Edge Therapeutics, Inc.
Form 10-Q
November 01, 2018

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

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

For the transition period from_____to_____

Commission file number 001-37568

Edge Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	26-4231384
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922
(Address of principal executive offices)

(800) 208-3343
(Registrant's telephone number)

(Former name, former address and former fiscal year, if changed since last report)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

The number of shares of the registrant's Common Stock, par value $0.00033 per share, outstanding as of October 25, 2018 was 31,328,128.

Edge Therapeutics, Inc.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EDGE THERAPEUTICS, INC.

Condensed Balance Sheets

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$36,814,899	$88,067,647
Prepaid expenses and other current assets	247,182	986,680
Total current assets	37,062,081	89,054,327
Property and equipment, net	468,170	3,423,880
Other assets	142,870	142,870
Total assets	$37,673,121	$92,621,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	$590,694	$4,369,133
Accrued expenses	917,871	5,422,205
Restructuring reserve	5,179,722	–
Short term debt	–	3,075,421
Total current liabilities	6,688,287	12,866,759
Noncurrent liability:		
Long term debt	–	17,382,907
STOCKHOLDERS' EQUITY		
Preferred stock, 5,000,000 shares authorized at September 30, 2018 and December 31, 2017, 0 outstanding	–	–
Common stock, $0.00033 par value, 75,000,000 shares authorized at September 30, 2018 and December 31, 2017, 31,328,128 shares and 30,869,205 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	10,551	10,400
Additional paid-in capital	220,705,548	214,309,370
Accumulated deficit	(189,731,265)	(151,948,359)
Total stockholders' equity	30,984,834	62,371,411
Total liabilities and stockholders' equity	$37,673,121	$92,621,077

See accompanying notes to the condensed financial statements.

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EDGE THERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development expenses	$317,684	$6,913,171	$15,583,565	$23,477,971
General and administrative expenses	3,286,891	3,990,283	11,303,446	12,365,509
Restructuring expenses	847,852	–	7,494,094	–
Impairment charges	–	–	2,672,581	–
Total operating expenses	4,452,427	10,903,454	37,053,686	35,843,480
Loss from operations	(4,452,427)	(10,903,454)	(37,053,686)	(35,843,480)
Other income (expense):				
Interest income	187,256	214,064	696,035	479,297
Interest expense	–	(592,089)	(1,425,255)	(1,591,998)
Net loss and comprehensive loss	(4,265,171)	(11,281,479)	(37,782,906)	(36,956,181)
Loss per share basic and diluted	$(0.14)	$(0.37)	$(1.21)	$(1.23)
Weighted average common shares outstanding basic and diluted	31,328,128	30,852,514	31,198,804	30,091,640

See accompanying notes to the condensed financial statements.

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EDGE THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(37,782,906)	$(36,956,181)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,551,573	4,637,142
Stock-based 401K company common match	123,561	170,620
Depreciation expense	133,130	134,569
Impairment of machinery and equipment	2,672,581	–
Amortization of debt discount	1,039	28,871
Amortization of debt issuance costs	125,355	81,306
Non-cash interest expense	405,278	274,530
Changes in assets and liabilities:		
Prepaid expenses and other assets	889,497	627,848
Accounts payable	(3,778,439)	(524,145)
Accrued expenses	(4,504,334)	68,683
Restructuring reserve	5,179,722	–
Net cash used in operating activities	(30,983,943)	(31,456,757)
Cash flows from investing activities:		
Purchases of property and equipment	–	(160,751)
Net cash used in investing activities	–	(160,751)
Cash flows from financing activities:		
Proceeds from issuance of debt	–	5,000,000
Proceeds from exercise of stock options	721,195	91,982
Proceeds from exercise of warrants	–	50,922
Payments for debt back-end fees	(990,000)	–
Repayment of debt	(20,000,000)	–
Proceeds from issuance of common stock, net of issuance costs	–	17,382,943
Net cash (used in) provided by financing activities	(20,268,805)	22,525,847
Net decrease in cash	(51,252,748)	(9,091,661)
Cash and cash equivalents at beginning of period	88,067,647	106,398,919
Cash and cash equivalents at end of period	$36,814,899	$97,307,258
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$1,051,167	$1,172,979

Supplemental cash flow information:		
Accrued capital expenditures included in accrued expenses and accounts payable	$–	$18,084

See accompanying notes to the condensed financial statements.

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Edge Therapeutics, Inc.
Notes to Condensed Financial Statements (Unaudited)

Note 1 – Nature of Operations

Edge Therapeutics, Inc. (the "Company") is a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel therapies capable of transforming treatment paradigms in the management of medical conditions. On March 28, 2018, the Company announced that a pre-specified interim analysis performed on data from the Day 90 visit of the first 210 subjects randomized and treated in the Phase 3 multi-center, randomized, double-blind, placebo-controlled NEWTON 2 study of EG-1962 in adults with aneurysmal subarachnoid hemorrhage demonstrated a low probability of achieving a statistically significant difference compared to the standard of care in the study's primary endpoint, if the study were to be fully enrolled. The independent Data Monitoring Committee ("DMC") for the NEWTON 2 study recommended that the study be stopped based on this demonstration. The DMC also reported that there were no safety concerns attributed to EG-1962.

Based on the DMC recommendation, the Company decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study.

On April 30, 2018, the Company announced that it is exploring strategic alternatives, which may include, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of the Company, a sale of stock, a strategic merger or other business combination transaction or other transaction between the Company and a third party. The Company has retained Piper Jaffray & Co. to serve as the financial advisor to its Board of Directors in the process. The Company does not have a defined timeline for the exploration of strategic alternatives and there can be no assurance that the process will result in any strategic alternative being announced or consummated. The Company does not intend to discuss or disclose further developments during this process unless and until its Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate. The Company has reduced the scope of its operations, including the size of its workforce, in order to preserve its cash resources.

In the second quarter of 2018, the Company recorded an initial restructuring charge of $6.3 million. The components of the restructuring charge included expenses of $4.0 million for severance benefits and $2.3 million for financial advisor fees, as well as ongoing legal fees expensed as incurred, and accrued retention compensation related to the restructuring of the organization.

The restructuring activity during 2018 is as follows:

Restructuring reserve at December 31, 2017	$–
Initial restructuring charge	6,276,563
Incurred legal fees	334,212
Retention compensation	618,349
Restructuring expenses to date (1)	7,229,124
Payment of legal fees	(191,976)
Payment of retention compensation	(56,925)
Payment of severance benefits	(1,800,501)
Restructuring reserve as of September 30, 2018	$5,179,722

(1) Excludes non-cash stock based retention compensation of $264,970 expensed to date through restructuring expenses.

From the Company's inception, it has devoted substantially all of its efforts to business planning, engaging regulatory, manufacturing and other technical consultants, acquiring operating assets, planning and executing clinical trials and raising capital. The Company's future operations are highly dependent on the success of its strategic alternatives review and any transactions and operations resulting from that process.

