following factors:

- valuations performed by unrelated third-party specialists;
- the prices, rights, preferences, and privileges of our convertible preferred stock relative to those of our Common Stock;
- the prices of Aerpio's former convertible preferred stock sold to outside investors in arm's-length transactions;
- the lack of marketability of our common stock;
- our actual operating and financial performance;
- current business conditions and projections;
- our hiring of key personnel and the experience of our management;

- our stage of development;
- the likelihood of achieving a liquidity event, such as a public offering or a merger or acquisition of our business given prevailing market conditions;
- the illiquidity of stock-based awards involving securities in a private company;
- the market performance of comparable publicly traded companies; and
- the U.S. and global capital market conditions.

For the valuation of our common stock at December 31, 2016, we used the hybrid method. As described in the AICPA's accounting and valuation guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, the hybrid method is a hybrid between the probability-weighted expected returns method (PWERM) and the option-pricing method (OPM). We considered a "go-public scenario", in which our preferred shares convert to common stock, and a second scenario, in which equity value is allocated using the OPM. We used the guideline public company method under the market approach to value our equity. We estimated our equity value based on a multiple of paid-in capital as indicated by a group of guideline public companies. The group consisted of clinical-stage drug development companies which completed initial public offerings in the six months preceding our appraisal date. In addition, for each of the guideline companies, we considered the increase, or step-up, in per share value from the preferred financing preceding the public offering to the common stock value in the public offering. We also considered the equity value of each guideline company, not including the proceeds of the public offering.

The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred liquidation preference at the time of a liquidity event, such as a strategic sale, merger or initial public offering. For each Black-Scholes calculation in the OPM, the option "strike price" is determined by the company's capital structure. Additional inputs to the OPM include the estimated time to liquidity and estimated equity volatility.

We applied a discount for lack of marketability to the values indicated for the common stock in the go-public and OPM scenarios. Our estimate of the appropriate discount for lack of marketability relied on an Asian put option calculation.

The following table summarizes the significant assumptions used in the hybrid method to determine the fair value of our common stock as of December 31, 2016:

	Go-Public Scenario	OPM
Key assumptions		
Probability weighting	50%	50%
Years to liquidity	0.2	2.8
Weighted-average cost of equity	25%	
Annual volatility		61%
Risk-free interest rate		1.4%
Discount for lack of marketability (DLOM)	5%	23%

Based on these assumptions, we estimated the fair value of our common stock on a pre-Merger basis to be $1.20 as of December 31, 2016 ($2.80 as of December 31, 2016 on an as converted basis to reflect the effect of the Merger).

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful enrollment and completion of our clinical studies as well as the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense could have been different. The foregoing valuation methodologies are not the only methodologies available and they will not be used to value our common stock once this offering is complete. We cannot make assurances as to any particular valuation for our common stock. Accordingly, we caution you not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

