

**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 **September 30, 2018**

OR

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

For the transition period from _____ to _____

Commission File Number: **001-38560**

Aerpio Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

EIN 61-1547850
(I.R.S. Employer
Identification No.)

9987 Carver Road
Cincinnati, OH
(Address of principal executive offices)

45242
(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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of November 7, 2018, the registrant had 40,588,004 shares of common stock, \$0.0001 par value per share, outstanding.

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Item 1. Financial Statements.

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	September 30, 2018 <i>(unaudited)</i>	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 68,807,267	\$ 20,264,109
Prepaid research and development contracts	337,192	313,140
Other current assets	895,091	322,221
Total current assets	70,039,550	20,899,470
Furniture and equipment, net	101,291	107,223
Deposits	20,960	20,960
Total assets	\$ 70,161,801	\$ 21,027,653
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,644,685	\$ 3,592,164
Total current liabilities	3,644,685	3,592,164
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.0001 par value per share; 300,000,000 shares authorized and 40,588,004 and 27,070,038 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	4,059	2,707
Additional paid-in capital	176,953,759	125,995,438
Accumulated deficit	(110,440,702)	(108,562,656)
Total stockholders' equity	66,517,116	17,435,489
Total liabilities and stockholders' equity	\$ 70,161,801	\$ 21,027,653

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

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	<i>(unaudited)</i>		<i>(unaudited)</i>	
License revenue, and other	\$ 18,821,953	\$ —	\$ 20,155,286	\$ —
Operating expenses				
Research and development	4,346,381	2,942,170	12,604,125	8,366,869
General and administrative	3,277,535	1,814,068	9,866,227	6,732,816
Total operating expenses	<u>7,623,916</u>	<u>4,756,238</u>	<u>22,470,352</u>	<u>15,099,685</u>
Income (loss) from operations	11,198,037	(4,756,238)	(2,315,066)	(15,099,685)
Grant income	6,394	46,824	6,394	93,720
Interest income (expense), net	333,047	59,847	430,626	(159,612)
Total other income (expense)	<u>339,441</u>	<u>106,671</u>	<u>437,020</u>	<u>(65,892)</u>
Net and comprehensive income (loss)	<u>\$ 11,537,478</u>	<u>\$ (4,649,567)</u>	<u>\$ (1,878,046)</u>	<u>\$ (15,165,577)</u>
Reconciliation of net income (loss) attributable to common stockholders:				
Net and comprehensive income (loss)	\$ 11,537,478	\$ (4,649,567)	\$ (1,878,046)	\$ (15,165,577)
Adjustment of redeemable convertible preferred stock to redemption value	—	—	—	(943,297)
Net income (loss) attributable to common stockholders	<u>\$ 11,537,478</u>	<u>\$ (4,649,567)</u>	<u>\$ (1,878,046)</u>	<u>\$ (16,108,874)</u>
Net income (loss) per share				
Basic and diluted	<u>\$ 0.28</u>	<u>\$ (0.17)</u>	<u>\$ (0.06)</u>	<u>\$ (0.81)</u>
Weighted average number of common shares used in computing net income (loss) per share				
Basic	<u>40,527,722</u>	<u>26,926,673</u>	<u>31,687,434</u>	<u>19,889,984</u>
Diluted	<u>40,961,620</u>	<u>26,926,673</u>	<u>31,687,434</u>	<u>19,889,984</u>

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

Condensed Consolidated Statement of Stockholders' Equity

	For the Nine Months Ended September 30, 2018 (unaudited)				Total
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	
	Shares	Par Value			
Balance at December 31, 2017	27,070,038	\$ 2,707	125,995,438	\$ (108,562,656)	\$ 17,435,489
Issuance of restricted stock	60,000	6	(6)	—	—
Issuance of common stock upon exercise of stock options	52,099	5	76,751	—	76,756
Issuance of common stock, net of issuance costs of \$3,502,543	13,408,200	1,341	48,117,686	—	48,119,027
Forfeiture of restricted stock	(2,333)	—	—	—	—
Share-based compensation expense	—	—	2,763,890	—	2,763,890
Net and comprehensive loss	—	—	—	(1,878,046)	(1,878,046)
Balance at September 30, 2018	<u>40,588,004</u>	<u>\$ 4,059</u>	<u>\$ 176,953,759</u>	<u>\$ (110,440,702)</u>	<u>\$ 66,517,116</u>

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

AERPIO PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

	Nine Months Ended September 30,	
	2018	2017
Operating activities:	<i>(unaudited)</i>	
Net and comprehensive loss	\$ (1,878,046)	\$ (15,165,577)
Adjustments to reconcile net and comprehensive loss to net cash provided by (used in) operating activities:		
Depreciation	35,312	39,269
Stock-based compensation	2,763,890	394,268
Amortization of debt issuance costs	—	75,561
Interest expense related to convertible note conversion	—	204,929
Changes in operating assets and liabilities:		
Prepaid research and development contracts	(24,052)	238,658
Other current assets	(572,870)	(656,896)
Accounts payable and other current liabilities	52,521	598,706
Net cash provided by (used in) operating activities	376,755	(14,271,082)
Investing activities:		
Purchase of furniture and equipment	(29,380)	(6,547)
Net cash used in investing activities	(29,380)	(6,547)
Financing activities:		
Proceeds from exercise of stock options	76,756	36,101
Proceeds from issuances of convertible notes	—	297,354
Proceeds from sale of common stock	51,621,570	40,247,775
Cash paid in connection with the sale of common stock	(3,502,543)	(3,084,385)
Net cash provided by financing activities	48,195,783	37,496,845
Net increase in cash and cash equivalents	48,543,158	23,219,216
Cash and cash equivalents at beginning of year	20,264,109	1,609,694
Cash and cash equivalents, nine months ended	\$ 68,807,267	\$ 24,828,910
Non-cash financing activities		
Conversion of redeemable convertible preferred stock into common stock	\$ —	\$ 74,701,187
Conversion of convertible notes and accrued interest into common stock	—	13,447,934
Accretion of redeemable convertible preferred stock to redemption value	—	943,297