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Note 2 – Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at September 30, 2018, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), and following the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of its financial information. The results of operations for the nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The balance sheet as of December 31, 2017 included herein was derived from the audited condensed financial statements as of that date. These condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Form 10-K for the year ended December 31, 2017.

(B) Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(C) Significant risks and uncertainties:

The Company's operations are subject to a number of factors that may affect its operating results and financial condition. Such factors include, but are not limited to: the Company's review of strategic alternatives, the Company's ability to preserve its cash resources, the Company's ability to add product candidates to its pipeline, the Company's intellectual property, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products if approved for sale, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products and has ceased all research and development activities related to EG-1962 and suspended research for its other product candidates. As such, there can be no assurance that the Company's future research and development programs will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting its intellectual property.

(D) Cash equivalents and concentration of cash balance:

The Company considers all highly liquid securities with a maturity weighted average of less than three months to be cash equivalents. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits.

(E) Research and development:

Costs incurred in connection with research and development activities are expensed as incurred. These costs include licensing fees to use certain technology in the Company's research and development projects as well as fees paid to consultants and various entities that perform certain research and testing on behalf of the Company.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data, such as patient enrollment, clinical site activations or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

Following the DMC’s recommendation that the NEWTON 2 Trial for EG-1962 be stopped, the Company decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study. The Company has ceased all further research and development activities for EG-1962 and suspended research for its other product candidates and implemented operating cost reductions and organizational restructurings while it seeks a strategic alternative, including a reduction in the Company’s workforce, to preserve its cash resources and better align the organization with its current operating plan. The estimated costs associated with the study discontinuance have been accrued as of September 30, 2018.

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(F) Patent costs:

The Company expenses patent costs as incurred and classifies such costs as general and administrative expenses in the accompanying statements of operations and comprehensive loss. In light of the Company's cessation of all further research and development activities for EG-1962 and suspension of research for its other product candidates, the Company has substantially scaled back its patent prosecution activities.

(G) Stock-based compensation:

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award.

Determining the appropriate fair value of stock-based awards requires the input of subjective assumptions, including, for stock options, the expected life of the option, and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and employment duration for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of options grants. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

(H) Net loss per common share:

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted average common shares outstanding during the period. For all periods presented, the common shares underlying the preferred stock, common stock options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted average shares outstanding used to calculate both basic and diluted loss per common share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as they would be anti-dilutive:

	As of September 30,	
	2018	2017
Stock options to purchase Common Stock	7,149,374	6,387,495
Unvested Restricted Stock Units	601,394	–
Warrants to purchase Common Stock	78,596	376,682
Total	7,829,364	6,764,177

(I) Accounting standards not yet adopted:

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)." The new standard requires organizations that lease assets—referred to as "lessees"—to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases (see Note

9). This standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The standard requires a modified retroactive approach, but use of certain practical expedients is permitted as per ASU 2018-11. The Company expects to use the package of practical expedients that allows it to not reassess: (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any expired or existing leases. The Company additionally expects to use the practical expedient that allows it to treat the lease and non-lease components of its leases as a single component. The Company expects to adopt ASU 2016-2 in the first quarter of 2019 and is in the process of evaluating the impact of adoption on its consolidated financial statements.

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(J) Accounting standards adopted:

In March 2016, the FASB issued ASU No. 2016-09 which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Public companies were required to adopt this standard in annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted this ASU on January 1, 2017.

The impact of adopting ASU 2016-09 resulted in the following:

The Company recognized $84,786 of tax benefit along with a full valuation allowance as of the adoption date related to the historical excess tax benefits from historical option exercises related to employee equity award activity. The Company elected to recognize forfeitures as they occur. The cumulative effect adjustment as a result of the adoption of this amendment on a modified retrospective basis was not material.

There were no other material impacts to the Company's condensed financial statements as a result of adopting this updated standard.

Note 3 – Fair Value of Financial Instruments

There were no transfers among Levels 1, 2, or 3 during 2018 or 2017.

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets (Level 1)	Quoted Prices in Inactive Markets (Level 2)	Significant Unobservable Inputs (Level 3)
As of September 30, 2018: (unaudited)				
Cash and cash equivalents	$36,814,899	$36,814,899	$ –	$ –
As of December 31, 2017:				
Cash and cash equivalents	$88,067,647	$88,067,647	$ –	$ –

Note 4 – Property and Equipment

In March 2018, following the recommendation of the Data Monitoring Committee, the Company made the decision to close down the EG-1962 NEWTON 2 study. The Company believes that it would be highly unlikely that the Company would be able to use the manufacturing equipment associated with EG-1962 for future use. As a result, the Company has taken an equipment impairment charge of $2,672,581. The write-down would bring down the value of the equipment to the Company’s best estimate of its future value based on a range of estimates from a third-party seller. The equipment is being classified as Other Current Assets on the condensed balance sheet.

Note 5 – Accrued Expenses

Accrued expenses and other liabilities consist of the following:

	As of	As of

	September 30, 2018	December 31, 2017
Accrued research and development costs (1)	$224,786	$2,857,025
Accrued professional fees	404,940	267,646
Accrued compensation	41,605	1,886,638
Accrued other	214,615	385,896
Deferred rent	31,925	25,000
Total	$917,871	$5,422,205

(1) Balance as of September 30, 2018 represents estimated close down NEWTON 2 trial costs.

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Note 6 – Stock-Based Compensation

The Company has three equity compensation plans: the 2010 Equity Incentive Plan, the 2012 Equity Incentive Plan and the 2014 Equity Incentive Plan (the "Plans"). Originally, the Company was able to grant up to 548,206 and 1,096,411 shares of Common Stock as both incentive stock options ("ISOs") and nonqualified stock options ("NQs") under the 2010 Equity Incentive Plan and the 2012 Equity Incentive Plan, respectively. In 2013, the Company's stockholders approved an increase to 1,279,146 shares authorized for issuance under the 2010 Equity Incentive Plan. In 2014, the Board of Directors of the Company (the "Board") approved an increase to 1,350,412 shares authorized for issuance under the 2010 Equity Incentive Plan.

In 2014, the Company's stockholders approved the 2014 Equity Incentive Plan pursuant to which the Company may grant up to 1,827,351 shares as ISOs, NQs and restricted stock units ("RSUs"), subject to increases as hereafter described (the "Plan Limit"). In addition, on January 1, 2015 and each January 1 thereafter prior to the termination of the 2014 Equity Incentive Plan, pursuant to the terms of the 2014 Equity Incentive Plan, the Plan Limit was and shall be increased by the lesser of (x) 4% of the number of shares of Common Stock outstanding as of the immediately preceding December 31 and (y) such lesser number as the Board of Directors may determine in its discretion. On January 1, 2016, 2017 and 2018 the Plan Limit was increased to 3,047,323 shares, 4,204,063 shares and 5,438,831 shares, respectively.

