

Edge Therapeutics, Inc.
Form 10-Q
November 01, 2016

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, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting

Edgar Filing: Edge Therapeutics, Inc. - Form 10-Q

company” in Rule 12b-2 of the Securities Exchange Act of 1934.

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

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 28, 2016 was 28,917,419.

Table of Contents

Edge Therapeutics, Inc.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2016

INDEX

	Page
<u>Part I – Financial Information</u>	
Item 1. <u>Financial Statements (Unaudited):</u>	
<u>Balance Sheets</u>	3
<u>Statements of Operations and Comprehensive Loss</u>	4
<u>Statements of Cash Flows</u>	5
<u>Notes to Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<u>Part II – Other Information</u>	23
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<u>SIGNATURE</u>	24
<u>EXHIBIT</u>	25
<u>INDEX</u>	25

Index

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EDGE THERAPEUTICS, INC.

Balance Sheets

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 112,784,622	\$ 130,189,421
Prepaid expenses and other current assets	359,863	1,081,084
Total current assets	113,144,485	131,270,505
Property and equipment, net	3,291,873	2,766,992
Other assets	142,870	55,161
Total assets	\$ 116,579,228	\$ 134,092,658
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	\$ 1,963,350	\$ 2,584,249
Accrued expenses	2,290,249	3,734,348
Short term debt	-	2,271,111
Total current liabilities	4,253,599	8,589,708
Noncurrent liability:		
Long term debt	14,817,482	3,025,423
STOCKHOLDERS' EQUITY		
Common stock, \$0.00033 par value, 75,000,000 shares authorized at September 30, 2016 and December 31, 2015, 28,915,226 shares and 28,810,845 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	9,754	9,720
Additional paid-in capital	189,058,164	184,721,777
Accumulated deficit	(91,559,771)	(62,253,970)
Total stockholders' equity	97,508,147	122,477,527
Total liabilities and stockholders' equity	\$ 116,579,228	\$ 134,092,658

See accompanying notes to the financial statements.

Index

EDGE THERAPEUTICS, INC.

Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2016	
	2016	2015	2016	2015
Operating expenses:				
Research and development expenses	\$ 6,724,503	\$ 6,507,972	\$ 18,046,572	\$ 12,574,455
General and administrative expenses	3,552,289	1,976,888	10,526,775	5,052,983
Total operating expenses	10,276,792	8,484,860	28,573,347	17,627,438
Loss from operations	(10,276,792)	(8,484,860)	(28,573,347)	(17,627,438)
Other income (expense):				
Warrant remeasurement	-	(1,433,502)	-	(1,879,823)
Other expense	(163,463)	-	(163,463)	-
Interest income	56,082	1,333	148,272	2,810
Interest expense	(375,089)	(213,021)	(717,263)	(615,047)
Net loss and comprehensive loss	(10,759,262)	(10,130,050)	(29,305,801)	(20,119,498)
Cumulative dividend on Series C , C-1 and C-2 convertible preferred stock	-	(1,827,568)	-	(4,257,083)
Net loss attributable to common stockholders	\$ (10,759,262)	\$ (11,957,618)	\$ (29,305,801)	\$ (24,376,581)
Loss per share attributable to common stockholders basic and diluted	\$ (0.37)	\$ (7.08)	\$ (1.02)	\$ (14.44)
Weighted average common shares outstanding basic and diluted	28,896,941	1,688,475	28,848,842	1,688,475

See accompanying notes to the financial statements.

Index

EDGE THERAPEUTICS, INC.

Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (29,305,801) \$ (20,119,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,029,326	1,566,562
Warrant remeasurement	-	1,879,823
Depreciation expense	60,331	38,360
Loss on disposal of fixed assets	102,789	-
Amortization of debt discount	60,206	79,400
Amortization of debt issuance costs	63,699	-
Non-cash interest expense	82,357	28,667
Changes in assets and liabilities:		
Prepaid expenses and other assets	633,513	78,814
Accounts payable	(399,708) (126,415)
Accrued expenses	(1,469,109) 1,604,432
Net cash used in operating activities	(26,142,397) (14,969,855)
Cash flows from investing activities:		
Purchases of property and equipment	(339,410) (799,424)
Net cash used in investing activities	(339,410) (799,424)
Cash flows from financing activities:		
Proceeds from issuance of debt	11,022,286	3,000,000
Proceeds from exercise of stock options	293,988	-
Proceeds from exercise of warrants	13,107	-
Payments for issuance costs	(544,773) (474,357)
Payments for debt issuance costs	(219,042) -
Repayment of debt	(1,488,558) -
Proceeds from issuance of preferred stock, net of issuance costs	-	52,394,571
Net cash provided by financing activities	9,077,008	54,920,214
Net (decrease) increase in cash	(17,404,799) 39,150,935
Cash and cash equivalents at beginning of period	130,189,421	13,728,972
Cash and cash equivalents at end of period	\$ 112,784,622	\$ 52,879,907
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	\$ 443,464	\$ 412,717

Edgar Filing: Edge Therapeutics, Inc. - Form 10-Q

Supplemental cash flow information:

Deferred issuance costs included in accrued expenses and accounts payable	\$ -	\$ 552,410
Non-cash financing costs	\$ -	\$ 175,114
Accrued capital expenditures included in accrued expenses and accounts payable	\$ 348,591	\$ 576,839

See accompanying notes to the financial statements.