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

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)**

1. Nature of Organization and Operations

Aerpio Pharmaceuticals, Inc. (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 Tie2 pathway, is being developed for the treatment of non-proliferative diabetic retinopathy, or NPDR, a disease characterized by progressive compromise of blood vessels in the back of the eye. 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 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 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 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 “2017 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 \$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 2017 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 financial statements for the periods ended September 30, 2018 and 2017, include the accounts of the Company and its wholly owned subsidiary, Aerpio Therapeutics, LLC.

On June 28, 2018, the Company closed an underwritten public offering for the sale of 11,688,000 shares of its common stock, and subsequently on July 2, 2018, the Company closed on the sale of an additional 1,720,200 shares of its common stock, pursuant to the underwriters’ partial exercise of their option to purchase additional shares of common stock (the “2018 Offering”). In the aggregate, the Company received net proceeds of approximately \$ 48.1 million from the 2018 Offering after a deduction of \$3.5 million related to underwriting discounts and commissions and offering expenses paid in conjunction with the 2018 Offering.

On June 24, 2018, the Company entered into a License Agreement (the "Agreement") with a wholly-owned subsidiary of Gossamer Bio, Inc., GB004, Inc. (collectively "Gossamer"), under which the Company granted Gossamer an exclusive, sublicensable license to develop and commercialize AKB-4924 and other structurally related products worldwide, with initial development expected in the indications of induction and maintenance in ulcerative colitis and Crohn's Disease.

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's revenue to date has been primarily limited to license revenue from Gossamer. Future revenue is dependent on the terms of the Agreement. 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 U.S. generally accepted accounting principles ("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, changes in stockholders' equity and cash flows for each period presented. All adjustments are of a normal and recurring in nature. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements of the Company for the year ended December 31, 2017, included in the Annual Report on Form 10-K filed with the SEC on March 15, 2018. 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.

Reclassification

Certain prior year balances within the condensed consolidated statement of cash flows were reclassified to conform with current period presentation. As a result of the current year reclassification, there were no changes in any subtotals of the condensed consolidated statement of cash flows.

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.

Use of Estimates

The preparation of condensed consolidated 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 condensed consolidated financial statements and the reported amounts of revenue 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 used in the preparation of these condensed 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: grant date fair value of the Company's stock-based awards, accrued expenses, revenue recognition and income taxes.

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 original 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.

Revenue Recognition

At the inception of an arrangement, the Company evaluates if a counterparty to a contract is a customer, if the arrangement is within the scope of revenue from contracts with customers guidance and the term of the contract. The Company recognizes revenue when its customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. The Company recognizes the amount of the transaction price as revenue that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied.

The Company enters into collaboration arrangements, under which it licenses certain rights to its intellectual property to third parties. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable upfront license fees; development, sale and commercial milestone payments and royalties on net sales of licensed products. Each of these types of payments are classified as license revenue except for revenue from royalties on net sales of licensed products, which are classified as royalty revenue.

For each collaboration agreement that results in revenues, the Company identifies all material promised goods and services, which may include a license to intellectual property, research and development activities and/or transition activities. Promised goods or services are considered to be separate performance obligations if they are distinct. In order to determine the transaction price to be allocated to each performance obligation, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that could result in a significant reversal of revenue. In making these assessments, the Company considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Once the estimated transaction price is established, amounts are allocated to the performance obligations that have been identified. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price basis. The Company must develop assumptions that require judgment to determine the standalone selling price (SSP) in order to account for these agreements. To determine the standalone selling price the Company's assumptions may include (i) assumptions regarding the probability of obtaining marketing approval for the drug candidate; (ii) estimates regarding the timing of and the expected costs to develop and commercialize the drug candidate; (iii) estimates of future cash flows from potential product sales with respect to the drug candidate; and (iv) appropriate discount and tax rates. Standalone selling prices used to perform the initial allocation are not updated after contract inception. The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year.

Upfront License Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Development Milestone Payments: Depending on facts and circumstances, the Company may conclude it is appropriate to include the milestone in the estimated transaction price using the most likely amount method or it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period the Company concludes that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. The Company may record revenues from certain milestones in a reporting period before the milestone is achieved if the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. These milestones remain fully constrained until the Company concludes that achievement of the milestone is probable and recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company re-evaluates the probability of achievement of such development milestones and any related constraint each reporting period. The Company adjusts its estimate of the overall transaction price, including the amount of collaborative revenue that it has recorded, if necessary.

Sales-based Milestone and Royalty Payments: The Company's collaborators may be required to pay the Company sales-based milestone payments or royalties on future sales of commercial products. The Company recognizes revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to the Company's intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

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* (ASC 740), 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 condensed consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the condensed consolidated 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 September 30, 2018, and December 31, 2017, 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 Income (Loss) per Share Attributable to Common Stockholders

The Company’s basic net income (loss) per share attributable to common stockholders is calculated by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The diluted net income (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.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation* (ASC 718), which requires that all stock-based payments to employees, including grants of employee stock options and restricted stock, be recognized in the condensed consolidated statements of operations and comprehensive income (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 option 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 SEC 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.