Pursuant to the terms of the Plans, ISOs have a term of ten years from the date of grant or such shorter term as may be provided in the option agreement. Unless specified otherwise in an individual option agreement, ISOs generally vest over a four year term and NQs generally vest over a one, three or four year term. Unless terminated by the Board, the Plans shall continue to remain effective for a term of ten years or until such time as no further awards may be granted and all awards granted under the Plans are no longer outstanding.

The Company issued the following non-qualified options to purchase shares of common stock to its newly appointed executives who are still employed by the Company. The awards were granted outside of the Company's 2014 Equity Incentive Plan and vest over four years with 25% vesting one year following the date of hire, and the remaining 75% vesting in 36 equal monthly installments thereafter, subject to continued service to the Company through each vesting date and subject to acceleration or forfeiture upon the occurrence of certain events as set forth in the applicable option agreement and employment agreement. The grant awards were made pursuant to the NASDAQ inducement grant exception as a material component of employment compensation.

Issue Date	25% Vesting Date	Executive	Number of Options
November 16, 2015	October 30, 2016	SVP, General Counsel and Secretary	80,000
March 1, 2017	February 28, 2018	SVP, Regulatory Affairs	80,000
November 1, 2017	October 31, 2018	Chief Financial Officer	200,000

The Company’s stock-based compensation expense related to stock options and RSUs was recognized in operating expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018 (unaudited)	2017	2018 (unaudited)	2017
Stock-Based Compensation				
Research and development	$612,218	$702,284	$2,041,070	$2,090,076
General and administrative	1,029,980	868,630	3,245,533	2,547,066
Retention Compensation	264,970	–	264,970	–

Total	$1,907,168	$1,570,914	$5,551,573	$4,637,142

The fair value of options granted during the nine months ended September 30, 2018 and the three and nine months ended September 30, 2017 was estimated using the Black-Scholes option valuation model utilizing the following assumptions. There were no options granted during the three months ended September 30, 2018.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	Weighted Average (unaudited)	Weighted Average	Weighted Average (unaudited)	Weighted Average
Volatility	0.00%	86.98 %	89.06%	88.82 %
Risk-Free Interest Rate	0.00%	1.83 %	2.31 %	1.89 %
Expected Term in Years	–	6.03	4.24	5.99
Dividend Rate	0.00%	0.00 %	0.00 %	0.00 %
Fair Value of Option on Grant Date	$–	$ 7.22	$5.54	$ 6.76

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The following table summarizes the number of options outstanding and the weighted average exercise price:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at December 31, 2017	6,462,795	$ 6.50		
Granted	2,322,906	7.52		
Exercised	(198,300)	3.64		
Forfeited	(1,438,027)	10.13		
Options outstanding at September 30, 2018	7,149,374	$ 6.18	6.13	$ 42,723
Vested and expected to vest at September 30, 2018	7,149,374	$ 6.18	6.13	$ 42,723
Exercisable at September 30, 2018	4,120,549	$ 5.54	5.73	$ 42,723

At September 30, 2018 there was approximately $13,294,326 of unamortized stock option compensation expense, which is expected to be recognized over a remaining average vesting period of 2.64 years.

The Company may grant RSUs to eligible employees, including its executives, and non-employee directors.

RSUs represent a right to receive one share of the Company’s common stock, upon the completion of a specific period of continued service or achievement of a certain milestone. RSU awards are valued at the market price of the Company’s common stock on the date of grant. The Company recognizes noncash compensation expense for the fair values of these RSU awards on a straight-line basis over the requisite service period of these awards.

The following table summarizes the number of RSUs outstanding and the weighted average grant price:

	Number of RSUs	Weighted Average Grant Price
RSUs outstanding at December 31, 2017	–	$ –
Granted	601,394	0.85
Released	–	–
Forfeited	–	–
RSUs outstanding at September 30, 2018	601,394	$ 0.85

At September 30, 2018, there was approximately $444,667 of unamortized RSU compensation expense, which is expected to be recognized over a remaining average vesting period of 0.87 years.

Note 7 – Income Taxes

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence to determine whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. There was a full valuation allowance against the net deferred tax assets as of September 30, 2018 and December 31, 2017.

At December 31, 2017, the Company had federal net operating loss ("NOL") carryforwards of approximately $101.5 million which expire between 2029 and 2037. At December 31, 2017, the Company had federal research and development credits carryforwards of approximately $1.9 million and an orphan drug credit carryover of approximately $22.1 million. The Company may be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

At December 31, 2017, the Company had approximately $31.9 million of State of New Jersey NOLs which expire between 2030 and 2037. At December 31, 2017, the Company had approximately $0.4 million of the State of New Jersey research development credits carryforwards. The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net loss carryforwards. The Technology Business Tax Certificate Transfer Program enables qualified, unprofitable NJ-based technology or biotechnology companies with fewer than 225 US employees (including parent company and all subsidiaries) to sell a percentage of New Jersey NOLs and research and development ("R&D") tax credits to unrelated profitable corporations. In 2017, the Company sold $26,097,607 of State of New Jersey NOLs and $424,466 of State of New Jersey R&D Credits for $2,586,057. In 2016, the Company sold $19,196,765 of State of New Jersey NOLs and $257,222 of State of New Jersey R&D Credits for $1,845,986.

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Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2017, there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2009 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. In September 2017, the IRS concluded auditing the Company's 2015 tax year resulting in a no change letter. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the nine months ended September 30, 2018 and 2017.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the “Act”)) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces U.S. federal corporate tax rate to 21%. As a result, the most significant impact on its condensed financial statements was the reduction of approximately $13.6 million for the deferred tax assets related to net operating losses and other assets. Such reduction is offset by changes to the Company’s valuation allowance. The Company is also in the process of considering the impact under the Act of the disallowance of certain incentive based compensation tax deductibility under Internal Revenue Code Section 162(m). If an adjustment to the deferred tax asset is required, the impact will be offset by a corresponding adjustment to the valuation allowance.

On July 1, 2018, the New Jersey governor signed into law a bill which included significant changes to the New Jersey taxation of corporations. Chiefly, this legislation imposes a 2.5% surtax on taxpayers with allocated net income over $1 million for 2018 and 2019, and a 1.5% surtax for taxpayers with allocated net income over $1 million for 2020 and 2021. In addition, the state is changing its filing requirements from separate entity reporting to combined reporting on a water’s edge basis. Further, there are changes to the state’s computation of its dividend received deduction and application of IRC section 163(j). The Company has considered these changes and does not believe this change in law will have a material impact on its tax provision going forward, due to the full valuation allowance, significant New Jersey NOLs and current year losses.

Note 8 – Commitments and Contingencies

Evonik

The Company entered into an agreement with SurModics Pharmaceuticals, Inc. ("SurModics") in October 2010 for the exclusive worldwide licensing of certain technology, patent rights and know-how rights related to the production of EG-1962, (the "Evonik Agreement"). This agreement was later transferred to Evonik Industries AG ("Evonik") when it purchased substantially all the assets of SurModics.