Page | 5

Index

Edge Therapeutics, Inc.

Notes to Financial Statements (Unaudited)

Note 1 - Nature of Operations

Edge Therapeutics, Inc. (the “Company”) is a clinical-stage biotechnology company that discovers, develops and seeks to commercialize novel, hospital-based therapies capable of transforming treatment paradigms in the management of acute, life-threatening neurological conditions. The Company’s product candidates utilize its proprietary, programmable, biodegradable polymer-based development platform (the Precisa Platform™), and a novel delivery mechanism that seeks to enable targeted and sustained drug exposure and avoid the dose-limiting side effects associated with the current standard of care.

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 a combination of factors, including (i) the success of its research and development, (ii) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (iii) regulatory approval and market acceptance of the Company’s proposed future products.

On October 6, 2015, the Company completed an initial public offering (the “IPO”) of 8,412,423 shares of its common stock which included 1,097,272 shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option at a price of \$11.00 per share for aggregate gross proceeds of approximately \$92.5 million. The Company received approximately \$82.8 million in net proceeds after deducting underwriting discounts and commissions and other offering costs of approximately \$9.7 million. Immediately prior to the closing of the IPO, all of the Company’s outstanding shares of convertible preferred stock, including shares issued for accrued dividends, automatically converted into 18,566,856 shares of common stock at the applicable conversion ratio then in effect. There are no shares of preferred stock outstanding. In connection with the IPO, the Company amended and restated its Seventh Amended and Restated Certificate of Incorporation to change the authorized capital stock to 75,000,000 shares designated as common stock and 5,000,000 shares designated as preferred stock, all with a par value of \$0.00033 per share.

Note 2 - Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at September 30, 2016, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, and cash flows for the nine months ended September 30, 2016 and 2015 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 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, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other future annual or interim period. The balance sheet as of December 31, 2015 included herein was derived from the audited financial statements as of that date. These 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, 2015.

(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 results of clinical testing and trial activities of the Company's product candidates, the Company's ability to obtain regulatory approval to market its products, 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.

Index

The Company currently has no commercially approved products and there can be no assurance that the Company's 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 an original maturity 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.

(F) 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.

The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

(G) 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:

Page | 7

Index

	As of September 30,	
	2016	2015
Stock options to purchase Common Stock	5,166,511	4,227,022
Convertible preferred stock to purchase Common Stock	-	17,497,815
Warrants to purchase Common Stock	544,705	99,401
Warrants to purchase Series C Preferred Stock	-	338,534
Warrants to purchase Series C-1 Preferred Stock	-	332,480
Total	5,711,216	22,495,252

(H) Recently adopted standards:

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. 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 Company is evaluating the impact of adoption.

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 will be required to adopt this standard in annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period provided that the entire standard is adopted. The Company does not expect adoption of the ASU will have a material impact on the financial statements based upon preliminary evaluation.

Note 3 – Fair Value of Financial Instruments

There were no transfers between Levels 1, 2, or 3 during 2016 or 2015.

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, 2016: (unaudited)				
Cash and cash equivalents	\$ 112,784,622	\$ 112,784,622	\$ -	\$ -
As of December 31, 2015:				
Cash and cash equivalents	\$ 130,189,421	\$ 130,189,421	\$ -	\$ -

Prior to our IPO, which closed on October 6, 2015, Level 3 instruments consisted of the Company’s Series C and Series C-1 convertible preferred stock warrant liability and common stock warrant liability. The fair values of the outstanding warrants were measured using the Black-Scholes option-pricing model (Note 5). Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the

underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. After the IPO, the warrants were no longer liability classified and were no longer considered Level 3 instruments.

Index

Note 4 – Accrued Expenses

Accrued expenses and other liabilities consist of the following:

	As of September 30, 2016	As of December 31, 2015
Accrued research and development costs	\$ 377,294	\$ 1,874,126
Accrued professional fees	440,799	258,568
Accrued compensation	1,300,793	1,510,430
Accrued other	169,385	56,835
Deferred rent	1,978	34,389
Total	\$ 2,290,249	\$ 3,734,348

Note 5 - Stock Options

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 both ISOs and NQs (the “Plan Limit”). However, 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, 2015 and January 1, 2016 the Plan Limit was increased to 1,894,890 and 3,047,323 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 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.

On November 16, 2015, the Company issued non-qualified options to purchase a total of 80,000 shares of common stock to W. Bradford Middlekauff, its newly appointed Senior Vice President, General Counsel and Secretary. The award was granted outside of the Company’s 2014 Equity Incentive Plan and vests over four years with 25% vesting on October 30, 2016, which is one year following Mr. Middlekauff’s date of hire, and the remaining 75% vesting in 36 equal monthly installments thereafter, subject to Mr. Middlekauff’s 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 Mr. Middlekauff’s option agreement and employment agreement. The foregoing grant award was made pursuant to the NASDAQ inducement grant exception as a material component of Mr. Middlekauff’s employment compensation.