For the valuation of our common stock at March 31, and June 30, 2017, we used $5.00 per share; the share price paid by outside investors in our private placement closed on March 15, 2017. There were no stock awards granted or issued in the six months ended June 30, 2017.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's cash balance as of June 30, 2017 consisted of cash held in an operating account that earns nominal interest income. Therefore, there was minimal or no interest rate risk.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our President and Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2017, the end of the period covered by this Quarterly Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level due to a material weakness in internal control over financial reporting. The material weakness was initially identified at December 31, 2016 as previously disclosed and relates to the effectiveness of controls over our review and approval procedures with respect to financial information generated to prepare our consolidated financial statements, coupled with a lack of segregation of duties. We are taking steps to remediate this material weakness.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2017, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. In addition to the information, documents or reports included or incorporated by reference in this Quarterly Report on Form 10-Q for the period ended June 30, 2017, you should carefully consider the risks described below, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. As a result, you could lose some or all of your investment in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred net losses each year since our inception, including net losses of $17.0 million and $17.1 million for the years ended December 31, 2016 and 2015, respectively, and $10.5 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $97.7 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through private placements of our preferred stock. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our ability to obtain funding through equity or debt financings, strategic collaborations or grants. Our lead product candidate, AKB-9778, recently completed a proof of concept Phase 2 clinical trial in April 2015. Our product candidate AKB-4924 in our HIF-1-a stabilization program recently completed a Phase 1a trial. Our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market AKB-9778, our future revenues will depend upon the size of any markets in which AKB-9778 has received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our Phase 2 program and prepare for a future Phase 3 development program of AKB-9778 for the treatment of diabetic retinopathy, or DR, including as we continue our ongoing TIME-2b clinical trial.
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for AKB-9778, AKB-4924, ARP-1536 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, if at all, we will be able to achieve profitability. If we are required by the United States Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of June 30, 2017, our cash and cash equivalents and short-term investments were $28.9 million. We believe that we will continue to expend substantial resources for the foreseeable future developing AKB-9778 and any other product candidates that we may develop or acquire. Additionally, we may expend substantial resources to further develop AKB-4924 if we secure sufficient additional funding, likely from a strategic and commercial partner for that candidate, as well as ARP-1536 if we secure sufficient additional funding, which may be from a partner for that candidate. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the rate of progress, results and cost of completing our Phase 2 program of AKB-9778 and our operating costs incurred as we conduct these trials and through our end of Phase 2 meeting with the FDA, and equivalent meetings with the EMA and other regulatory authorities;
- assuming AKB-9778 advances to Phase 3 clinical trials, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-9778;
- assuming favorable clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for AKB-9778 in the United States, Europe and in other jurisdictions, including to fund the preparation and filing of regulatory submissions for AKB-9778 with the FDA, the EMA and other regulatory authorities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials that we may undertake for AKB-4924, ARP-1536 and any other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-4924 and ARP-1536 if we continue their further development upon securing sufficient additional funding and/or a strategic and commercial partner, and clinical trials of these product candidates are successful;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation.

Based on our current operating plan, and absent any future financings or strategic partnerships, we believe that our existing cash and cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into the first quarter of fiscal year 2019. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for AKB-9778, AKB-4924, ARP-1536 or any other product candidates that we develop or acquire, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and license, development and commercialization agreements with collaborators. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for AKB-9778 and, if we secure sufficient additional funding and/or a strategic and commercial partner, to continue their development, for AKB-4924, ARP-1536 or any other product candidates that we develop or acquire, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in 2011, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. We currently have three product candidates, one of which is in preclinical development. Of these product candidates, we may further develop AKB-4924 and ARP-1536 only if we secure sufficient additional funding and/or a strategic and commercial partner, to continue their clinical development. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Only a small fraction of biopharmaceutical development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to obtain regulatory approval for, and to manufacture, market and sell, a product. We have not yet demonstrated our ability to successfully complete later stage clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

Risks Related to Our Business and the Clinical Development, Regulatory Review and Approval of Product Candidates

We depend heavily on the success of one product candidate, AKB-9778, which is in Phase 2 clinical development. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, AKB-9778.

We currently have only one product candidate, AKB-9778, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of that product candidate, which may never occur. We currently have no products for sale, generate no revenues from sales of any drugs, and may never be able to develop marketable products. AKB-9778, which recently completed a proof of concept Phase 2 clinical trial, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. In June 2017, we announced the initiation of patient dosing in our ongoing Phase 2b clinical trial of AKB-9778 in patients with DR. Our other product candidate, AKB-4924, recently completed a Phase 1a trial. We currently may further develop AKB-4924 only if we secure sufficient additional funding, likely from a strategic and commercial partner, to continue its development. In addition, we currently may further develop ARP-1536 only if we secure sufficient additional funding , which may be from a strategic and commercial partner to continue its clinical development. There can be no assurance that we will be able to secure such additional funding or a strategic or commercial partner on commercially reasonable terms or at all. Any failure to do so would impair our ability to advance AKB-4924 and ARP-1536, resulting in our even greater dependence on AKB-9778. None of our product candidates has advanced into a pivotal trial, and it may be years before such trial is initiated, if ever. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that any drug candidate is safe and effective and any biological product candidate is safe, pure, and potent for use in each target indication. This process can take many years. Of the large number of drugs in development in the United States, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize AKB-9778.