Pursuant to the Evonik Agreement, in exchange for the license, the Company agreed to make milestone payments totaling up to $14.75 million upon the achievement of certain development, regulatory and sales milestones detailed in the Evonik Agreement. The Company paid $0.25 million upon execution of the Evonik Agreement. In August 2016, the Company paid a milestone of $1.0 million after the first patient in the Phase 3 clinical trial of EG-1962 was dosed. In addition, the Evonik Agreement calls for the Company to pay royalties on sales of certain products based on a mid-single digit percentage of net sales. The Evonik Agreement provides for the reduction of royalties in certain limited circumstances.

The term of the Evonik Agreement will continue until the expiration of the Company’s obligation to pay royalties to Evonik. Either party may terminate the Evonik Agreement due to material breach by the other party. Evonik may terminate the Evonik Agreement or convert it to a non-exclusive license, in either case upon giving the Company written notice, if the Company fails to use commercially reasonable efforts to hit certain specified development,

regulatory and commercial milestones.

Following the discontinuation of the NEWTON 2 trial for EG-1962, the Company has ceased all research and development efforts related to EG-1962 and suspended efforts on its other product candidates as it pursues strategic alternatives. As such, unless the Company resumes such development activities, it is unlikely that the Company will have any additional milestone or royalty obligations to Evonik in the future.

Oakwood Amended and Restated Master Formulation Development Agreement

In June 2017, the Company entered into an Amended and Restated Master Formulation Development Agreement (the "Restated Development Agreement") with Oakwood Laboratories, L.L.C. ("Oakwood"), pursuant to which Oakwood agreed to continue to provide the Company with certain drug formulation development and non-commercial manufacturing services for EG-1962, in accordance with project plans that may be entered into from time to time.

Under the Restated Development Agreement, the Company agreed to pay Oakwood to perform services under agreed upon project plans and to pay Oakwood up to an aggregate of $4.5 million. In July 2017 and April 2018, the Company paid $1.5 million and $0.5 million, respectively, of such aggregate amount in connection with entering into the Restated Development Agreement. The remaining $2.5 million was payable no later than April 1, 2019. The remaining payment was discounted to $2.375 million and paid pursuant to an accelerated payment agreement entered into in August 2018. As of September 30, 2018, there are no remaining payments under the Restated Development Agreement.

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As additional consideration for performance under the Restated Development Agreement and the Supply Agreement (as defined below), the Company agreed to pay Oakwood a royalty, during the Royalty Term, in an amount equal to a low single digit percentage of net sales of EG-1962, regardless of the manufacturer or supplier thereof. The "Royalty Term" is the period commencing upon the commercial launch of EG-1962 by the Company and continuing until twelve (12) years following such launch.

The term of the Restated Development Agreement continues until the expiration or termination of the Supply Agreement, unless earlier terminated (the "Term"). The Company has the right to terminate project plans upon the occurrence of various circumstances described in the Restated Development Agreement. In the event that the Company terminates the most recent project plan prior to completion (which would include the Company's decision to discontinue the development or commercialization of EG-1962), the Company must pay to Oakwood a termination fee for work completed, which has been accrued as of September 30, 2018.

Oakwood Manufacturing and Supply Agreement

Concurrent with its entry into the Restated Development Agreement, on June 30, 2017, the Company entered into a Manufacturing and Supply Agreement with Oakwood (the "Supply Agreement"), pursuant to which Oakwood agreed to manufacture and supply, and the Company agreed to purchase from Oakwood, EG-1962 in commercial quantities following the commercial launch of the product.

Pursuant to the Supply Agreement, the Company agreed to pay Oakwood milestone payments that could total up to an aggregate of $2.25 million upon the achievement of certain development and regulatory milestones.

The term of the Supply Agreement will terminate automatically upon the termination of the Restated Development Agreement for any reason. Additionally, either party may terminate the Supply Agreement upon a material breach by the other party that fails to be cured in the applicable cure period.

Following the discontinuation of the NEWTON 2 trial for EG-1962, the Company has ceased all research and development efforts related to EG-1962 and suspended efforts on its other product candidates. As such, the Company may terminate the Supply Agreement immediately upon notice to Oakwood (which will also result in the automatic termination of the Restated Development Agreement); provided, that if it chooses to do so prior to completion of the most recent project plan attached to the Restated Development Agreement, the Company must pay to Oakwood a termination fee. While certain of the Company's milestone payments to Oakwood will remain outstanding (including the termination fee in the event the Restated Development Agreement is terminated), unless the Company resumes such development activities, it is unlikely that the Company will be required to pay additional milestone or royalty payments to Oakwood in the future pursuant to the Restated Development Agreement or the Supply Agreement.

Class Action Civil Litigation

On April 23, 2018, a purported securities class action complaint was filed against the Company, Brian Leuthner (the Company's President and Chief Executive Officer) and Andrew Saik (the Company's Chief Financial Officer) in the United States District Court for the District of New Jersey, captioned Sanfilippo v. Edge Therapeutics, Inc., Case No. 2:18-cv-8236. The complaint alleges that the Company, Mr. Leuthner and Mr. Saik violated Section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements concerning the Company's business, operations and prospects by failing to disclose that EG-1962 would likely fail a futility analysis. The complaint is brought on behalf of all purchasers of the Company's common stock between December 27, 2017 and March 27, 2018, and seeks unspecified damages. None of the Company, Mr. Leuthner, or Mr. Saik has been served with the complaint and their time to respond has not yet expired. Various individuals have moved to be appointed lead plaintiff to act on behalf of the putative class. After the court appoints that party (or parties), it is expected that the lead plaintiff will file

an amended complaint. The Company and its executives intend to defend themselves vigorously in the action. There can be no guarantee as to the outcome or timing of any resolution.

Employment Matters

The Company has entered into employment agreements with each of its executive officers. The agreements generally provide for, among other things, salary, bonus and severance payments. The employment agreements generally provide for between 12 months and 18 months of severance benefits to be paid to an executive (as well as certain potential bonus, COBRA and equity award benefits), subject to the effectiveness of a general release of claims, if the executive terminates his or her employment for good reason or if the Company terminates the executive's employment without cause. Such severance payments may be provided for as long as 24 months in connection with a termination following a change of control. The continued provision of severance benefits is conditioned on each executive's compliance with the terms of the Company's confidentiality and invention and assignment agreement as well as his or her release of claims.

On April 30, 2018, the Company initiated a corporate realignment to focus its efforts and resources on its ongoing operations and future plans that include a reduction in its workforce. This realignment was initiated following the Company’s recent announcement that it is discontinuing the Phase 3 NEWTON 2 study, based on the recommendation of an independent Data Monitoring Committee (the “DMC”) that the Company stop its Phase 3 NEWTON 2 study. The DMC recommendation was based on its conclusion that the study had a low probability of meeting its primary endpoint.

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During the second and third quarters, the Company reduced its workforce from 37 employees to 14 employees. The Company anticipates a further reduction of its workforce as the Company completes NEWTON 2 closedown activities and completes the analysis of the related NEWTON 2 data. In addition, the Company anticipates completing the payment of certain employee severance and benefits and certain retention compensation, as approved by the Compensation Committee of the Board of Directors, by the fourth quarter of fiscal year 2019.