On July 1, 2016, the Company issued non-qualified options to purchase a total of 85,000 shares of common stock to Harry J. Sacks, its newly appointed Vice President, Clinical Development. The award was granted outside of the Company’s 2014 Equity Incentive Plan and vests over four years with 25% vesting on June 20, 2017, which is one

year following Dr. Sack's date of hire, and the remaining 75% vesting in 36 equal monthly installments thereafter, subject to Dr. Sack's 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 Dr. Sack's option agreement. The foregoing grant award was made pursuant to the NASDAQ inducement grant exception as a material component of Dr. Sack's employment compensation.

Index

The Company's stock-based compensation expense was recognized in operating expense as follows:

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Stock-Based Compensation				
Research and development	\$567,452	\$273,782	\$1,609,683	\$702,322
General and administrative	665,579	338,096	2,419,643	864,240
Total	\$1,233,031	\$611,878	\$4,029,326	\$1,566,562

The fair value of options and warrants granted during the three and nine months ended September 30, 2016 and 2015 was estimated using the Black-Scholes option valuation model utilizing the following assumptions:

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2016	2015	2016	2015
	Weighted	Weighted	Weighted	Weighted
	Average		Average	
	(unaudited)		(unaudited)	
Volatility	71.80 %	79.80 %	77.96 %	79.80 %
Risk-Free Interest Rate	1.19 %	1.59 %	1.38 %	1.74 %
Expected Term in Years	6.07	6.08	6.02	6.08
Dividend Rate	0.00 %	0.00 %	0.00 %	0.00 %
Fair Value of Option on Grant Date	\$ 6.78	\$ 7.51	\$ 5.24	\$ 5.22

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

	Number of	Weighted	Weighted	Aggregate
	Shares	Average	Average	Intrinsic Value
		Exercise	Remaining	
		Price	Contractual	
			Life in Years	
Options outstanding at December 31, 2015	4,302,267	\$ 5.19		
Granted	1,061,400	7.81		
Exercised	(63,639)	4.62		
Forfeited	(133,517)	5.79		
Options outstanding at September 30, 2016	5,166,511	\$ 5.72	7.78	\$ 24,994,623
Vested and expected to vest at September 30, 2016	5,077,867	\$ 5.68	7.76	\$ 24,747,792
Exercisable at September 30, 2016	2,810,161	\$ 4.22	6.94	\$ 17,557,732

At September 30, 2016 there was approximately \$10,353,101 of unamortized stock compensation expense, which is expected to be recognized over a remaining average vesting period of 1.39 years.

Note 6 – 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, 2016 and December 31, 2015.

Index

At December 31, 2015, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$47.5 million which expire between 2029 and 2035. At December 31, 2015, the Company had federal research and development credits carryforwards of approximately \$0.8 million and an orphan drug credit carryover of approximately \$4.0 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 would be limited.

At December 31, 2015, the Company had approximately \$23.3 million of NJ NOL’s which expire between 2030 and 2035. At December 31, 2015, the Company had approximately \$0.3 million of the State of New Jersey research development credits carryforwards.

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, 2015, 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. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. There was no income tax related interest and penalties included in the income tax provision for the nine months ended September 30, 2016 and 2015.

Note 7 – 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 Company’s lead product candidate (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 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.

In September 2015, the Company and Evonik entered into Amendment No. 1 to the Evonik Agreement. This amendment clarified the Company’s obligations to pay Evonik certain royalty and milestone payments in respect of certain products whether or not manufactured by Evonik and removed the Company’s obligation to negotiate exclusively with Evonik for Phase 3 and commercial supply of EG-1962. 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.

Employment Agreements

The Company has entered into employment agreements with each of its executives. The agreements generally provide for, among other things, salary, bonus and severance payments. The employment agreements 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. 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.

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.

Index

Rent expense is recognized on a straight line basis where there are escalating payments, and was approximately \$82,163 and \$58,271 for the three months ended September 30, 2016 and 2015, respectively and \$196,322 and \$149,371 for the nine months ended September 30, 2016 and 2015, 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, 2016:

Year ended December 31,	
2016 (remaining)	\$ 148,799
2017	592,256
2018	602,461
2019	604,541
2020	603,371
2021 and after	530,384
Total minimum payments required	\$3,081,812

Note 8 - Debt

On August 28, 2014, the Company entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., (the "Original Loan Agreement"). The Original Loan Agreement provided funding for an aggregate principal amount of up to \$10,000,000 in three separate term loans. The first term loan was funded on August 28, 2014 in the amount of \$3,000,000. The second tranche of \$3,000,000 was funded on January 29, 2015. Both the first and second tranches were due to mature on March 1, 2018. The Company elected not to draw the third tranche of \$4.0 million, the availability of which expired on June 30, 2015. Initially, the loans bore interest at a rate per annum equal to the greater of (i) 10.45% or (ii) the sum of (a) 10.45% plus (b) the prime rate (as reported in The Wall Street Journal) minus 4.50%. On April 6, 2015, the second milestone event was met where the Company received gross cash proceeds in an amount greater than \$55,000,000 which lowered the base interest rate on all loans to the greater of (i) 9.95% or (ii) the sum of (a) 9.95% plus (b) the prime rate (as reported in The Wall Street Journal) minus 4.50%. The Company was required to make interest-only payments on each term loan through September 2015.