Fair Value of Financial Instruments

The Company’s financial instruments consist of cash equivalents, accounts payable and accrued expenses. The Company values cash equivalents using quoted market prices. The fair value of accounts payable and accrued expenses approximates its carrying value because of its 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* (ASC 820), 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 during the nine months ended September 30, 2018. The assets of the Company measured at fair value on a recurring basis as of September 30, 2018, and December 31, 2017, are summarized below:

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
September 30, 2018				
Assets:				
Cash and cash equivalents	\$ 68,807,267	\$ —	\$ —	\$ 68,807,267
Total assets	<u>\$ 68,807,267</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 68,807,267</u>
December 31, 2017				
Assets:				
Cash and cash equivalents	\$ 20,264,109	\$ —	\$ —	\$ 20,264,109
Total assets	<u>\$ 20,264,109</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 20,264,109</u>

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents are the only financial instruments that potentially subject the Company to concentrations of credit risk. At September 30, 2018, and December 31, 2017, all the Company's cash was deposited in accounts at two principal financial institutions. The Company maintains its cash and cash equivalents with high-quality, accredited financial institutions 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 Income (Loss)

Comprehensive income (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 income (loss) equaled net income (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 furniture 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).

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 condensed consolidated financial position or results of operations upon adoption.

In May 2014, the FASB issued amended guidance for revenue recognition, Accounting Standards Update (“ASU”) 2014-09, “*Revenue from Contracts with Customers (Topic 606)*.” This ASU outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The core principle of the guidance is that an entity should recognize revenue for the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. Additionally, the ASU requires improved disclosure to help users of financial statements better understand the nature, amount, timing and uncertainty of revenue that is recognized. The Company adopted the new guidance on January 1, 2018, as it relates to the Agreement discussed in Footnote 12.

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 statement of operations 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 evaluating the complete population of leases assessed under this ASU and evaluating the effect that adoption of this new standard will have on its accounting and disclosures. The adoption of this ASU will likely have a material impact on the condensed consolidated balance sheet.

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 has applied the new guidance related to excess tax benefits on a prospective basis. The Company also elected to account for forfeitures of share-based payments as they occur. The adoption of this ASU was not material to the condensed consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “*Statement of Cash Flows (Topic 230)*.” The objective of this ASU is to provide additional guidance and reduce diversity in practice when classifying certain transactions within the statement of cash flows. In November 2016, the FASB issued ASU 2016-18, “*Statement of Cash Flows (Topic 230): Restricted Cash*.” This ASU requires that the 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. These ASUs are effective for financial statements issued for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted these ASUs as of January 1, 2018. The adoption of these ASUs did not have a material impact on the Company’s condensed consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “*Stock Compensation - Scope of Modification Accounting*.” This ASU provides clarification around which changes to the terms or conditions of a share-based payment award require the application of modification accounting under ASC 718. The Company adopted this ASU as of January 1, 2018. The adoption of this ASU did not have a material impact on the Company’s condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, “*Improvements to Nonemployee Share-Based Payment Accounting*.” This ASU improves financial reporting for share-based payments issued to nonemployees under ASC 718 by expanding the scope of the employee share-based payments guidance to include share-based payments issued to nonemployees. The amendments in this ASU are effective for public companies for fiscal years beginning after December 31, 2018, including interim periods within that fiscal year. The Company has not yet adopted this ASU and is currently evaluating the effect that adoption of this new standard will have on its condensed consolidated financial statements.

3. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses are as follows:

	September 30, 2018	December 31, 2017
Accounts payable	\$ 717,000	\$ 1,276,537
Professional fees	499,835	277,217
Accrued bonus	1,077,901	833,650
Accrued vacation	228,048	69,549
Accrued project costs	1,032,787	1,069,852
Other	89,114	65,359
Total accounts payable and accrued expenses	<u>\$ 3,644,685</u>	<u>\$ 3,592,164</u>

4. Notes Payable to Investors

In 2016, Aerpio entered into a senior secured convertible note financing (the “Convertible Notes” or the “Convertible Note Financing”) totaling approximately \$9,000,000. The Convertible Notes accrued interest at 8% per annum, compounded annually. The Convertible Notes were subject to mandatory prepayment upon the occurrence of certain events, such as a liquidation, dissolution or 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 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 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 investors of Aerpio. The terms of the Additional Convertible Notes were identical to the Convertible Notes and were 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 were accounted for as a modification for accounting purposes.

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

5. Common Stock

As of September 30, 2018 and December 31, 2017, the Company had 300,000,000 shares of authorized common stock with par value of \$0.0001 per share.

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.

Warrants to Purchase Common Stock

At September 30, 2018, and December 31, 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 2017 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 common stock.

6. Preferred Stock

As of both September 30, 2018 and December 31, 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 September 30, 2018 and December 31, 2017.

7. Stock-Based Compensation

Pursuant to the Merger (Note 1), the Company assumed the Aerpio Therapeutics, Inc. 2011 Equity Incentive Plan (the "2011 Plan"). Options covering an aggregate of 821,914 and 898,962 shares of the Company's common stock at September 30, 2018, and December 31, 2017, respectively, are still governed by the 2011 Plan except that all references in the 2011 Plan to Aerpio, will now be the Company.

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. In April 2018, the Company's Board of Directors approved a 4% increase adding 1,082,802 shares to the 2017 Plan. As of September 30, 2018, and December 31, 2017, 2,615,062 and 1,179,410 stock awards were outstanding under the 2017 Plan and the 2011 Plan, respectively. This excludes 733,570 inducement stock awards issued outside of the 2017 Plan and the 2011 Plan outstanding at September 30, 2018, and December 31, 2017.