Leases

Effective December 13, 2013, the Company entered into a 63 month lease for approximately 8,000 square feet of office space in Berkeley Heights, New Jersey. On February 18, 2016, the Company entered into a new 63 month lease for approximately 20,410 square feet of office space within the same office complex in Berkeley Heights, New Jersey. The terms of the new lease were structured so that the termination date of the December 13, 2013 lease coincided with the commencement date of the new lease on August 13, 2016. As a result of the lease termination, the Company wrote off $67,118 of leasehold improvements.

Rent expense is recognized on a straight line basis where there are escalating payments, and was approximately $148,284 and $152,026 for the three months ended September 30, 2018 and 2017, respectively and $450,053 and $450,700 for the nine months ended September 30, 2018 and 2017, respectively.

The following is a schedule by years of future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of September 30, 2018:

Year ended December 31,	
2018 (remaining)	$151,572
2019	604,541
2020	603,371
2021	530,385
2022 and after	–
Total minimum payments required	$1,889,869

Note 9 – Debt

On August 1, 2016, the Company entered into an Amended and Restated Loan and Security Agreement (the “Amended Loan Agreement”) with Hercules Capital, Inc., formerly known as Hercules Technology Growth Capital, Inc. (“Hercules”). Pursuant to the Amended Loan Agreement, the Company was able to borrow up to $20,000,000. At closing, the Company borrowed $15,000,000 of the amount available for draw under the Amended Loan Agreement (and received proceeds net of the amount then outstanding under the Original Loan Agreement, fees and expenses). On May 23, 2017, the Company elected to draw down the second tranche of $5 million. Pursuant to the Amended Loan Agreement, in March 2018, the Company made a payment of $90,000, which is equal to 1.5% of the total amounts funded under the Original Loan Agreement.

In June 2018, the Company agreed with Hercules Capital, Inc. to pay off its entire outstanding debt under the Amended Loan Agreement. The payment consisted of $20.0 million for the principal amount, an additional $0.9 million in back-end fees and $0.1 million in accrued and unpaid interest.

As of September 30, 2018, the Company has no outstanding debt.

Note 10 – Retirement Plan

The Company has a 401(k) defined contribution plan for the benefit for all employees and permits voluntary contributions by employees subject to IRS-imposed limitations. The 401K employer contributions were $21,605 and $46,916 for the three months ended September 30, 2018 and 2017, respectively and $152,154 and $217,536 for the nine months ended September 30, 2018 and 2017, respectively.

Note 11 – Subsequent Events

Subsequent events have been evaluated through the date these financial statements were issued.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report") and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017 (the "Annual Report") filed with the SEC on March 1, 2018. Except as otherwise indicated herein or as the context otherwise requires, references in this Quarterly Report to "Edge," "the Company," "we," "us" and "our" refer to Edge Therapeutics, Inc., a Delaware corporation.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," negative of these terms or other comparable terminology. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" contained in the Annual Report. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Quarterly Report and you should not place undue reliance on these forward-looking statements.

These forward-looking statements may include, but are not limited to, statements about:

our plans to explore strategic alternatives for the Company and our ability to successfully complete a strategic transaction;

the timing of completion of any strategic transaction, sale and/or liquidation, if any;

our ability to reduce operating expenses and conserve cash resources;

timing and amount of termination costs incurred in connection with our workforce reduction plan;

the accuracy of estimates of our expenses, future revenue, capital requirements and our needs for additional financing;

our ability to obtain funding for our operations in the event we determine to raise additional capital;

our ability to retain key management personnel;

the accuracy of our estimates regarding expenses, future revenues and capital requirements;

the possibility of dissolving our Company;

the pending class action civil litigation against the Company;

our ability to maintain our listing on the Nasdaq Stock Market;

regulatory developments in the United States and foreign countries;

our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”); and

other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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Overview

We are a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel therapies capable of transforming treatment paradigms in the management of medical conditions.

On March 28, 2018, we announced that a pre-specified interim analysis performed on data from the Day 90 visit of the first 210 subjects randomized and treated in the Phase 3 multi-center, randomized, double-blind, placebo-controlled, NEWTON 2 study of EG-1962 in adults with aneurysmal subarachnoid hemorrhage demonstrated a low probability of achieving a statistically-significant difference compared to the standard of care in the study's primary endpoint, if the study were to be fully enrolled. The independent Data Monitoring Committee, or the DMC, for the NEWTON 2 study recommended that the study be stopped based on this demonstration. The DMC also reported that there were no safety concerns attributed to EG-1962.

Based on the DMC recommendation, we decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study.

On April 17, 2018, our Board of Directors established a committee of convenience, our Transactions Committee, to explore strategic alternatives for Edge in order to maximize both near and long-term value for our shareholders, which may include, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of Edge, a sale of stock, a strategic merger or other business combination transaction or other transaction between us and a third party.

In April 2018, our Board of Directors retained Piper Jaffray & Co ("Piper") to serve as its financial advisor in the strategic review process. During the strategic alternatives process, we plan to continue to finance our operations with our existing cash. In the near term, we have reduced the scope of our operations, including the size of our workforce, in order to preserve our cash resources. Our ability to continue to support our operations is dependent, in the near-term, upon managing our cash resources as we pursue such strategic alternatives. We have ceased research and development on EG-1962, other than the wind-down of the NEWTON 2 study, and all of our other product candidates. We do not have a defined timeline for the exploration of strategic alternatives and we can provide no assurance that the process will result in any strategic alternative being announced or consummated. We do not intend to discuss or disclose further developments during this process unless and until our Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate.

The NEWTON 2 study was designed to detect a 15% absolute improvement in favorable outcomes at Day 90 for the EG-1962 treatment group with a target enrollment of 374 subjects with WFNS grades 2-4 and an external ventricular drain (EVD). Prior to discontinuation of the study, 289 subjects were randomized and 282 were treated. The final analysis showed that overall in the study's primary endpoint, 46% (64/138) of subjects treated with a single intraventricular injection of EG-1962 experienced a favorable outcome (a score of 6 to 8 on the extended Glasgow Outcome Scale, or GOSE) at Day 90, compared to 43% (62/144) of subjects treated with oral nimodipine. The GOSE is a clinically validated scale to assess recovery for patients who have suffered a brain injury.
In the NEWTON 2 study, at randomization, subjects were stratified by baseline severity as measured by the World Federation of Neurological Surgeons (WFNS) grade. Results of a logistic regression analysis of Day 90 GOSE outcomes including interactions revealed a statistically significant treatment by WFNS group interaction (p=0.0381). In the pre-specified subgroup of subjects with WFNS grade 3 or 4 (i.e.,severe aSAH subjects), 46% (32/69) of subjects treated with EG-1962 experienced a favorable outcome as measured by GOSE, compared to 32% (24/75) of subjects treated with oral nimodipine. While these results did not achieve statistical significance (as the NEWTON 2 study was not powered to provide statistical significance for subgroups), they suggest a clinically meaningful potential benefit for EG-1962 in subjects with WFNS grade 3 or 4. Further, these results are consistent with results from our Phase 1/2 NEWTON study. In that study, EG-1962 demonstrated a similar efficacy trend in favorable outcome rate

compared to oral nimodipine in severe aSAH subjects with WFNS grades 3 or 4, with 37% (10/27) of the subjects treated with EG-1962 experiencing a favorable outcome, compared to 23% (3/13) of the subjects treated with oral nimodipine.