Commencing in October 2015, the term loans began amortizing in equal monthly installments of principal and interest over 30 months. On the maturity date or the date the loans otherwise became due, the Company was also required to pay additional interest equal to 1.5% of the total amounts funded under the Original Loan 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., pursuant to which the Company may borrow a term loan up to \$20,000,000. The Amended Loan Agreement amends and restates the Original Loan Agreement. At closing, the Company borrowed \$15,000,000 available for draw under the Amended Loan Agreement (and received proceeds net of the current amount outstanding under the Original Loan Agreement, fees and expenses). The Amended Loan Agreement allows the Company, at its option, to drawn down a second tranche of \$5 million on or before June 15, 2017. Amounts drawn under the Amended Loan Agreement bear interest at a rate per annum equal to the greater of either (i) the sum of (a) 9.15%, plus (b) the prime rate as reported in The Wall Street Journal minus 4.50% or (ii) 9.15%. The effective interest rate at September 30, 2016 was 9.15%. Pursuant to the terms of the Amended Loan Agreement, the Company will make interest-only payments for 18 months, and then repay the principal balance of the loan in 24 equal monthly payments of principal and interest through the scheduled maturity date on February 3, 2020. The period of interest-only payments and the maturity date may be extended if the Company satisfies certain conditions as described in the Amended Loan Agreement.

Pursuant to the Original Loan Agreement, in March 2018, the Company must pay additional interest of \$90,000, which is equal to 1.5% of the total amounts funded under the Original Loan Agreement. On the maturity date or the

date the term loan otherwise becomes due, under the Amended Loan Agreement the Company must also pay additional interest of \$900,000, which is equal to 4.5% of the total amounts available under such agreement. In addition, if the Company prepays the term loan during the first year following the initial closing, the Company must pay a prepayment charge equal to 2% of the amount being prepaid, if the Company prepays the term loan during the second year following the closing, the Company must pay a prepayment charge equal to 1% of the amount being prepaid, and if the Company prepays the term loan after the second year following the closing, the Company must pay a prepayment charge equal to 0.5% of the amount being prepaid.

Index

The term loan is secured by substantially all of the Company's assets, other than intellectual property, which is the subject of a negative pledge. Under the Amended Loan Agreement, the Company is subject to certain customary covenants that limit or restrict its ability to, among other things, incur additional indebtedness, investments, distributions, transfer assets, make acquisitions, grant any security interests, pay cash dividends, repurchase its common stock, make loans, or enter into certain transactions without prior consent. The Amended Loan Agreement contains several events of default, including, among others, payment defaults, breaches of covenants or representations, material impairment in the perfection of Hercules' security interest or in the collateral and events related to bankruptcy or insolvency. Upon an event of default, Hercules may declare all outstanding obligations immediately due and payable (along with a prepayment charge), a default rate of an additional 5.0% may be applied to the outstanding loan balances, and Hercules may take such further actions as set forth in the Amended Loan Agreement, including collecting or taking such other action with respect to the collateral pledged in connection with the Amended Loan Agreement.

Future principal payments on the note as of September 30, 2016 were as follows:

Year Ending in December 31:	(000's)
remaining 2016	\$-
2017	-
2018	5,912
2019	7,716
2020	1,372
	\$15,000

The estimated fair value of the debt (categorized as a Level 2 liability for fair value measurement purposes) is determined using current market factors and the ability of the Company to obtain debt at comparable terms to those that are currently in place. The Company believes the estimated fair value at September 30, 2016 approximates the carrying amount.

Note 9- Subsequent Events

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

Index

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 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, 2015 (the "Annual Report") filed with the SEC on March 8, 2016. 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.

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 Quarterly 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," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" 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 manufacture, develop and commercialize our product candidates;
- our ability to complete our ongoing clinical trials and to advance our product candidates into additional clinical trials, including pivotal clinical trials, and successfully complete such clinical trials;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain intellectual property protection for our proprietary assets;
- the size of the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates for any indication once approved;
- the performance of our third-party manufacturers and contract research organizations;
- the success of competing products that are or become available for the indications that we are pursuing;
- the loss of key scientific or management personnel;
- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- our use of the net proceeds from our initial public offering ("IPO") of common stock and future financings, if any;

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

Page | 14

Index

Overview

We are a clinical-stage biotechnology company that discovers, develops and seeks to commercialize novel, hospital-based therapies capable of transforming treatment paradigms in the management of acute, life-threatening neurological conditions. Our initial product candidates target rare, acute, life-threatening neurological conditions for which we believe the approved existing therapies, if any, are inadequate.