Stock Options

The options granted generally vest over 48 months. Under the 2017 Plan, options vest in installments of 25% at the one-year anniversary and thereafter in 36 equal monthly installments beginning on the 1st of the month after the one-year anniversary 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. 97,500 and 1,612,700 option awards were granted in the three and nine months ended September 30, 2018, respectively, and no option awards were granted in the three and nine months ended September 30, 2017. As of September 30, 2018, and December 31, 2017, 2,962,062 and 3,391,960 shares are reserved for issuance under the 2017 Plan, respectively.

The following table summarizes the stock option activity during the nine months ended September 30, 2018:

	Stock Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2018	1,912,980	\$ 3.72	8.24	\$ 2,738,704
Granted	1,612,700	3.64		
Exercised	(52,099)	1.47		
Expired/cancelled	(124,949)	3.23		
Outstanding, September 30, 2018	<u>3,348,632</u>	<u>\$ 3.73</u>	<u>8.47</u>	<u>\$ 1,129,828</u>
Expected to vest, September 30, 2018	2,436,229	\$ 4.27	9.41	\$ 61,555
Options exercisable, September 30, 2018	912,403	\$ 2.28	5.96	\$ 1,068,273

Aggregate intrinsic value represents the estimated fair value of the Company's common stock at September 30, 2018, in excess of the weighted average exercise price multiplied by the number of options outstanding or exercisable.

Compensation expense for stock options was \$759,978 and \$53,814 for the three months ended September 30, 2018 and 2017, respectively and \$2,314,201 and \$173,888 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, there was \$4,568,480 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.63 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 nine months ended September 30, 2018 is as follows:

	Restricted Stock Shares	Weighted Average Grant Date Fair Value
Nonvested, January 1, 2018	91,576	\$ 2.12
Granted	60,000	4.75
Vested	(142,205)	3.23
Forfeited	(2,333)	2.25
Nonvested, September 30, 2018	<u>7,038</u>	<u>\$ 2.21</u>

The Company recognized compensation expense for restricted stock of \$46,433 and \$73,545 for the three months ended September 30, 2018 and 2017, respectively, and \$449,689 and \$220,380 for the nine months ended September 30, 2018 and 2017, respectively.

Compensation Expense Summary

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 139,492	\$ 88,443	\$ 313,505	\$ 276,778
General and administrative	666,919	38,916	2,450,385	117,490
Total	<u>\$ 806,411</u>	<u>\$ 127,359</u>	<u>\$ 2,763,890</u>	<u>\$ 394,268</u>

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option pricing and 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 nine months ended September 30, 2018 was \$2.13 and \$2.24 per share, respectively. The calculation was based on the following assumptions.

	<u>Three Months Ended September 30, 2018</u>	<u>Nine Months Ended September 30, 2018</u>
Expected term (years)	6.00	6.07
Risk-free interest rate	2.83%	2.85%
Expected volatility	65.12%	66.04%
Expected dividend yield	0.00%	0.00%

8. Income Taxes

The Company did not record a current or deferred income tax expense or benefit for the nine months ended September 30, 2018 and 2017 due to the Company's net losses and increases in its deferred tax asset valuation allowance. The impacts of The Tax Cuts and Jobs Act (the "2017 Tax Act") disclosed in the December 31, 2017 Form 10-K were provisional in nature and there have been no adjustments the provisional amounts in the nine months ended September 30, 2018. We will continue to evaluate the provisional amounts in light of the requirements of the 2017 Tax Act until our 2017 Federal Income Tax Return is filed with the Internal Revenue Service Agency.

9. Net Income (Loss) per Share Attributable to Common Stockholders

The following is a reconciliation of the numerator and denominator of the basic and diluted net income (loss) per share ("EPS") computations:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Numerator:				
Net and comprehensive income (loss)	\$ 11,537,478	\$ (4,649,567)	\$ (1,878,046)	\$ (15,165,577)
Adjustment of redeemable convertible preferred stock to redemption value	—	—	—	(943,297)
Net income (loss) attributable to common stockholders	<u>\$ 11,537,478</u>	<u>\$ (4,649,567)</u>	<u>\$ (1,878,046)</u>	<u>\$ (16,108,874)</u>
Denominator:				
Denominator for basic EPS - weighted-average common shares	40,527,722	26,926,673	31,687,434	19,889,984
Dilutive effect of options to purchase common shares	426,860	-	-	-
Dilutive effect of unvested restricted stock	7,038	-	-	-
Denominator for diluted EPS - adjusted weighted-average common shares	<u>40,961,620</u>	<u>26,926,673</u>	<u>31,687,434</u>	<u>19,889,984</u>
Basic and diluted EPS	<u>\$ 0.28</u>	<u>\$ (0.17)</u>	<u>\$ (0.06)</u>	<u>\$ (0.81)</u>

The diluted EPS calculation for the three months ended September 30, 2018 excludes 2.4 million options to purchase common stock that was outstanding but unvested and the effect of weighted average common stock share equivalents of 0.1 million for options to purchase common stock and 0.3 million for warrants to purchase common stock as their effect is anti-dilutive. Holders of non-vested stock-based compensation awards do not have voting rights.