In the WFNS grade 2 subgroup (i.e., moderate aSAH subjects), favorable outcome rates from the NEWTON 2 study were inconsistent with those observed in the Phase 1/2 NEWTON study in both the EG-1962 and oral nimodipine treatment groups. In addition, the favorable response rate in the control group in NEWTON 2 was higher than, and inconsistent with, that reported in the medical literature.

We did not identify any safety concerns that would have halted the NEWTON 2 study or precluded further development of EG-1962. Notably, the incidence of vasospasm was significantly lower in the EG-1962 treatment group compared to standard of care oral nimodipine. In addition, there was a lower incidence of both mortality and hypotension in the EG-1962 treatment group.

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We have discontinued the Phase 1 study of the safety, pharmacokinetics and clinical outcomes of EG-1962 administered intracisternally, or directly into the basal cisterns of the brain.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $37.8 million and $37.0 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of approximately $189.7 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur expenses and operating losses for the foreseeable future.

In the nine months ended September 30, 2018, we recorded restructuring charges of $7.5 million. The components of the restructuring charge included expenses of $4.0 million for severance benefits and $2.3 million for financial advisor fees. Additionally, we incurred $0.3 million for legal fees, $0.3 million for non cash stock based retention compensation and accrued $0.6 million for retention compensation related to the restructuring of the organization.

We expect the restructuring charge to amount to approximately $5.2 million for employee severance, retention compensation and related costs. In addition, we expect these actions to result in annualized cost savings of approximately $6.5 million. These savings may be partially offset by higher costs for outsourced services which cannot be quantified at this time.

As of September 30, 2018, we had $36.8 million in cash and cash equivalents.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenue

We have not generated any revenues from commercial product sales and do not expect to generate any such revenue in the near future. We may generate revenue in the future from a combination of research and development payments, license fees and other upfront payments or milestone payments.

Research and Development

Research and development expenses include employee-related expenses, licensing fees to use certain technology in our research and development projects, costs of acquiring, developing and manufacturing clinical trial materials, as well as fees paid to consultants and various entities that perform certain research and testing on our behalf. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the condensed financial statements as prepaid or accrued expenses. Costs incurred in connection with research and development activities are expensed as incurred.

We expect our research and development expenses to decrease in the near term as we wind down our activities on the NEWTON 2 study. We have ceased all further research and development on EG-1962 and suspended development of our other product candidates.

Results of Operations

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

The following table summarizes the results of our operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Increase (Decrease)	
	2018	2017	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$317	$6,913	$(6,596)	(95)%
General and administrative expenses	3,287	3,990	(703)	(18)%
Restructuring expenses	848	–	848	100 %
Total operating expenses	4,452	10,903	(6,451)	(59)%
Loss from operations	(4,452)	(10,903)	6,451	(59)%
Interest income (expense), net	187	(378)	565	(149)%
Net loss and comprehensive loss	$(4,265)	$(11,281)	$7,016	(62)%

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Research and Development Expenses

Research and development (R&D) expenses decreased to $0.3 million for the three months ended September 30, 2018 from $6.9 million for the same period in 2017. The decrease of $6.6 million in 2018 was primarily attributable to a decrease in external expenses for the clinical studies of $5.4 million and R&D internal department costs of $1.2 million resulting from the discontinuance of the clinical studies and reduction in force.

General and Administrative Expenses

General and administrative expenses decreased to $3.3 million for the three months ended September 30, 2018 from $4.0 million for the same period in 2017. The $0.7 million decrease was due to decreases in departmental operating expenses of $0.2 million, professional fees and marketing costs of $0.7 million offset by an increase of legal fees of $0.2 million.

Restructuring Expenses

Restructuring expenses amounted to $0.8 million for the three months ended September 30, 2018 related to the previously announced discontinuance of the NEWTON 2 study. The components consisted of $0.2 million for legal fees and $0.6 million for retention compensation.

Interest Expense, net

Interest income and expense, net increase of $0.6 million due primarily to a decrease in interest expense for our loan and debt back end fees of $0.6 million as a result of the debt elimination in June 2018.

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

The following table summarizes the results of our operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Increase (Decrease)	
	2018	2017	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$15,584	$23,478	$(7,894)	(34)%
General and administrative expenses	11,303	12,365	(1,062)	(9)%
Restructuring expenses	7,494	–	7,494	100%
Impairment charges	2,673	–	2,673	100%
Total operating expenses	37,054	35,843	1,211	3%
Loss from operations	(37,054)	(35,843)	(1,211)	3%
Interest (expense), net	(729)	(1,113)	384	(35)%
Net loss and comprehensive loss	$(37,783)	$(36,956)	$(827)	2%

Research and Development Expenses

Research and development (R&D) expenses decreased to $15.6 million for the nine months ended September 30, 2018 from $23.4 million for the same period in 2017. The decrease of $7.8 million in 2018 was primarily attributable to a decrease in external expenses for clinical studies of $6.2 million and internal R&D personnel and departmental costs of $1.6 million resulting from the discontinuance of the clinical studies and reduction in force.

General and Administrative Expenses

General and administrative expenses decreased to $11.3 million for the nine months ended September 30, 2018 from $12.4 million for the same period in 2017. The $1.1 million decrease was primarily due to decreases in professional fees of $0.7 million and $0.3 million in other expenses, and personnel costs of $0.1 million.

Restructuring Expenses

Restructuring expenses amounted to $7.5 million for the nine months ended September 30, 2018 related to the previously announced discontinuance of the NEWTON 2 study. The components consisted of $4.0 million for severance benefits, $2.3 million for financial advisory fees, $0.3 million for legal fees and $0.9 million for retention compensation.

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Impairment Charges

The charge in 2018 reflects the impairment charge to the write-down of machinery and equipment no longer needed as a consequence of ceasing research and development on EG-1962.

Interest Expense, net

Interest expense, net decrease primarily due to interest expense for our loan of $0.2 million offset by an increase in interest income from interest earned on our cash and cash equivalents of $0.2 million.

Liquidity and Capital Resources

Since our inception and through September 30, 2018, we have raised aggregate net proceeds of $207.9 million to fund our operations, primarily $82.8 million from the sale of Common Stock, $87.5 million from the sale of preferred stock, par value of $0.00033 per share (“Preferred Stock”), $17.4 million net proceeds from a registered direct common stock offering and $20.0 million from a loan. As of September 30, 2018, we had total cash and cash equivalents of $36.8 million as compared to $88.1 million as of December 31, 2017. The $51.3 million decrease in total cash was due to repayment of debt totaling $20.9 million and to increased funding of operations, which mainly consisted of research and development activities and general and administrative expenses offset by proceeds from exercise of stock options.