On October 6, 2015, we completed the IPO of 8,412,423 shares of our common stock which included 1,097,272 shares of common stock issued upon the exercise in full by the underwriters of their over-allotment option at a price of \$11.00 per share 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. Immediately prior to the closing of the IPO, all of the outstanding shares of convertible preferred stock, including shares for accrued dividends, automatically converted into 18,566,856 shares of common stock at the applicable conversion ratio then in effect. There are no shares of preferred stock outstanding. In connection with the IPO, we amended and restated our Seventh Amended and Restated Certificate of Incorporation to change the authorized capital stock to 75,000,000 shares designated as common stock and 5,000,000 shares designated as preferred stock, all with a par value of \$0.00033 per share.

We believe EG-1962, our lead product candidate, can fundamentally improve patient outcomes and transform the management of aneurysmal subarachnoid hemorrhage, or aSAH, which is bleeding around the brain due to a ruptured brain aneurysm. A single dose of EG-1962 delivers a high concentration of nimodipine, the current standard of care, directly to the brain with sustained drug exposure over 21 days. EG-1962 utilizes our proprietary, programmable, biodegradable polymer-based development platform, or our Precisa Platform™, a novel delivery mechanism that enables targeted and sustained drug exposure while potentially avoiding the dose-limiting side effects associated with currently available formulations of nimodipine. EG-1962 has been granted orphan drug designation and Fast Track designation by the U.S. Food and Drug Administration (the “FDA”) for the treatment of patients with subarachnoid hemorrhage, and orphan drug designation by the European Commission for the treatment of patients with aneurysmal subarachnoid hemorrhage.

In July 2015, the 90-day outcome data were available for analysis for our Phase 1/2 clinical study of EG-1962 in North America, which we refer to as our NEWTON North America study. The NEWTON North America study met its primary and secondary endpoints of safety, tolerability, maximum tolerated dose (“MTD”) and pharmacokinetics. The results of the principal exploratory endpoint from the 90-day follow-up available for patients in the NEWTON North America study cohorts demonstrated that 60% (27 of 45) of patients treated with EG-1962 experienced a favorable clinical outcome (a score of 6 – 8 on the extended Glasgow Outcome Scale, or GOSE) versus only 28% (5 of 18) of patients treated with the standard of care, oral nimodipine. At final assessment, of the 45 patients treated with EG-1962 in NEWTON North America, 29% (13 of 45) of patients across 17 sites achieved the highest clinical outcome score (GOSE = 8, Upper Good Recovery) versus only 6% (1 of 18) of patients treated with the standard of care, oral nimodipine.

In July 2016, we commenced the Phase 3 NEWTON 2 trial. NEWTON 2 is a Phase 3, multi-center, multi-national, randomized, double-blind, placebo-controlled, parallel-group study comparing the efficacy and safety of EG-1962 to standard of care oral nimodipine in adults with an aneurysmal subarachnoid hemorrhage resulting from a ruptured brain aneurysm. The primary endpoint of the NEWTON 2 trial is the proportional difference in the rate favorable clinical outcome (a score of 6 – 8 on the GOSE) between EG-1962 and the standard of care oral nimodipine. The key secondary endpoint is the subject’s score on the Montreal Cognitive Assessment scale, or MoCA. We expect the results of an interim analysis to be completed in early 2018 with the results of the full study to be available in late 2018.

We have also initiated a study of the safety, pharmacokinetics and clinical outcomes of EG-1962 administered directly into the basal cisterns of the brain in patients with aSAH who do not receive an external-ventricular drain (“EVD”) but remain at risk for delayed neurological complications following surgical repair of a ruptured aneurysm. This study is a US multicenter, randomized, controlled, open-label study in which nine patients are expected to receive EG-1962 via intracisternal administration and three patients are expected to receive standard of care oral nimodipine. We expect data to be available from this study during 2017.

In addition to EG-1962, we are using our Precisa™ development platform to develop additional product candidates targeting other acute, serious conditions where limited or no effective therapies currently exist. We are developing our second product candidate, EG-1964, as a potential prophylactic treatment in the management of chronic subdural hematoma, or cSDH, to prevent recurrent bleeding on the surface of the brain. A cSDH is a liquefied hematoma that has accumulated on the surface of the brain in an area referred to as the subdural space and is often caused by minor head trauma. Following neurosurgical intervention to drain the hematoma, recurrent bleeding occurs in up to 30% of cSDH patients, requires repeat neurosurgical intervention and is associated with risks of serious complications, including death. There are currently no approved pharmacological treatments that reduce the risk of recurrent bleeding after cSDH. By way of a single administration at the time of the initial neurosurgical intervention, we are formulating EG-1964 to deliver a high concentration of aprotinin, a pancreatic trypsin inhibitor, directly to the subdural space with sustained drug exposure over 21 to 28 days. Aprotinin preserves the ability for blood to clot by inhibiting plasminogen, a naturally produced enzyme that breaks down blood clots, thereby limiting recurrent bleeding. If approved, we believe that EG-1964 can become the standard of care as a prophylactic treatment in the management of cSDH to prevent recurrent bleeding. We intend to complete formulation development activities and commence non-clinical studies of EG-1964 in 2017. Based on the results of those studies, we may submit an Investigational New Drug Application, or IND, for EG-1964 in 2018.

