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	$