On October 6, 2015, we completed the IPO of our Common Stock for aggregate gross proceeds of approximately $92.5 million. We received approximately $82.8 million in net proceeds after deducting underwriting discounts and commissions and other offering costs of approximately $9.7 million. All of the net proceeds were utilized by the end of February 2018. In connection with the IPO, all Preferred Stock was converted into common stock. There is no Preferred Stock outstanding as of September 30, 2018.

On April 21, 2017, we completed a registered direct common stock offering for gross proceeds of $18.0 million. We received approximately $17.4 million in net proceeds after deducting the finder's fee and other offering costs.

In April 2018, we announced that we plan to explore strategic alternatives for the Company in order to maximize both near and long-term value for our shareholders, which may include, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of the Company, a sale of stock, a strategic merger or other business combination transaction or other transaction between the Company and a third party. In April 2018, our Board of Directors retained Piper to serve as its financial advisor in the strategic review process. During the strategic alternatives process, we plan to continue to finance our operations with our existing cash. Our ability to continue to support our operations is dependent, in the near-term, upon managing our cash resources as we pursue such strategic alternatives. We have ceased research and development on EG-1962, other than the wind-down of the NEWTON 2 study, and all of our other product candidates. We do not have a defined timeline for the exploration of strategic alternatives and we can provide no assurance that the process will result in any strategic alternative being announced or consummated. We do not intend to discuss or disclose further developments during this process unless and until our Board of Directors has approved a specific action or otherwise determined that further disclosure is appropriate.

Hercules Loan and Security Agreement

On August 1, 2016, the Company entered into an Amended and Restated Loan and Security Agreement (the “Amended Loan Agreement”) with Hercules Capital, Inc., formerly known as Hercules Technology Growth Capital, Inc. (“Hercules”). Pursuant to the Amended Loan Agreement, the Company was able to borrow up to $20,000,000. At

closing, the Company borrowed $15,000,000 of the amount available for draw under the Amended Loan Agreement (and received proceeds net of the amount then outstanding under the Original Loan Agreement, fees and expenses). On May 23, 2017, the Company elected to draw down the second tranche of $5 million. Pursuant to the Amended Loan Agreement, in March 2018, the Company made a payment of $90,000, which is equal to 1.5% of the total amounts funded under the Original Loan Agreement.

In June 2018, the Company agreed with Hercules Capital, Inc. to pay off its entire outstanding debt under the Amended Loan Agreement. The payment consisted of $20.0 million for the principal amount, an additional $0.9 million in back-end fees and $0.1 million in accrued and unpaid interest.

As of June 30, 2018, there are no future principal payments due under the Amended Loan Agreement.

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Cash Flows

The following table shows a summary of our cash flows for each of the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(30,984)	$(31,457)
Net cash used in investing activities	–	(161)
Net cash (used in) provided by financing activities	(20,269)	22,526
Net (decrease) increase in cash	$(51,253)	$(9,092)

Net Cash Used in Operating Activities

Net cash used in operating activities was $31.0.million and $31.5 million for the nine months ended September 30, 2018 and 2017, respectively. The decrease in cash used in operating activities of $0.5 million was primarily due to the reduction of operating activities as compared to the prior year.

Net Cash Used in Investing Activities

Net cash used in investing activities in 2017 relates entirely to purchases of property and equipment.

Net Cash (Used In) Provided by Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2018 was due primarily to the repayment of debt and debt fees totaling $21.0 million offset by receipt of net proceeds from exercise of stock options of $0.7 million.

Net cash provided by financing activities for the nine months ended September 30, 2017 was due to the receipt of net proceeds of $17.4 million from a registered direct stock offering and $5.0 million from issuance of debt.

Operating Capital Requirements

Our future capital requirements are difficult to forecast. We expect that our research and development expenses will decrease significantly due to the discontinuation of the NEWTON 2 study for EG-1962 and further research and development activities for EG-1962 and our other product candidates, at least until the strategic review process is complete.

We believe that our existing cash and cash equivalents as of September 30, 2018, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements are difficult to forecast and will depend on many factors, including:

our plans to explore strategic alternatives for the Company and our ability to execute on those plans;

our ability to manage costs associated with winding down our current research and development activities and restructuring our organization;

the timing and nature of any strategic transactions that we undertake;

personnel-related expenses, including salaries, benefits, severance, stock-based compensation expense and other compensation costs related to implementing our restructuring plan;

the scope and nature of activities we may pursue to advance clinical development for our product candidates, if any;

the number and characteristics of product candidates that we develop or may acquire or in-license;

the costs incurred in defending the class action civil litigation; and

the costs incurred in responding to disruptive actions by activist stockholders.

Please see the section titled “Risk Factors” elsewhere in the Annual Report for additional risks associated with our operations.

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Contractual Obligations and Commitments

The following is a summary of our contractual obligations as of the date indicated:

As of September 30, 2018	Total	Less than one year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	$1,890	$607	$1,212	$ 71	$ –
Total contractual obligations	$1,890	$607	$1,212	$ 71	$ –

This table above does not include (a) any milestone payments related to contingent events which may become payable to third parties under our license agreements as the timing and likelihood of such payments are not known, or (b) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

Purchase Commitments

We have no material non-cancelable purchase commitments with service providers as we have generally contracted on a cancelable, purchase order basis.

Milestone and Royalty-based Commitments

Pursuant to the Evonik Agreement, in exchange for the license, we agreed to make milestone payments totaling up to $14.75 million upon the achievement of certain development, regulatory and sales milestones detailed in the Evonik Agreement. We paid $0.25 million upon execution of the Evonik Agreement. In August 2016, we paid a milestone of $1.0 million after we dosed the first patient in the Phase 3 clinical trial of EG-1962. In addition, the Evonik Agreement calls for us to pay royalties on sales of certain products based on a mid-single digit percentage of net sales. The Evonik Agreement provides for the reduction of royalties in certain circumstances. Following the discontinuation of the NEWTON 2 trial for EG-1962, we have ceased all research and development efforts related to EG-1962 and suspended our other product candidates as we pursue strategic alternatives. As such, unless we resume such development activities, it is unlikely that we will have any additional milestones or royalty obligations to Evonik in the future.

Under the Restated Development Agreement, we agreed to pay Oakwood to perform services under agreed upon project plans and to pay Oakwood up to an aggregate of $4.5 million. In July 2017 and April 2018, the Company paid $1.5 million and $0.5 million, respectively, of such aggregate amount in connection with entering into the Restated Development Agreement. The remaining $2.5 million was payable no later than April 1, 2019. The remaining payment was discounted to $2.375 million pursuant to an accelerated payment agreement entered into in August 2018. As of September 30, 2018, there are no remaining payments under the Restated Development Agreement. In addition, the Restated Development Agreement calls for us to pay royalties on sales of certain products based on a low single digit percentage of net sales of EG-1962, regardless of the manufacturer or supplier thereof.