Index

From our inception in 2009, we have devoted substantially all of our efforts to business planning, engaging regulatory, manufacturing and other technical consultants, developing operating assets, planning and executing clinical trials and raising capital.

We have never generated any revenue and have incurred net losses in each year since inception. Our net losses were \$28.1 million for the year ended December 31, 2015 and \$29.3 million for the nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of approximately \$91.6 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 significant expenses and increasing operating losses for the foreseeable future as we continue to develop and conduct clinical trials, and seek regulatory approval for, our product candidates, as well as to scale-up manufacturing capabilities, protect and expand our intellectual property portfolio and hire additional personnel. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. We initiated our Phase 3 program for EG-1962 for the treatment of aSAH in July 2016. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Furthermore, as a result of the IPO in 2015, we expect to incur additional costs associated with operating as a public company. Accordingly, at least until we can generate significant revenue from product sales, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all and could be forced to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us in strategic partnerships and alliances and licensing arrangements. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop our product candidates.

As of September 30, 2016, we had \$112.8 million in cash and cash equivalents.

Index

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 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 increase for the foreseeable future as we advance our product candidates through preclinical studies and clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. Successful development of future product candidates from our research and development programs is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We anticipate we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of our product candidates. We will need to raise additional capital and may seek collaborations in the future in order to advance our various product candidates. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Increase (Decrease)	
	2016	2015	\$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	\$ 6,725	\$ 6,508	\$ 217	3 %

Edgar Filing: Edge Therapeutics, Inc. - Form 10-Q

General and administrative expenses	3,552		1,977		1,575	80	%
Total operating expenses	10,277		8,485		1,792	21	%
Loss from operations	(10,277))	(8,485))	(1,792)	21	%
Warrant remeasurement	-		(1,434))	1,434	-100	%
Other Expense	(163))	-		(163)	100	%
Interest income (expense), net	(318))	(211))	(107)	51	%
Net loss and comprehensive loss	\$ (10,758))	\$ (10,130))	\$ (628)	6	%

Research and Development Expenses

Research and development (R&D) expenses increased to \$6.7 million in the three months ended September 30, 2016 from \$6.5 million for the same period in 2015. The increase of \$0.2 million in 2016 was primarily attributable to an increase in internal R&D personnel and departmental costs of \$0.6 million offset by a decrease in external expenses for clinical trial costs of \$0.4 million.

Index

General and Administrative Expenses

General and administrative expenses increased to \$3.6 million in the three months ended September 30, 2016 from \$2.0 million for the same period in 2015. The \$1.6 million increase was due primarily to increases in personnel costs of \$0.3 million, stock based compensation of \$0.3 million, facilities expense of \$0.3 million, professional fees of \$0.4 million and \$0.3 million additional fees associated with being a public company.

Warrant Remeasurement

Warrant remeasurement reflects adjustments to fair value of our liability-classified warrants. As of December 31, 2015 we no longer had liability classified warrants.

Other Expense

Other expense reflects the loss on asset disposal representing the book value of leasehold improvements at our former location due to the Company's relocation of its corporate office and debt issuance costs on our new loan.

Interest Income and Expense, net

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

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Increase (Decrease)		
	2016	2015	\$	%	
	(in thousands)				
Operating expenses:					
Research and development expenses	\$ 18,047	\$ 12,574	\$ 5,473	44	%
General and administrative expenses	10,527	5,053	5,474	108	%
Total operating expenses	28,574	17,627	10,947	62	%
Loss from operations	(28,574)	(17,627)	(10,947)	62	%
Warrant remeasurement	-	(1,880)	1,880	-100	%
Other Expense	(163)	-	(163)	100	%
Interest income (expense), net	(568)	(611)	43	-7	%
Net loss and comprehensive loss	\$ (29,305)	\$ (20,118)	\$ (9,187)	46	%

Research and Development Expenses

Research and development (R&D) expenses increased to \$18.0 million in the nine months ended September 30, 2016 from \$12.6 million for the same period in 2015. The increase of \$5.4 million in 2016 was primarily attributable to an increase in external expenses for clinical trials of \$3.1 million and additional internal R&D personnel and departmental costs of \$2.3 million.

General and Administrative Expenses

General and administrative expenses increased to \$10.5 million in the nine months ended September 30, 2016 from \$5.1 million for the same period in 2015. The \$5.4 million increase was due primarily to increases in personnel costs

of \$0.9 million, stock based compensation of \$1.6 million, facilities expense of \$0.6 million, professional fees of \$1.6 million and \$0.7 million additional fees associated with being a public company.

Warrant Remeasurement

Warrant remeasurement reflects adjustments to fair value of our liability-classified warrants. As of December 31, 2015 we no longer had liability classified warrants.

