Edge Therapeutics, Inc.
Form 10-Q
August 03, 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 June 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.)

200 Connell Drive, Suite 1600, 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 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 July 28, 2016 was 28,898,583.

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

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EDGE THERAPEUTICS, INC.

Balance Sheets

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$111,022,034	$ 130,189,421
Prepaid expenses and other current assets	793,808	1,081,084
Total current assets	111,815,842	131,270,505
Property and equipment, net	3,461,121	2,766,992
Other assets	142,870	55,161
Total assets	$115,419,833	$ 134,092,658
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Current liabilities:		
Accounts payable	$2,854,796	$ 2,584,249
Accrued expenses	1,519,909	3,734,348
Short term debt	2,389,222	2,271,111
Total current liabilities	6,763,927	8,589,708
Noncurrent liability:		
Long term debt	1,899,802	3,025,423
STOCKHOLDERS' EQUITY		
Common stock, $0.00033 par value, 75,000,000 shares authorized at June 30, 2016 and December 31, 2015, 28,849,446 shares and 28,810,845 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	9,733	9,720
Additional paid-in capital	187,546,880	184,721,777
Accumulated deficit	(80,800,509)	(62,253,970)
Total stockholders' equity	106,756,104	122,477,527
Total liabilities and stockholders' equity	$115,419,833	$ 134,092,658

See accompanying notes to the financial statements.

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EDGE THERAPEUTICS, INC.

Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development expenses	$ 5,975,306	$ 3,195,244	$ 11,322,069	$ 6,066,483
General and administrative expenses	3,288,889	1,765,065	6,974,486	3,076,095
Total operating expenses	9,264,195	4,960,309	18,296,555	9,142,578
Loss from operations	(9,264,195)	(4,960,309)	(18,296,555)	(9,142,578)
Other income (expense):				
Warrant remeasurement	-	(350,129)	-	(446,321)
Interest income	49,376	1,338	92,190	1,477
Interest expense	(161,310)	(211,863)	(342,174)	(402,026)
Net loss and comprehensive loss	(9,376,129)	(5,520,963)	(18,546,539)	(9,989,448)
Cumulative dividend on Series C , C-1 and C-2 convertible preferred stock	-	(1,746,334)	-	(2,429,515)
Net loss attributable to common stockholders	$ (9,376,129)	$ (7,267,297)	$ (18,546,539)	$ (12,418,963)
Loss per share attributable to common stockholders basic and diluted	$ (0.33)	$ (4.30)	$ (0.64)	$ (7.36)
Weighted average common shares outstanding basic and diluted	28,828,449	1,688,475	28,820,678	1,688,475

See accompanying notes to the financial statements.

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EDGE THERAPEUTICS, INC.

Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(18,546,539)	$(9,989,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,796,296	954,684
Warrant remeasurement	-	446,321
Depreciation expense	31,689	23,714
Amortization of debt discount	42,623	52,933
Amortization of debt issuance costs	39,847	-
Non-cash interest expense	16,982	18,516
Changes in assets and liabilities:		
Prepaid expenses and other assets	262,600	61,923
Accounts payable	289,820	(1,202,721)
Accrued expenses	(2,282,473)	(336,896)
Net cash used in operating activities	(17,349,155)	(9,970,974)
Cash flows from investing activities:		
Purchases of property and equipment	(195,317)	(447,170)
Net cash used in investing activities	(195,317)	(447,170)
Cash flows from financing activities:		
Proceeds from issuance of debt	-	3,000,000
Proceeds from exercise of stock options	26,199	-
Proceeds from exercise of warrants	2,621	-
Payments for issuance costs	(544,773)	(240,316)
Payments for debt payable	(1,106,962)	-
Proceeds from issuance of preferred stock, net of issuance costs	-	52,394,571
Net cash (used in) provided by financing activities	(1,622,915)	55,154,255
Net (decrease) increase in cash	(19,167,387)	44,736,111
Cash and cash equivalents at beginning of period	130,189,421	13,728,972
Cash and cash equivalents at end of period	$111,022,034	$58,465,083
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$253,412	$264,733
Supplemental cash flow information:		
Deferred issuance costs included in accrued expenses and accounts payable	$-	$33,826

Accrued capital expenditures included in accrued expenses and accounts payable	$530,500	$266,967

See accompanying notes to the financial statements.

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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 ™ development 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 currently 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 June 30, 2016, the statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015, and cash flows for the six months ended June 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 six months ended June 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.