The following weighted average common stock equivalents were excluded from the calculation of basic and diluted net loss per share attributable to common stockholders for the nine-month periods presented:

	Nine Months Ended September 30,	
	2018	2017
Options to purchase common stock	3,348,632	898,962
Unvested restricted stock	7,038	129,835
Warrants to purchase common stock	317,562	317,562

10. Commitments and Contingencies

The Company is a party to a lease covering 7,580 square feet of space in Cincinnati, Ohio. The Company signed a fourth lease amendment in March 2018, extending the lease through July 2021. The lease agreement contains free rent and escalating rent payments. 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. In November 2017, the Company renewed a lease covering 687 square feet of space in Dexter, MI that expires in October 2019. Total rent expense for all operating leases was \$116,640 and \$155,513 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, future payments related to operating leases activities are presented in the table below.

	2018	2019	2020 and Thereafter	Total
Operating leases	\$ 31,653	\$ 125,660	\$ 187,466	\$ 344,779

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 be liable for the cost and expenses incurred to date as well as any close out costs of the service arrangement.

11. Employee Stock Purchase Plan

In March 2017, the Board of Directors adopted and the stockholders approved the Employee Stock Purchase Plan that became effective in April 2017. On June 20, 2018, the Company's shareholders approved the Amended and Restated 2017 Employee Stock Purchase Plan ("ESPP") at the Annual Meeting of Shareholders. Pursuant to the terms of the ESPP, the Company will reserve for issuance 300,000 shares of the Company's common stock in the aggregate, plus, on January 1, 2019 and each January 1 thereafter through January 1, 2028, the number of shares of the Company's common stock reserved and available for issuance under the ESPP will be cumulatively increased by the least of (i) one percent of the number of shares of the Company's common stock issued and outstanding on the immediately preceding December 31; (ii) 350,000 shares; or (iii) such lesser number of shares of the Company's common stock as determined by the Board of Directors, in each case subject to adjustment in accordance with the terms of the ESPP. No shares under the ESPP are outstanding at September 30, 2018 and December 31, 2017.

12. License Agreement

On June 24, 2018, the Company entered into a License Agreement (the "Agreement") with a wholly-owned subsidiary of Gossamer Bio, Inc., GB004, Inc. (collectively "Gossamer"), under which the Company granted Gossamer an exclusive, sublicensable license to develop and commercialize AKB-4924 and other structurally related products worldwide, with initial development expected in the indications of induction and maintenance in ulcerative colitis and Crohn's Disease (collectively "initial indications").

Gossamer is responsible for the development and commercialization of the licensed products, and a joint development committee has been formed to oversee the development and manufacturing activities related to the licensed products. Under the terms of the Agreement, Gossamer is obligated to use its commercially reasonable efforts to develop and commercialize licensed products in the United States, two major European countries and Japan for at least one of the initial indications. The Agreement includes an exclusivity provision that prohibits the Company from developing, manufacturing or commercializing, and prohibits Gossamer from clinically developing or commercializing certain HIF stabilizing compounds other than as permitted in the Agreement. Pursuant to the terms of the Agreement, Gossamer made an upfront payment to the Company of \$20.0 million on June 28, 2018.

The Company is also eligible to receive development, commercial and sales milestone payments, with such payments contingent on the achievement of specified milestones with respect to the first licensed product for each of the first two initial indications. The Company is also eligible to receive tiered royalties on sales of licensed products at percentages ranging from a high-single-digit to mid-teens, subject to certain customary reductions. In addition, under certain circumstances, in lieu of receiving the foregoing milestone payments and royalties, the Company may elect to receive a specified percentage of payments received by Gossamer and its stockholders (with some exclusions) in connection with Gossamer's grant of a sublicense or other rights to the licensed products or if Gossamer undergoes a change of control and the value of the transaction exceeds a certain value (provided that Gossamer can prevent the Company from exercising this option if the parent company of Gossamer is the entity undergoing the change of control). Conversely, the Company could be required to accept such a specified percentage of those payments if Gossamer agrees to pay the Company a certain minimum upon Gossamer and its stockholders being paid. Such amount may be reduced if the subject transaction includes pharmaceutical candidates or products or other named asset categories in addition to the licensed products.

The Agreement expires on a licensed-product-by-licensed-product and country-by-country basis on the later of fifteen years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product in such country. Either party may terminate the Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. Gossamer may terminate the Agreement in the event Gossamer determines there is a potential safety or efficacy issue with the licensed products. The Company may terminate the Agreement if Gossamer institutes certain actions related to the licensed patents. Under certain termination circumstances, the Company would have worldwide rights to the terminated program.

As of September 30, 2018 all development milestones, sales-based milestones and royalty payments within the Agreement are constrained to the point where no transaction price has been allocated to the future milestones or royalty payments. Consequently, at the date the Agreement was signed, the transaction price was solely attributable to the upfront payment which was recognized ratably over a ninety-day transition period in accordance with Topic 606 and the Company's policy. The aforementioned transition period commenced on June 25, 2018 and \$18.7 million and \$20.0 million of license revenue was recorded within the condensed consolidated statement of operations and comprehensive income (loss) for the three and nine months ended September 30, 2018, respectively.

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 condensed consolidated financial statements and the notes to those statements included in this Quarterly Report on Form 10-Q for the period ended September 30, 2018. 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 our Annual Report on Form 10K for the fiscal year ended December 31, 2017 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.

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 our cash reserves, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations, including with Gossamer, as well as the expected benefits from such collaboration;
- 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.