Other Expense

Other expense reflects the loss on asset disposal representing the book value of leasehold improvements at our former location due to the Company's relocation of its corporate office and debt issuance costs on our new loan.

Index

Interest Income and Expense, net

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

Liquidity and Capital Resources

Since our inception and through September 30, 2016, we have raised aggregate net proceeds of \$185.5 million to fund our operations, primarily \$82.8 million from the sale of common stock, \$87.5 million from the sale of preferred stock and \$15.0 million from a loan. As of September 30, 2016, we had total cash and cash equivalents of \$112.8 million as compared to \$130.2 million as of December 31, 2015. The \$17.4 million decrease in total cash, net of proceeds from new debt of \$10.8 million, was due primarily to funding of operations, which mainly consisted of research and development activities, general and administrative expenses and payments for debt principal reduction offset by proceeds from the issuance of debt.

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. In connection with the IPO, all preferred stock was converted into common stock. There is no preferred stock outstanding as of September 30, 2016, nor are there any preferred stock dividends accrued or payable.

Hercules Loan and Security Agreement

On August 28, 2014, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., (the "Original Loan Agreement"). The Original Loan Agreement provided funding for an aggregate principal amount of up to \$10.0 million in three separate term loans. The first term loan was funded on August 28, 2014 in the amount of \$3.0 million. The second tranche of \$3.0 million was funded on January 29, 2015. Both the first and second tranches were due to mature on March 1, 2018. We elected not to draw the third tranche of \$4.0 million, the availability of which expired on June 30, 2015. Initially, the loans bore interest at a rate per annum equal to the greater of (i) 10.45% or (ii) the sum of (a) 10.45% plus (b) the prime rate (as reported in The Wall Street Journal) minus 4.50%. On April 6, 2015, the second milestone event was met where we received gross cash proceeds in an amount greater than \$55.0 million which lowered the base interest rate on all loans to the greater of (i) 9.95% or (ii) the sum of (a) 9.95% plus (b) the prime rate (as reported in The Wall Street Journal) minus 4.50%. We were required to make interest-only payments on each term loan through September 2015.

Commencing in October 2015, the term loans began amortizing in equal monthly installments of principal and interest over 30 months. On the maturity date or the date the loans otherwise became due, we are also required to pay additional interest equal to 1.5% of the total amounts funded under the Original Loan Agreement.

On August 1, 2016, we 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., pursuant to which we may borrow a term loan up to \$20.0 million. The Amended Loan Agreement amends and restates the Original Loan Agreement. At closing, we borrowed \$15.0 million available for draw under the Amended Loan Agreement (and received proceeds net of the current amount outstanding under the Original Loan Agreement, fees and expenses). The Amended Loan Agreement allows us, at our option, to draw down a second tranche of \$5 million on or before June 15, 2017. Amounts drawn under the Amended Loan Agreement bear interest at a rate per annum equal to the greater of either (i) the sum of (a) 9.15%, plus (b) the prime rate as reported in The Wall Street Journal minus 4.50% or (ii) 9.15%. The effective interest rate at September 30, 2016 was 9.15%. Pursuant to the terms of the Amended Loan Agreement, we will make interest-only payments for 18 months, and then repay the principal balance of the loan in 24 equal monthly payments of principal and interest through the scheduled maturity date on February 3,

2020. The period of interest-only payments and the maturity date may be extended if we satisfy certain conditions as described in the Amended Loan Agreement.

Pursuant to the Original Loan Agreement, in March 2018, we must pay additional interest of \$90,000 which is equal to 1.5% of the total amounts funded under the Original Loan Agreement. On the maturity date or the date the term loan otherwise becomes due, under the Amended Loan Agreement we must also pay additional interest of \$900,000, which is equal to 4.5% of the total amounts available under such agreement. In addition, if we prepay the term loan during the first year following the initial closing, we must pay a prepayment charge equal to 2% of the amount being prepaid, if we prepay the term loan during the second year following the closing, we must pay a prepayment charge equal to 1% of the amount being prepaid, and if we prepay the term loan after the second year following the closing, we must pay a prepayment charge equal to 0.5% of the amount being prepaid.

The term loan is secured by substantially all of our assets, other than intellectual property, which is the subject of a negative pledge. Under the Amended Loan Agreement, we are subject to certain customary covenants that limit or restrict its ability to, among other things, incur additional indebtedness, investments, distributions, transfer assets, make acquisitions, grant any security interests, pay cash dividends, repurchase its common stock, make loans, or enter into certain transactions without prior consent. The Amended Loan Agreement contains several events of default, including, among others, payment defaults, breaches of covenants or representations, material impairment in the perfection of Hercules' security interest or in the collateral and events related to bankruptcy or insolvency. Upon an event of default, Hercules may declare all outstanding obligations immediately due and payable (along with a prepayment charge), a default rate of an additional 5.0% may be applied to the outstanding loan balances, and Hercules may take such further actions as set forth in the Amended Loan Agreement, including collecting or taking such other action with respect to the collateral pledged in connection with the Amended Loan Agreement.