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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:

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	As of June 30, 2016	2015
Stock options to purchase Common Stock	5,137,775	3,707,719
Convertible preferred stock to purchase Common Stock	-	17,497,815
Warrants to purchase Common Stock	562,539	99,401
Warrants to purchase Series C Preferred Stock	-	338,534
Warrants to purchase Series C-1 Preferred Stock	-	332,480
Total	5,700,314	21,975,950

(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 is evaluating the impact of the adoption of this ASU.

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 June 30, 2016: (unaudited)				
Cash and cash equivalents	$ 111,022,034	$ 111,022,034	$ -	$ -
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.

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Note 4 – Accrued Expenses

Accrued expenses and other liabilities consist of the following:

	As of June 30, 2016	As of December 31, 2015
Accrued research and development costs	$ 250,760	$ 1,874,126
Accrued professional fees	352,617	258,568
Accrued compensation	846,759	1,510,430
Accrued other	41,146	56,835
Deferred rent	28,627	34,389
Total	$ 1,519,909	$ 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 qualified and nonqualified stock options under the 2010 Equity Incentive Plan and the 2012 Equity Incentive Plan, respectively. Nonqualified stock options ("NQs") may be granted to service providers. Incentive stock options ("ISOs") may be granted only to employees. 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 qualified and nonqualified options (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 st and (y) such lesser number as the Board 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. No options were granted in 2014 under this Plan.

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. In the case of an ISO granted to an option holder who, at the time the ISO is granted, owns, directly or indirectly, stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company, the term of the ISO is five years from the date of grant or such shorter term as may be provided in the option agreement. 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016 (unaudited)	2015	2016 (unaudited)	2015
Stock-Based Compensation				
Research and development	$544,702	$265,029	$1,042,232	$428,541
General and administrative	836,292	318,486	1,754,064	526,143
Total	$1,380,994	$583,515	$2,796,296	$954,684

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016 Weighted Average (unaudited)	2015 Weighted Average	2016 Weighted Average (unaudited)	2015 Weighted Average
Volatility	71.80 %	79.80 %	78.50 %	79.80 %
Risk-Free Interest Rate	1.29 %	1.58 %	1.39 %	1.79 %
Expected Term in Years	5.68	6.08	6.01	6.07
Dividend Rate	0.00 %	0.00 %	0.00 %	0.00 %
Fair Value of Option on Grant Date	$5.81	$ 4.39	$5.11	$ 4.28

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, 2015	4,302,267	$ 5.19		
Granted	976,400	7.56		
Exercised	(7,375)	3.55		
Forfeited	(133,517)	5.79		
Expirations	-	-		
Options outstanding at June 30, 2016	5,137,775	$ 5.62	8.00	$ 23,960,058
Vested and expected to vest at June 30, 2016	5,035,892	$ 5.58	7.98	$ 23,679,976
Exercisable at June 30, 2016	2,617,577	$ 3.97	7.10	$ 16,226,531

At June 30, 2016 there was approximately $10,950,318 of unamortized stock compensation expense, which is expected to be recognized over a remaining average vesting period of 1.46 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 June 30, 2016 and December 31, 2015.

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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 we have 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 six months ended June 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. In July 2016, we dosed the first patient in the Phase III clinical trial of EG-1962. As a result, pursuant to the Evonik Agreement we are obligated to pay a milestone of $1.0 million within 30 days. 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 lease were structured so that the termination date of the December 13, 2013 lease coincided with the commencement date of the new lease which is anticipated to be on August 1, 2016.

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Rent expense is recognized on a straight line basis where there are escalating payments, and was approximately $56,050 and $36,854 for the three months ended June 30, 2016 and 2015, respectively and $114,159 and $91,100 for the six months ended June 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 June 30, 2016:

Year ended December 31,	
2016 (remaining)	$259,292
2017	573,181
2018	583,385
2019	593,591
2020	603,796
2021 and after	510,250
Total minimum payments required	$3,123,495

Note 8 - Debt

On August 28, 2014, the Company entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., or Hercules (the “Loan Agreement”). The 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 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 become due, the Company must also pay additional interest equal to 1.5% of the total amounts funded under the Loan Agreement. In addition, if the Company prepays any of the term loans during the second year following the initial closing, the Company must pay a prepayment charge equal to 2% of the amount being prepaid, and if the Company prepays any of the term loans after such time, the Company must pay a prepayment charge of 1% of the amount being prepaid.