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 non-proliferative diabetic retinopathy, or NPDR, a disease characterized by progressive compromise of blood vessels in the back of the eye. The Tie2 receptor is expressed almost exclusively in endothelial cells (cells that line the inside of blood vessels) and its activity is essential for maintaining vascular stability and preventing blood vessel compromise associated with diabetes. We have completed a Phase 2a trial of AKB-9778 in 144 patients with diabetic eye disease. Based on the results from this trial, we believe AKB-9778 has the potential to slow down or possibly reverse the damage to blood vessels caused by diabetes. In contrast to marketed treatments for NPDR that are administered by a physician via intraocular injection, we intend to deliver AKB-9778 systemically by self-administered subcutaneous injection, similar to insulin. We believe that this delivery method provides an opportunity to treat diabetic eye disease at an earlier stage and reduces the likelihood of developing vision-threatening complications.

In June 2017, we initiated a 48-week, double-masked, Phase 2b clinical trial, which we refer to as TIME-2b, in patients with NPDR who have not developed more serious complications such as diabetic macular edema, or DME or proliferative diabetic retinopathy, or PDR. The TIME-2b study is a double-masked, placebo-controlled multi-center trial that is currently on-going and has enrolled 167 patients randomized evenly to receive either AKB-9778 15 mg subcutaneously once daily, AKB-9778 15 mg subcutaneously twice daily or placebo for a 48-week treatment 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, or DRSS, in the study eye. We expect to report top line results of the Phase 2b clinical trial in the second quarter of 2019.

Compromise of Tie2 function is also implicated in other vascular complications of diabetes. We believe systemic treatment with AKB-9778 may address some of the most debilitating of these complications, including diabetic nephropathy. If we are successful in developing and commercializing AKB-9778 for NPDR, we may conduct clinical trials to evaluate AKB-9778's potential to reduce or delay the need for kidney dialysis. In a post-hoc analysis of Aerpio's TIME-2 clinical trial, there was a 21% reduction (geometric mean) in urine albumin-to-creatinine ratio (UACR) from baseline in the AKB-9778 treatment arms, but an overall increase in UACR in the placebo arm. The study provides clinical evidence of the potential beneficial effects of Tie2 activation in diabetic kidney disease.

In addition to diabetic vascular disease, existing preclinical and clinical evidence suggest the potential of AKB-9778 for reducing intraocular pressure in primary open angle glaucoma, or POAG, and ocular hypertension. We plan to initiate a Phase 1b clinical trial in the second quarter of 2019 to evaluate AKB-9778, administered via topical eye drops and, if we observe positive results, we expect to initiate a Phase 2 program for this indication.

In June 2018, we licensed AKB-4924, a selective stabilizer of hypoxia-inducible factor-1 alpha, or HIF-1 alpha to Gossamer Bio, Inc. AKB-4924 is being developed for the treatment of inflammatory bowel disease. HIF-1 alpha is involved in mucosal wound healing and the reduction of inflammation in the gastrointestinal tract. We have completed a single ascending dose clinical trial in healthy volunteers for AKB-4924 and initiated a multiple ascending dose, or MAD study in the second quarter of 2018. Gossamer is responsible for all remaining development and commercial activities for AKB-4924.

ARP-1536, our humanized monoclonal antibody directed at the same target as AKB-9778, is in preclinical development. We are evaluating development options for ARP-1536, including subcutaneous injection for the treatment of diabetic vascular complications and intravitreal injection for the treatment of advanced diabetic eye disease such as DME or PDR.

Except for the license agreement we entered into with Gossamer in June 2018, 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. For the nine months ended September 30, 2018, we generated \$20.2 million in revenue related to the license agreement and transition services to Gossamer. However, there can be no assurance of future revenues either from future payments related to the Gossamer license, transition services or from our product candidates. 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 September 30, 2018, we had an accumulated deficit of \$110.4 million and anticipate incurring additional losses for the next several years.

Our primary source of liquidity to date has been through the license agreement with Gossamer and public and private sales of our equity securities as well as the historical sales of redeemable convertible preferred stock, common stock and proceeds from convertible debt. 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 consolidated financial position.

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

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 condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's inability to obtain required funding in the near future could have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations. Based on the Company's current cash reserves of \$68.8 million at September 30, 2018 and financial condition as of this Quarterly Report on Form 10-Q, we believe our existing cash and cash equivalent will be sufficient to fund currently planned operations through the first quarter of fiscal year 2020.

Basis of Presentation

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 consolidated balance sheets and the consolidated statements of operation and comprehensive income (loss) presented herein. The following discussion and analysis are based on the Company's condensed consolidated financial statements contained in this Form 10-Q, which we have prepared in accordance with U.S. generally accepted accounting principles. You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

Components of Statements of Operations and Comprehensive Income (Loss)

License Revenue, and Other

License revenue and other consists of the upfront payment received upon execution of the Agreement with Gossamer during the second quarter of 2018 and certain transition services provided as part of the Agreement.

Operating Expenses

Research and Development Research and development expenses consist primarily 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. Research and development expenses are expensed 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 General and administrative expenses consist primarily of compensation and related costs for our finance, human resources and other administrative personnel, including stock-based compensation, employee benefits and travel. In addition, general and administrative expenses include third-party consulting, legal, patent, audit, accounting services and facilities costs. We expect to continue to incur general and administrative expenses 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 cash and cash equivalents. Interest expense consists primarily of interest and amortization of debt issuance costs related to our secured convertible promissory notes. The secured convertible notes converted into shares of our common stock in connection with the Merger and private placement offering.