Following the discontinuation of the NEWTON 2 trial for EG-1962, we have ceased all research and development efforts related to EG-1962 and our other product candidates. As such, we may terminate the Supply Agreement immediately upon notice to Oakwood (which will also result in the automatic termination of the Restated Development Agreement); provided, that if we choose to do so prior to completion of the most recent project plan attached to the Restated Development Agreement, we must pay to Oakwood a termination fee. While certain of our

milestone payments to Oakwood will remain outstanding (including the termination fee in the event the Restated Development Agreement is terminated), unless we resume such development activities, it is unlikely that we will be required to pay additional milestone or royalty payments to Oakwood in the future pursuant to the Restated Development Agreement or the Supply Agreement.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We consider our critical accounting policies and estimates to be related to stock-based compensation. There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2018 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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ITEM 3: Quantitative and Qualitative Disclosure about Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve principal, while at the same time maximizing the income we receive from our cash and marketable securities without significantly increasing risk. As of September 30, 2018, we had cash equivalents of $36.8 million that were held in a non-interest-bearing money operating account and an institutional U.S. Treasury money market fund. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are comprised of U.S. Treasury and Treasury backed repurchase agreements.

ITEM 4: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15 (e)) under the Securities Exchange Act of 1934, or the Exchange Act, as of the end of the period covered by this report. Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On April 23, 2018, a purported securities class action complaint was filed against the Company, Brian Leuthner (the Company's President and Chief Executive Officer) and Andrew Saik (the Company's Chief Financial Officer) in the United States District Court for the District of New Jersey, captioned Sanfilippo v. Edge Therapeutics, Inc., Case No. 2:18-cv-8236. The complaint alleges that the Company, Mr. Leuthner and Mr. Saik violated Section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements concerning the Company's business, operations and prospects by failing to disclose that EG-1962 would likely fail a futility analysis. The complaint is brought on behalf of all purchasers of the Company's common stock between December 27, 2017 and March 27, 2018, and seeks unspecified damages. None of the Company, Mr. Leuthner, or Mr. Saik has been served with the complaint and their time to respond has not yet expired. Various individuals have moved to be appointed lead plaintiff to act on behalf of the putative class. After the court appoints that party (or parties), it is expected that the lead plaintiff will file an amended complaint. The Company and its executives intend to defend themselves vigorously in the action. There can be no guarantee as to the outcome or timing of any resolution.

ITEM 1A. RISK FACTORS.

Any investment in our business involves a high degree of risk. Before making an investment decision, you should carefully consider the information we include in this Quarterly Report on Form 10-Q, including our condensed financial statements and accompanying notes, and the additional information in the other reports we file with the Securities and Exchange Commission along with the risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline and you could lose part or all of your investment. The risk factors set forth below contain material changes from, or additions to, the risk factors previously disclosed and included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Risks Related to Our Evaluation of Strategic Alternatives

If we fail to continue to meet all applicable Nasdaq Global Select Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on The Nasdaq Global Select Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a "public shell company". We have received written notice from Nasdaq stating that, at present, we are not in compliance with the audit committee requirements for continued listing on The Nasdaq Global Select Market, because we currently have an audit committee comprised of two members. If we do not regain compliance with audit committee requirements in a timely manner, Nasdaq will provide written notification to us that our securities will be subject to delisting. In addition, on September 4, 2018, we received written notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price for our common stock had closed below $1.00 per share for the previous 30 consecutive business days. We have 180 calendar days, or until March 4, 2019, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 for a minimum of 10 consecutive business days during the 180-day grace period. In the event that we do not regain compliance with Nasdaq's listing standards prior to the expiration of the grace period, or fail to meet any of Nasdaq's other continued listing requirements, we expect to receive written notification that our common stock is subject to delisting. If we receive such a delisting notification, we may either apply for listing on The Nasdaq Capital Market, provided we meet the continued listing requirements of that market, or appeal the decision to a Nasdaq

Hearings Panel. In the event of an appeal, our common stock would remain listed on The Nasdaq Global Select Market pending a decision by the panel following the hearing. There can be no assurance that we will be able to regain compliance with the continued listing requirements. If our common stock is delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent standards, and which may limit demand for our common stock among certain investors;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Additionally, if we conduct a reverse merger, the combined company following such transaction will need to meet Nasdaq's initial listing standards. If we are unable to achieve a strategic alternative, or we take too long to do so, our stock price may fall below the minimum price per share requirement. If we are unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist our common stock from The Nasdaq Global Select or other of Nasdaq's trading markets.

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Stockholder litigation and regulatory inquiries and investigations are expensive and could harm our business, financial condition and operating results and could divert management attention.

In the past, securities class action and/or stockholder derivative litigation and inquiries or investigations by regulatory authorities have often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from one or more clinical trials. We are currently and in the future may be the target of this type of action as a result of changes in our stock price, past transactions, results of clinical trials or other matters. Any stockholder litigation and/or regulatory investigations against us, whether or not resolved in our favor, could result in substantial costs and divert our management's attention from other business concerns, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our corporate restructuring plans, and our restructuring activities may adversely affect our ability to consummate a strategic transaction that enhances stockholder value.

On May 1, 2018, we announced a planned reduction in our workforce as a result of stopping the NEWTON 2 clinical trial for EG-1962 and suspending the related manufacturing activities. At present, we have reduced our headcount from 37 to 14 employees. We anticipate a further reduction of our workforce as we complete NEWTON 2 closedown activities, complete the analysis of the related NEWTON 2 data and better align our resources with our operational needs going forward. These reductions in force have resulted and will result in the loss of numerous long-term employees, the loss of institutional knowledge and expertise, and the reallocation of certain job responsibilities, all of which could negatively affect operational efficiencies and increase our operating expenses such that we may not fully realize anticipated savings from the restructuring, and could significantly impair our ability to successfully complete a potential strategic transaction on terms that are favorable to our stockholders, or at all.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Sales of Unregistered Securities

There were no unregistered sales of the Company’s equity securities during the quarter ended September 30, 2018.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits filed with this Quarterly Report or incorporated herein by reference is set forth in the Exhibit Index immediately preceding the signature page of this report and is incorporated into this Item 6 by reference.

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Eighth Amended and Restated Certificate of Incorporation of Edge Therapeutics, Inc. (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein).
3.2	Second Amended and Restated Bylaws of Edge Therapeutics, Inc. (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein).
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1 (1)	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.2 (1)	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
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

(1) This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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SIGNATURES

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

Edge Therapeutics, Inc.

November 1, 2018 By: /s/ Brian A. Leuthner
Brian A. Leuthner
President and Chief Executive Officer
(Principal Executive Officer)

November 1, 2018 By: /s/ Andrew Saik
Andrew Saik
Chief Financial Officer
(Principal Financial Officer)