We are not permitted to market AKB-9778 in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA to the FDA for AKB-9778 regarding its ability to treat patients with DR, we must complete our ongoing clinical trials, Phase 3 trials, and any additional non-clinical studies or clinical trials required by the FDA. To date, we have only completed a Phase 2 clinical trial for AKB-9778 and five other early stage trials. AKB-9778 may not be successful in clinical trials or receive regulatory approval. Further, AKB-9778 may not receive regulatory approval even if it is successful in clinical trials. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process that typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that AKB-9778 will never obtain regulatory approval. The FDA may delay, limit or deny approval of AKB-9778 for many reasons, including, among others:

- we may not be able to demonstrate that AKB-9778 is safe and effective in treating patients with DR to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications of AKB-9778;
- the FDA may require that we conduct additional clinical trials;
- the contract research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- we may fail to perform in accordance with the FDA's good clinical practice, or GCP, requirements;

- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval, or requiring that we amend or submit new clinical protocols.

In addition, similar reasons may cause the EMA or other regulatory authorities to delay, limit or deny approval of AKB-9778 outside the United States.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market AKB-9778. Because our business is almost entirely dependent upon AKB-9778, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as we intend or desire or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional, unanticipated clinical trials to obtain approval or be subject to additional post marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or the FDA may require a risk evaluation and mitigation strategy, or REMS, for a product, which could impose restrictions on its distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not obtained agreement with the FDA, EMA or other regulatory authorities on the design of our Phase 3 development program.

We have not obtained agreement with the FDA on the design of our Phase 3 development program. We plan to hold an end of Phase 2 meeting with the FDA upon successful completion of our Phase 2 clinical program. If the FDA determines that the Phase 2 trial results do not support moving into a pivotal program, we would be required to conduct additional Phase 2 studies. Alternatively, the FDA could disagree with our proposed design of our Phase 3 development program and could suggest a larger number of subjects or a longer course of treatment than our current expectations. If the FDA takes such positions, the costs of our AKB-9778 development program could increase materially and the potential market introduction of AKB-9778 could be delayed or we could risk not obtaining FDA approval even if the Phase 3 trials meet their primary endpoints. The FDA also may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will consider an NDA application.

While we intend to follow the regulatory pathway that ranibizumab and aflibercept undertook when they were approved for DR in the presence of DME, we have not yet sought guidance for the regulatory path for AKB-9778 with the EMA or other regulatory authorities. We cannot predict what additional requirements may be imposed by these regulatory authorities or how such requirements might delay or increase costs for our planned Phase 3 development program. For example, ranibizumab and aflibercept are anti-vascular endothelial growth factor, or anti-VEGF therapies, which block vascular endothelial growth factor, used in the treatment of DR, DME, age-related macular degeneration and retinal vein occlusion, while AKB-9778 is a small molecule activator of the Tie-2 pathway, and such differences may result in a different regulatory pathway for AKB-9778, including one that may be longer, more complex or expensive than that of ranibizumab or aflibercept. Because our business is almost entirely dependent upon the successful development, regulatory approval, and commercialization of AKB-9778, any such delay or increase costs would have an adverse effect on our business.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. Our competitors may have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, while we have initiated patient dosing in our TIME-2b clinical trial, there is no guarantee that we can successfully enroll patients in a timely manner. As a result, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our development of AKB-9778 or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials and clinicians' and patients' perceptions as to the potential advantages of AKB-9778 in relation to available therapies or other products under development;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

We may not be able to comply with requirements of foreign jurisdictions in conducting trials outside of the United States. In addition, we may not be able to obtain regulatory approval in foreign jurisdictions.