Index

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,	
	2016	2015
Net cash used in operating activities	\$ (26,143)	\$ (14,970)
Net cash used in investing activities	(339)	(799)
Net cash provided by financing activities	9,077	54,920
Net (decrease) increase in cash	\$ (17,405)	\$ 39,151

Net Cash Used in Operating Activities

Net cash used in operating activities was \$26.1 million and \$15.0 million for the nine months ended September 30, 2016 and 2015, respectively. The increase in cash used in operating activities of \$11.1 million was primarily due to an increase in our research and development expenses as well as general and administrative expenses.

Net Cash Used in Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities of \$9.1 million for the nine months ended September 30, 2016 was primarily due to the receipt of net proceeds from the issuance of debt of \$11.0 million less payments of our existing debt obligations of \$1.5 million and deferred offering costs of \$0.5 million.

Net cash provided by financing activities of \$54.9 million for the nine months ended September 30, 2015 was due to the net proceeds from the issuance of preferred stock of \$52.4 and issuance of debt of \$3.0 million less debt issuance costs of \$0.5 million.

Operating Capital Requirements

We expect that our primary uses of capital will continue to be third-party clinical research, development and manufacturing services, compensation and related expenses, laboratory and related supplies, legal and other regulatory expenses and general administrative costs. We believe that our existing cash and cash equivalents as of September 30, 2016, will be sufficient to meet our anticipated cash requirements through the full data readout of our current planned Phase 3 pivotal trial of EG-1962 for the treatment of aSAH which is anticipated to occur in 2018.

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:

the initiation, progress, timing, costs and results of the clinical trials for our product candidates to meet regulatory approval, particularly whether the FDA requires us to complete a second Phase 3 trials for EG-1962 or requires changes to the anticipated design of our Phase 3 program, such as changes in the required control arm of any such trial;

the outcome of planned interactions with the FDA and other non-U.S. health authorities that may alter our proposed Phase 3 program for EG-1962 that is required to meet the standards of a marketing authorization approval in aSAH;

the clinical development plans we establish for these product candidates;

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

the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;

Index

the effect of competing technological and market developments;

the cost and timing of completion of commercial-scale outsourced manufacturing activities; and

the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

Please see the section titled “Risk Factors” in the Annual Report for additional risks associated with our substantial capital requirements.

Until such time, if ever, that we generate product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and research collaboration and license agreements. We may be unable to raise capital or enter into such other arrangements when needed or on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed may have a negative impact on our financial condition and our ability to develop our product candidates.

Contractual Obligations and Commitments

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

As of September 30, 2016	Total	Less than one year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Debt principal and interest	\$ 18,464	\$ 347	\$ 16,727	\$ 1,390	\$ -
Operating lease obligations	3,082	149	\$ 1,799	1,134	-
Total contractual obligations	\$ 21,546	\$ 496	\$ 18,526	\$ 2,524	\$ -

This table above does not include (a) any milestone payments 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, 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. We paid \$0.25 million upon execution of the 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 the Company to pay royalties on certain products based on a mid-single digit percentage of net sales. The Evonik Agreement provides for the reduction of royalties in certain circumstances.

Critical Accounting Policies 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.

Index

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, 2016 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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.

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, 2016, we had cash equivalents of \$112.8 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 (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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Index

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We currently are not a party to any material litigation or other material legal proceedings.

ITEM 1A. RISK FACTORS.

There have been no material changes from our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2015.

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, 2016.

Use of Proceeds

On October 6, 2015, we issued and sold 8,412,423 shares of our Common Stock, including 1,097,272 shares of our Common Stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares, for aggregate gross offering proceeds of \$92.5 million at a price to the public of \$11.00 per share. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1, as amended (File No. 333-206416), which was declared effective by the SEC on September 30, 2015 and a Registration Statement on Form S-1 (File No. 333-207217) filed pursuant to Rule 462(b) of the Securities Act. The IPO commenced on September 30, 2015 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from our IPO of approximately \$82.8 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

We intend to use our net proceeds from the IPO for the overall development of our product candidates. We have invested the net proceeds of the IPO in short-term, investment-grade, interest-bearing securities. There has been no material change in our planned use of the net proceeds from the IPO described in the IPO prospectus.

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 following the signature page of this report and is incorporated into this Item 6 by reference.

Index

SIGNATURES

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

Edge Therapeutics, Inc.

November 1, 2016 By: /s/ Brian A. Leuthner
Brian A. Leuthner
President and Chief Executive Officer
(Principal Executive Officer)

November 1, 2016 By: /s/ Andrew J. Einhorn
Andrew J. Einhorn
Chief Financial Officer
(Principal Financial Officer)

Index

EXHIBIT INDEX

Exhibit Number	Exhibit Description
<u>10.1</u>	Amended and Restated Loan and Security Agreement, dated as of August 1, 2016, by and between the Company and Hercules Capital, Inc. (filed herewith).
<u>31.1</u>	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<u>31.2</u>	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<u>32.1(1)</u>	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<u>32.2(1)</u>	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

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