Grant Income

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

Results of Operations

The following table presents the results of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
License revenue, and other	\$ 18,821,953	\$ —	\$ 20,155,286	\$ —
Operating expenses:				
Research and development	4,346,381	2,942,170	12,604,125	8,366,869
General and administrative	3,277,535	1,814,068	9,866,227	6,732,816
Total operating expenses	7,623,916	4,756,238	22,470,352	15,099,685
Operating income (loss)	11,198,037	(4,756,238)	(2,315,066)	(15,099,685)
Grant income	6,394	46,824	6,394	93,720
Interest income (expense), net	333,047	59,847	430,626	(159,612)
Total other income (expense), net	339,441	106,671	437,020	(65,892)
Net and comprehensive income (loss)	\$ 11,537,478	\$ (4,649,567)	\$ (1,878,046)	\$ (15,165,577)

Comparison of the Three Months Ended September 30, 2018 and 2017

License Revenue, and Other

License revenue, and other for the three months ended September 30, 2018 reflects the remainder of the \$20.0 million upfront payment from the license agreement with Gossamer, recognized ratably over a ninety-day performance period beginning on June 25, 2018, along with revenue from certain transition services provided to Gossamer as part of the license agreement.

Operating Expenses

	Three Months Ended September 30,	
	2018	2017
Research and development	\$ 4,346,381	\$ 2,942,170
General and administrative	3,277,535	1,814,068
Total operating expenses	\$ 7,623,916	\$ 4,756,238

Research and Development

Research and development expenses for the three months ended September 30, 2018, increased approximately \$1.4 million or 47.7%, compared to the three months ended September 30, 2017. This increase was the result of \$1.6 million increased spending on AKB-9778, offset by a reduction of \$0.2 million of expenses related to AKB-4924. Research and development expenses are primarily attributed to the ongoing cost of the Phase 2 NPDR clinical trial initiated in the second quarter of 2017.

General and Administrative

General and administrative expenses for the three months ended September 30, 2018, increased approximately \$1.5 million, or 80.7%, compared to the three months ended September 30, 2017. This increase was primarily attributable to increases in stock-based compensation of \$0.6 million, personnel-related expenses of \$0.6 million and patent legal expenses of \$0.3 million. The increase in stock-based compensation and personnel-related expenses reflects a full quarter of expenses in 2018 for new employees who started in late 2017 and during 2018 compared to the prior year.

Other Income (Expense), net

	Three Months Ended September 30,	
	2018	2017
Grant income	\$ 6,394	\$ 46,824
Interest income, net	333,047	59,847
Total other income, net	<u>\$ 339,441</u>	<u>\$ 106,671</u>

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

Interest income in the three months ended September 30, 2018 and 2017, reflects interest earned on short term money market instruments. The net proceeds from our 2018 Offering and upfront payment received in conjunction with the execution of the license agreement with Gossamer, less cash used in operations, were available for investment and generated more interest income in the three months ended September 30, 2018, compared to the prior period.

Comparison of the Nine Months Ended September 30, 2018 and 2017

License Revenue, and Other

License revenue, and other for the nine months ended September 30, 2018 reflects the \$20.0 million upfront payment from the license agreement with Gossamer along with revenue for certain transition services provided to Gossamer as part of the license agreement.

Operating Expenses

	Nine Months Ended September 30,	
	2018	2017
Research and development	\$ 12,604,125	\$ 8,366,869
General and administrative	9,866,227	6,732,816
Total operating expenses	<u>\$ 22,470,352</u>	<u>\$ 15,099,685</u>

Research and Development

Research and development expenses for the nine months ended September 30, 2018, increased approximately \$4.2 million or 50.6%, compared to the nine months ended September 30, 2017. This increase is primarily attributed to the ongoing research activity related to AKB-9778, the Phase 2 NPDR clinical trial initiated in the second quarter of 2017.

General and Administrative

General and administrative expenses for the nine months ended September 30, 2018, increased approximately \$3.1 million, or 46.5%, compared to the nine months ended September 30, 2017. This increase was primarily attributable to an increase in shared-based compensation of \$2.3 million related to stock-based awards granted new employees in 2017 and 2018, and personnel-related expenses of \$1.3 million for salaries and related benefits for new employees who started in late 2017 and during 2018, offset by a reduction of \$0.5 million in legal and other expenses.

Other Income (Expense), net

	Nine Months Ended September 30,	
	2018	2017
Grant income	\$ 6,394	\$ 93,720
Interest income (expense), net	430,626	(159,612)
Total other income (expense), net	\$ 437,020	\$ (65,892)

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 for the nine months ended September 30, 2018, reflects interest earned on short term money market instruments. Interest expense for the nine months ended September 30, 2017 was primarily related to the senior secured convertible notes issued 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, offset in part by interest earned on invested cash balances related to net proceeds of issuance of common stock of \$37.2 million. The notes accrued interest at the rate of eight percent annum, compounded annually. The principal and accrued interest on the secured convertible notes were converted into common stock on March 15, 2017, in connection with the Merger.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and negative cash flows from operations. For the nine months ended September 30, 2018 and 2017, we had net loss of \$1.9 million and \$15.2 million, respectively. At September 30, 2018, and December 31, 2017, we had an accumulated deficit of \$110.4 million and \$108.6 million, respectively.

In February 2018, we filed a shelf registration statement on Form S-3 with the SEC which was declared effective by the Securities and Exchange Commission on April 11, 2018 (the "Form S-3"). The shelf registration statement allows us to sell from time-to-time up to \$150.0 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings. The shelf registration statement is intended to provide us flexibility to conduct registered sales of our securities, subject to market conditions and our future capital needs. The terms of any offering under the shelf registration statement will be established at the time of such offering and will be described in a prospectus supplement filed with the SEC prior to the completion of any such offering.