If AKB-9778 is successful in Phase 2 development, we currently expect to conduct our Phase 3 clinical trial of AKB-9778 that may include trial sites outside of the United States, including Japan and the European Union, and seek regulatory approval for AKB-9778 for the treatment of patients with DR in major markets in addition to the United States, including the European Union. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country, should we attempt to do so, is subject to numerous risks unique to conducting business in international markets, including:

- difficulty in establishing or managing relationships with qualified CROs and physicians;
- different local standards for the conduct of clinical trials;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments; and
- the acceptability of data obtained from trials conducted in the United States to the EMA and other regulatory authorities.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for AKB-9778 in countries outside of the United States.

Regulatory authorities outside the United States will require compliance with numerous and varying regulatory requirements. The approval procedures vary among jurisdictions and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. 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 by the FDA. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Clinical drug development is a lengthy and expensive process with an uncertain outcome, and positive results from Phase 1 and Phase 2 clinical trials of AKB-9778 are not necessarily predictive of the results of our completed and any future clinical trials of AKB-9778. If we cannot replicate the positive results from our Phase 1 and Phase 2 clinical trials of AKB-9778 in our ongoing and subsequent clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize AKB-9778.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials may not be replicated in later and larger clinical trials. For example, our early encouraging preclinical and clinical results for AKB-9778 do not ensure that the results of our ongoing clinical trials, including TIME-2b, or any future clinical trials will demonstrate similar results. Our planned Phase 2 and Phase 3 development program will enroll a larger number of subjects and will treat subjects for longer periods than our prior trials, which will result in a greater likelihood that adverse events may be observed. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we may face similar setbacks. If the results of our ongoing or future clinical trials for AKB-9778 are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are safety concerns or adverse events, we may be prevented from or delayed in obtaining marketing approval for AKB-9778.

We may experience delays in our planned Phase 2 clinical trial for AKB-9778 and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.

Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a clinical trial;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- recruit, enroll and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols and regulatory requirements through the completion of clinical trials;
- address any patient safety concerns that arise during the course of the trial;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs at the sites at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or lack of adequate funding to continue the clinical trial. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the products. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, requirements and GCP requirements for any clinical trials that we conduct post-approval.

Post-approval discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency or relating to manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- a REMS program; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We rely on third party CROs and other third parties to assist in managing, monitoring and otherwise carrying out our ongoing trials of AKB-9778. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our clinical trials in the future, including our Phase 3 development program for AKB-9778. We compete with many other companies for the resources of these third parties. The third parties on whom we rely may terminate their engagements with us at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP requirements, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our investigators or CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We intend to rely on third parties to conduct some or all aspects of our product manufacturing, and these third parties may not perform satisfactorily.

We do not have any manufacturing facilities and do not expect to independently conduct our product candidate manufacturing for research and preclinical and clinical testing. We currently rely, and expect to rely, on third parties to manufacture and supply drug products for our AKB-9778 clinical trials, and we expect to continue to rely on third parties for the manufacture of clinical and, if necessary, commercial quantities of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties may terminate their engagement with us at any time. We believe we have sufficient drug product to complete our ongoing trials of AKB-9778. We have entered into an agreement for the manufacturing of the drug substance for the Phase 2 development program of AKB-9778. However, if this manufacturer cannot perform as agreed, we may be required to find replacement manufacturers. We do not currently have arrangements in place for the manufacturing of drug product for the Phase 3 development program. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur significant delays and added costs in identifying, qualifying and contracting with any such replacement, as well as producing the drug product. The FDA or comparable foreign regulatory authorities may find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies. 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 relating to quality control, quality assurance and corresponding maintenance of records and documents. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. These delays could result in a suspension of our clinical trials or, if AKB-9778 is approved and marketed, a failure to satisfy patient demand.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- disruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers or suppliers.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP requirements for manufacture of both drug substance and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or other regulatory authorities find deficiencies with or do not approve these facilities for the manufacture of our product candidates or if they find deficiencies or withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug products or product candidates.