The term loans are secured by substantially all of the Company’s assets, other than intellectual property, which is the subject of a negative pledge. Under the Loan Agreement, the Company is subject to certain customary covenants that limit or restrict its ability to, among other things, incur additional indebtedness, grant any security interests, pay cash dividends, repurchase its common stock, make loans, or enter into certain transactions without prior consent of Hercules.

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

Year Ending in December 31:	(000's)
remaining 2016	$1,164
2017	2,513
2018	682
	$4,359

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 June 30, 2016 approximates the carrying amount.

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Note 9- Subsequent Events

On July 28, 2016, the Company was informed that the first patient was treated in the NEWTON 2 trial (Nimodipine microparticles to Enhance recovery While reducing TOxicity after subarachNoid hemorrhage). 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 (aSAH) resulting from a ruptured brain aneurysm. As a result, pursuant to the Evonik Agreement we are obligated to pay a milestone of $1.0 million within 30 days.

On August 1, 2016, Edge 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) ("Hercules"). The Amended Loan Agreement amended and restated Edge's existing loan and security agreement (the "Existing Loan Agreement") with Hercules entered into on August 28, 2014. At closing, Edge borrowed the full $15.0 million (less the amount currently outstanding under the Existing Loan Agreement) available for draw under the Amended Loan Agreement. The Amended Loan Agreement allows Edge, at its option, to drawn down a second tranche of $5.0 million on or before June 15, 2017. Amounts drawn under the Amended Loan Agreement bear interest at rate per annum equal to the greater of (i) 9.15% or (ii) the sum of (a) 9.15% plus (b) the prime rate (as reported in the Wall Street Journal) minus 4.50%. Edge will make interest-only payments through April 2018, which period may be extended to April 2019 under certain circumstances, after which it will make equal monthly payments of principal and interest. The loan will mature on February 3, 2020. The loan is secured by substantially all of Edge's assets, other than intellectual property, which is the subject of a negative pledge. Under the Amended Loan Agreement, Edge is subject to certain customary covenants that limit or restrict its ability to, among other things, incur additional indebtedness, grant any security interests, pay cash dividends, repurchase its common stock, make loans, or enter into certain transactions without prior consent.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 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 of these terms or other comparable terminology. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" contained in the Annual Report. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this quarterly report and you should not place undue reliance on these forward-looking statements.

These forward-looking statements 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 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.

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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 development 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. In May 2015, the U.S. Food and Drug Administration (the “FDA”) granted us orphan drug designation for EG-1962 for the treatment of patients with subarachnoid hemorrhage and in October, 2015 the European Commission granted orphan drug designation of EG-1962 for treatment of aneurysmal subarachnoid hemorrhage.

In July 2015, the 90-day outcome data were available for analysis for our Phase 1/2 clinical trial of EG-1962 in North America, which we refer to as our NEWTON trial. The NEWTON trial 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 trial 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. Of the 45 patients treated with EG-1962, 90 days following treatment 27% (12 of 45) of patients across 17 sites achieved the highest clinical outcome score (GOSE = 8, Upper Good Recovery) versus only 6% (1 of 18) patients treated with the standard of care, oral nimodipine.

Based on End-of-Phase 2 correspondence from the FDA and subsequent interactions with the FDA in 2015 and 2016, we have determined the design and key elements of our planned Phase 3 clinical program for EG-1962 for the treatment of aSAH. In May, 2016, the FDA granted us Fast Track Designation for our investigational new drug applications for EG-1962. We initiated the Phase 3 trial in July 2016. The final results of the pivotal Phase 3 study, if positive, are expected to form the basis for a marketing application to the FDA and other global health regulatory authorities for the approval of EG-1962 in aSAH. In the United States, we plan to use the FDA Section 505(b)(2) regulatory pathway.

We also plan to study 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 EVD but remain at risk for delayed neurological complications following surgical repair of a ruptured aneurysm. We intend to initiate an open-label study

in which 9 patients will receive EG-1962 via intracisternal administration and 3 patients will receive standard of care oral nimodipine in the second half of 2016.

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 current therapies 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 therapeutic 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 brain 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 submit an Investigational New Drug Application, or IND, for EG-1964 in 2017.

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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 $18.5 million for the six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of approximately $80.8 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, 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 June 30, 2016, we had $111.0 million in cash and cash equivalents.

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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 June 30, 2016 and 2015

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

	Three Months Ended June 30,		Increase (Decrease)	
	2016	2015	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$ 5,975	$ 3,195	$ 2,780	87 %

General and administrative expenses	3,289	1,765	1,524	86 %
Total operating expenses	9,264	4,960	4,304	