Additionally, on February 21, 2018, and pursuant to the Form S-3, we entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to \$75.0 million through Cantor as our sales agent. Cantor may sell our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through the Nasdaq Capital Market or any other existing trade market for our common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. The shares of our common stock to be sold under the Sales Agreement will be sold and issued pursuant to the Form S-3 and the related prospectus and one or more prospectus supplements. We will pay Cantor 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. As of September 30, 2018, no shares had been sold under this Sales Agreement.

In June 2018, we generated \$20.0 million of cash in connection with the license agreement with Gossamer. On June 28, 2018, we closed an underwritten public offering for the sale of 11,688,000 shares of our common stock and subsequently, on July 2, 2018, we closed on the sale of an additional 1,720,200 shares of our common stock, pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock (the "2018 Offering"). In the aggregate, we received net proceeds of approximately \$48.1 million from the 2018 Offering after deducting underwriting discounts and commissions and offering expenses.

At September 30, 2018, we had cash and cash equivalents of \$68.8 million. To date, we have financed our operations principally through private and public offerings of our equity securities, private placements of our redeemable convertible preferred stock, common stock, issuances of secured convertible promissory notes and the license agreement. Based on our current plans, we expect that our existing cash and cash equivalents, will enable us to conduct our planned operations through the first quarter of fiscal 2020.

We could potentially use our available financial resources sooner than we currently expect, and we may incur additional indebtedness to meet future operation liquidity. 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.

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

	Nine Months Ended September 30,	
	2018	2017
Net cash provided by (used in) operating activities	\$ 376,755	\$ (14,271,082)
Net cash used in investing activities	(29,380)	(6,547)
Net cash provided by financing activities	48,195,783	37,496,845
Net increase in cash and cash equivalents	<u>\$ 48,543,158</u>	<u>\$ 23,219,216</u>

Operating Activities

We have historically experienced negative cash outflows as we developed AKB-9778, ARP-1536 and AKB-4924. Our net cash provided by (used in) operating activities primarily results from our net income (loss) adjusted for non-cash expenses, changes in working capital components, amounts due to contract research organizations to conduct 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 by increased spending to advance and support our product candidates in the clinic and other operating and general administrative activities.

For the nine months ended September 30, 2018, operating activities generated \$0.4 million in cash proceeds as result of \$0.5 million of decrease in working capital and a net loss of approximately \$1.9 million, offset by \$2.8 million in non-cash expenses related to stock-based compensation and depreciation expense. For the nine months ended September 30, 2017, operating activities used \$14.3 million in cash, primarily as a result of a net loss of \$15.2 million offset by \$0.7 million of non-cash expenses, consisting of stock-based compensation expense, non-cash interest expense, amortization of debt issuance costs and depreciation expense.

Net cash provided by operating activities for the nine months ended September 30, 2018 includes \$20.2 million of revenue earned from the license agreement with Gossamer along with revenue for certain transition services provided to Gossamer as part of the license agreement. Since timing of revenue is based on the milestones outlined in the Agreement, net cash from operating activities is not expected to reoccur until milestones are achieved over the term of the Agreement.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2018 and 2017 was related to capital expenditures to support operations.

Financing Activities

For the nine months ended September 30, 2018, we received \$76,756 from the exercise of stock options and \$48.1 million net proceeds from the 2018 Offering.

For the nine months ended September 30, 2017, we received \$36,101 from the exercise of stock options and net proceeds of \$37.2 million from the sale of common stock in our March 2017 private placement and \$0.3 million in January 2017 from an extension to the Aerpio senior secured convertible notes. The outstanding principal and accrued interest under the secured convertible notes were 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 Form 10-Q from the contractual obligations and commitments as of December 31, 2017 as described in our Annual Report on Form 10-K filed with the SEC on March 15, 2018.

Off-Balance Sheet Arrangements

As of September 30, 2018 and December 31, 2017, 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 U.S. generally accepted accounting principles or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, 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.

We adopted the new accounting guidance for revenue recognition effective January 1, 2018. Beginning with the second quarter of 2018, our financial results reflect adoption of the guidance as it relates to the license agreement; however, the adoption had no impact on prior period results. See Note 12 to the Condensed Consolidated Financial Statements contained in Item 1 herein for further information.

For further information on all our significant accounting policies, see the notes to our condensed financial statements.

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.

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required by this Item.

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 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 September 30, 2018, 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 this evaluation, management concluded that our internal control over financial reporting was effective as of September 30, 2018.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2018, 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. For a detailed discussion of the risks that affect our business, please refer to the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the section titled “Risk Factors” in our Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2018. There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K as updated by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018.

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

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None

Item 6. Exhibits.

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

Exhibit Number	Description
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1**	<u>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.</u>
32.2**	<u>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.</u>
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.

**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, Stephen Hoffman, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 7, 2018

By: _____ /s/ Stephen Hoffman, M.D., Ph.D.

Stephen Hoffman, M.D., Ph.D.

Chief Executive Officer

(Principal Executive Officer)

**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, Michael Rogers, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aerieo 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: November 7, 2018

By: _____ /s/ Michael Rogers
Michael Rogers
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

**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 September 30, 2018 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: November 7, 2018

By: /s/ Stephen Hoffman, M.D., Ph.D.

Stephen Hoffman, M.D., Ph.D.

Chief Executive Officer

(Principal Executive Officer)

**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 September 30, 2018 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: November 7, 2018

By: _____ /s/ Michael Rogers

Michael Rogers
Chief Financial Officer
*(Principal Financial Officer and
Principal Accounting Officer)*