In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. Certain of these manufacturing facilities may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If we are unable to manufacture our product candidates in sufficient quantities, at sufficient yields, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale. We have limited experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise and facilities to manufacture our bulk drug product on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our drug product. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where a product might be sold; and
- lack of capital funding.

Any delay or interruption in our supply of product candidates could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may not be successful in establishing and maintaining strategic collaborations, which could adversely affect our ability to develop and commercialize our product candidates, negatively impacting our operating results.

If approved, we plan to commercialize AKB-9778 ourselves in the United States and intend to seek one or more strategic collaborators to commercialize AKB-9778 in additional markets. In addition, we may further develop and, if approved, commercialize, AKB-4924 only if we secure sufficient additional funding, likely from a strategic and commercial partner for that candidate. With respect to ARP-1536, we may further develop and, if approved, commercialize ARP-1536 only if we secure sufficient additional funding, which may be from a strategic or commercial partner. There can be no assurance that we will be able to secure such additional funding or a strategic or commercial partner on commercially reasonable terms or at all. We face competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully collaborate with a third party on our product candidates, potential collaborators must view these product candidates as economically valuable. Even if we are successful in our efforts to establish strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

In addition, our strategic collaborators may terminate any agreements they enter into with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic collaborators will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do.

If we fail to establish and maintain strategic collaborations related to our product candidates for the indications and in the geographies in which we do not intend develop and commercialize ourselves, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise. This could negatively affect the development of any product candidate for which we do not locate a suitable strategic partner.

Risks Related to Our Intellectual Property

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

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. 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 products 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.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office or the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2011), which brings into effect significant changes to the U.S. patent laws and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a “first to file” system in the United States. This will require us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

We currently have a non-exclusive license to one U.S. patent. We rely on the licensor to maintain this patent and otherwise protect the intellectual property covered by this non-exclusive license. We have limited control over these activities or over any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that activities by the licensor have been or will be conducted in compliance with applicable laws and regulations. We may have no control or input over whether, and in what manner, our licensor may enforce or defend the patent against a third-party. The licensor may enforce or defend the patent less vigorously than if we had enforced or defended the patent ourselves. Further, the licensor may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, the licensor may not enforce the patent against a competitor of ours who is not a direct competitor of the licensor. If our in-licensed intellectual property is found to be invalid or unenforceable, then the licensor may not be able to enforce the patent against a competitor of ours. Our non-exclusive license does not prevent a third party from seeking and obtaining a non-exclusive license to the same patent that we license. If we fail to meet our obligations under the non-exclusive license agreement, then the licensor may terminate the license agreement. If the license agreement is terminated, the former licensor may seek to enforce the intellectual property against us. We may choose to terminate the license agreement, and doing so would allow a third party to seek and obtain an exclusive license to the patent. If a third party obtains an exclusive license to intellectual property formerly licensed to us, then the third party may seek to enforce the intellectual property against us.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some other jurisdictions, 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, for example, 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 material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be 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 a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Third-party claims of intellectual property infringement may be costly and time consuming, and may delay or harm our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. The pharmaceutical and biotechnology industries are characterized by extensive litigation over patent and other intellectual property rights. We may become a party to, or threatened with, future adversarial litigation or other proceedings regarding intellectual property rights with respect to our drug candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials in the United States falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e), which provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

Third parties may hold or obtain patents or other intellectual property rights and allege in the future that the use of our product candidates infringes these patents or intellectual property rights, or that we are employing their proprietary technology without authorization. Under U.S. law, a party may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method.

There may be patents of third parties of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. Notwithstanding the above, third parties may in the future claim that our product candidates and other technologies infringe upon these patents and may file suit against us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize AKB-9778 or AKB-4924. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or our intended methods of use, the holders of any such patent may be able to block or impair our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may also elect to enter into a license in order to settle litigation or in order to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Should a license to a third-party patent become necessary, we cannot predict whether we would be able to obtain a license, or if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties or redesign our products, which may be impossible or require substantial time and monetary expenditure.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as 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 countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products 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 certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, 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 countries could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Commercialization

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and others in the medical community.

Even if we obtain marketing approval for AKB-9778, AKB-4924 or any other product candidates that we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, third-party payors, patients and others in the medical community. In addition, market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate coverage and reimbursement by third party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

For example, the current established treatments for DME are anti-VEGF medications, including bevacizumab and ranibizumab, and the current established treatments for DR in the absence of DME include laser photocoagulation. We believe that that prescribers may be resistant to prescribing AKB-9778 with or instead of anti-VEGF medications, or instead of laser photocoagulation, which is currently the standard of care for DME and DR, respectively.

Market acceptance is critical to our ability to generate significant revenue. In addition, any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market at all or to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform these services.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force are expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- our inability to effectively manage geographically dispersed sales and marketing team;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and have to enter into arrangements with third parties to perform these services, our profitability, if any, is likely to be materially diminished in relation to if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for any approved products, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors decide which drugs they will pay for and establish formularies and reimbursement levels. Coverage and 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 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 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 our products to the payor. Additionally, we may be required to enter into contracts with third-party payors to obtain favorable formulary status. 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. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. In addition, in the United States third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

Price controls may be imposed, which may adversely affect our future profitability.

In some countries, particularly member states of 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 receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the 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 physician-administered drugs. In addition, this legislation provided authority for limiting 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 products, we expect that there will be additional pressure to reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets which could similarly impact our business.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively ACA, was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The ACA, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and biologic products, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA Act that are repealed. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

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

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The development and commercialization of new products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we commercialize will compete with existing, market-leading products.

If AKB-9778 is approved and launched commercially, competing drugs may include current anti-VEGF drugs, including Lucentis, Eylea and Avastin in the treatment of DME, and current therapies including laser photocoagulation in the treatment of DR. We may face competition from potential DME and DR treatments.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. Large and established companies such as Roche and Regeneron, among others, compete in the market for products to treat DR and DME. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before, or more effectively than, we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

Our products may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our products or even competing products in development that utilize a common mechanism of action 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 and potential products liability claims. AKB-9778 is currently in Phase 2 clinical development. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common drug-related adverse events to date in the clinical trial evaluating the safety and tolerability of AKB-9778 in DME have been dizziness and asymptomatic decreases in blood pressure. Our understanding of the relationship between AKB-9778 and these events, as well as our understanding of adverse events in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- patient recruitment could be slowed, or enrolled patients may not want to complete a clinical trial;
- we may be unable to obtain regulatory approval for our product candidates or regulatory authorities may withdraw approvals of product candidates;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products and could substantially increase commercialization costs.

Risks Related to Our Business and Industry

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our senior management, including Joseph Gardner, our President and Chief Executive Officer, Kevin G. Peters, our Chief Scientific Officer and Stephen Pakola, our Chief Medical Officer. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. We may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our employees, independent contractors, principal investigators, contract research organizations, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations or CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations, or (4) laws that require the reporting of true and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare 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. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our 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 collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize AKB-9778, if approved, and any other 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, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is 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, 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 a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure 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 products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $10 million in the aggregate. Although we maintain product liability 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 also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Ownership of Our Common Stock

We are eligible to be treated as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure 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. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of these reduced reporting burdens. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Investors may find our common stock less attractive if we continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have total annual gross revenue of $1 billion (as may be inflation-adjusted by the SEC from time to time) 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 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" if the market value of our common stock held by non-affiliates is below $75 million as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Because we are quoted on the OTCQB instead of a national exchange or quotation system, our investors may experience significant volatility in the market price of our stock and have difficulty selling their shares.

Our common stock is currently quoted on the OTC Market Group's OTCQB Market quotation system under the ticker symbol "ARPO." The OTCQB are regulated quotation services that display real-time quotes, last sale prices and volume limitations in over-the-counter securities. Trading in shares quoted on the OTCQB is often thin and characterized by volatility in trading prices. This volatility may be caused by a variety of factors, including the lack of readily available price quotations, the absence of consistent administrative supervision of bid and ask quotations, lower trading volume and market conditions. As a result, there may be wide fluctuations in the market price of the shares of our common stock for reasons unrelated to operating performance, and this volatility, when it occurs, may have a negative effect on the market price for our securities. Moreover, the OTCQB is not a stock exchange, and trading of securities on them is often more sporadic than the trading of securities listed on a national quotation system or stock exchange. Accordingly, our stockholders may not be able to realize a fair price from their shares when they determine to sell them or may have to hold them for a substantial period of time until the market for our common stock improves.

The designation of our common stock as a "penny stock" would limit the liquidity of our common stock.

Our common stock may be deemed a "penny stock" (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a "penny stock" is a common stock that is not listed on a securities exchange and trades for less than $5.00 a share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stocks in start-up companies are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser's written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there may be less trading activity in penny stocks in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

The Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

The market price of our common stock may be highly volatile, and may be influenced by numerous factors, some of which are beyond our control.

If a market for our common stock develops, its market price could fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of March 15, 2017, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 65.9% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering of our common stock, and because we will not be listed on a national securities exchange, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an underwritten initial public offering, because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

Because the Merger was a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist as a result of our becoming a public reporting company through a "reverse merger." Securities analysts of major brokerage firms may not provide coverage of our capital stock or business. Because we became a public reporting operating company through a reverse merger, there is no incentive to brokerage firms to recommend the purchase of our common stock. We cannot assure you that brokerage firms will want to provide analyst coverage of our capital stock or business in the future.

The resale of shares covered by a registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to raise additional capital by selling equity or equity-linked securities. We filed and caused to become effective a registration statement with the SEC registering the resale of 27,367,117 shares of our common stock issued in connection with the Merger and the Offering. This registration statement permits the resale of these shares at any time. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our Common Stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to a registration statement, selling stockholders will continue to offer shares covered by such registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

Issuance of stock to fund our operations may dilute your investment and reduce your equity interest.

We may need to raise capital in the future to fund the development of our drug candidates or for other purposes. Any equity financing may have significant dilutive effect to stockholders and a material decrease in our stockholders' equity interest in us. Equity financing, if obtained, could result in substantial dilution to our existing stockholders. At its sole discretion, our board of directors may issue additional securities without seeking stockholder approval, and we do not know when we will need additional capital or, if we do, whether it will be available to us.

We have broad discretion in the use of our cash and may not use them effectively.

We currently intend to use our cash resources for continuing clinical development of AKB-9778 in patients with diabetic retinopathy, including the continuation of our ongoing trials and the preparation for and initiation of the Phase 3 trials and for working capital and other general corporate purposes. Although we currently intend to use our cash resources in such a manner, we will have broad discretion in the application of such cash resources. Our failure to apply these funds effectively could affect our ability to continue to develop and commercialize our product candidates. Pending their use, we may invest our cash resources in a manner that does not produce income or loses value.

We will incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we will incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with the Merger, pursuant to which we acquired Aerpio, we are increasing our directors' and officers' insurance coverage, which will increase our insurance cost. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, in order to comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934 as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to obtain listing on a national securities exchange.

Our management team and board of directors will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance and accounting staff and engaging consultants to assist in designing and implementing such procedures. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources. In addition, our management will be required to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statement.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

Our independent registered public accounting firm has identified a material weakness in our internal control over financial reporting which will require remediation.

Our independent registered public accounting firm issued a letter to our audit committee and management in which they identified certain matters that they consider to constitute material weaknesses in the design and operation of our internal control over financial reporting as of December 31, 2016. A deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for the oversight of the company's financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified by our auditors relate to deficiencies with our disclosure controls and procedures, including review and approval procedures with respect to financial information generated to prepare our consolidated financial statements, coupled with a lack of segregation of duties as a result of our size and overall lack of resources in the accounting department. This resulted in not ensuring appropriate segregation of duties between incompatible functions, and made it more difficult to ensure review of financial reporting issues.

We are taking steps to remediate this material weakness. If we fail to remediate the material weakness, we may fail to meet our future reporting obligations, our financial statements may contain material misstatements and our operational results may be harmed. Any such failure could also adversely affect the results of the periodic management evaluations and, to the extent we are no longer an emerging growth company, the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that will be required under Section 404 of the Sarbanes-Oxley Act of 2002. Internal control deficiencies could also cause investors to lose confidence in our reported financial information.

Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, 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 by-laws may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors pursuant to a resolution adopted by a majority of the directors then in office;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- prohibit the consummation of a liquidation event unless approved by a supermajority (66 2/3% and majority of the minority, if applicable) vote of the holders of our voting stock;
- prohibit the consummation of an affiliate transaction with a majority stockholder that holds more than 50% of the voting power of our capital stock unless approved by a supermajority (66 2/3%) vote of directors then in office;
- provide that the number of directors on our board of directors may only be changed with a supermajority (66 2/3%) of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause and by a supermajority (66 2/3%) vote of the holders of our voting stock;
- provide that vacancies on our board of directors may be filled only by a supermajority (66 2/3%) of directors then in office, even though less than a quorum;
- require a supermajority (66 2/3% and majority of the minority, if applicable) vote of the holders of our voting stock or the supermajority (66 2/3%) vote of the members of our board of directors then in office to amend our amended and restated by-laws; and
- require a supermajority (66 2/3% and majority of the minority, if applicable) vote of the holders of our voting stock and a supermajority (66 2/3%) vote of the holders of each class of our voting stock entitled to vote thereon to amend certain provisions of our amended and restated certificate of incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, our amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes, and if we undergo an ownership change in connection with our private placement offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. As described above under "—Risks related to our financial position and need for additional capital," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. A full valuation allowance has been provided for the entire amount of our NOLs.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

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

In April 2017, the Company issued 25,729 shares of common stock at a weighted average share price of $1.40 in connection with a stock option exercise under the Aerpio Therapeutics, Inc. 2011 Equity Incentive Plan. In addition, in April 2017, the Company, repurchased 5,246 shares of common stock, unvested under a restricted stock agreement at the time the agreement was terminated.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
4.2	Form of common stock certificate (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 14, 2017, File No. 333-217320).
10.8#	Employment Agreement, dated as of March 15, 2017, between the Company and Joseph H. Gardner (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 14, 2017, File No. 333-217320).
10.9#	Employment Agreement, dated as of March 15, 2017, between the Company and Kevin G. Peters (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 14, 2017, File No. 333-217320).
10.10#	Employment Agreement, dated as of March 15, 2017, between the Company and Stephen Pakola (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 14, 2017, File No. 333-217320).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

Company Name

Date: August 10, 2017

By: /s/ Joseph H. Gardner

Joseph H. Gardner
Chief Executive Officer and Director

Date: August 10, 2017

By: /s/ James B. Murphy

James B. Murphy
Chief Financial Officer

Exhibit Index

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

# Indicates a management contract or any compensatory plan, contract or arrangement.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph H. Gardner, certify that:

1. I have reviewed this quarterly report on Form 10Q of Aerpio Pharmaceuticals, 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)) for the registrant and have:

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

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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

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.

Date: August 10, 2017

By: /s/ Joseph H. Gardner

Joseph H. Gardner
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James B. Murphy, certify that:

1. I have reviewed this quarterly report on Form 10Q of Aerpio Pharmaceuticals, 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)) for the registrant and have:

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

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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

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.

Date: August 10, 2017

By: /s/ James B. Murphy

James B. Murphy
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aerpio Pharmaceuticals, Inc., (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2017

By: /s/ Joseph H. Gardner

Joseph H. Gardner
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aerpio Pharmaceuticals, Inc., (the "Company") on Form 10-Q for the period ending June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2017

By: /s/ James B. Murphy

James B. Murphy
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)