

Edge Therapeutics, Inc.
Form 10-Q
November 01, 2017

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, 2017

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated

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filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Securities Exchange Act of 1934.

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

Emerging growth company

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

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

The number of shares of the registrant’s Common Stock, par value \$0.00033 per share, outstanding as of October 25, 2017 was 30,859,200.

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Edge Therapeutics, Inc.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EDGE THERAPEUTICS, INC.

Balance Sheets

| | September 30, 2017 (unaudited) | December 31, 2016 |
|---|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 97,307,258 | \$ 106,398,919 |
| Prepaid expenses and other current assets | 326,733 | 954,581 |
| Total current assets | 97,633,991 | 107,353,500 |
| Property and equipment, net | 3,462,343 | 3,418,077 |
| Other assets | 142,870 | 142,870 |
| Total assets | \$ 101,239,204 | \$ 110,914,447 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| LIABILITIES | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,964,971 | \$ 3,471,032 |
| Accrued expenses | 3,282,398 | 3,213,715 |
| Short term debt | 5,454,610 | - |
| Total current liabilities | 11,701,979 | 6,684,747 |
| Noncurrent liability: | | |
| Long term debt | 14,883,240 | 14,953,143 |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, 5,000,000 shares authorized at September 30, 2017 and December 31, 2016, 0 outstanding | - | - |
| Common stock, \$0.00033 par value, 75,000,000 shares authorized at September 30, 2017 and December 31, 2016, 30,859,200 shares and 28,918,516 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively | 10,397 | 9,756 |
| Additional paid-in capital | 212,688,325 | 190,341,769 |
| Accumulated deficit | (138,044,737) | (101,074,968) |
| Total stockholders' equity | 74,653,985 | 89,276,557 |
| Total liabilities and stockholders' equity | \$ 101,239,204 | \$ 110,914,447 |

See accompanying notes to the financial statements.

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EDGE THERAPEUTICS, INC.

Statements of Operations and Comprehensive Loss

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------------|------------------------------------|---------------|
| | 2017 | 2016 | 2017 | 2016 |
| Operating expenses: | | | | |
| Research and development expenses | \$ 6,913,171 | \$ 6,724,503 | \$ 23,477,971 | \$ 18,046,572 |
| General and administrative expenses | 3,990,283 | 3,552,289 | 12,365,509 | 10,526,775 |
| Total operating expenses | 10,903,454 | 10,276,792 | 35,843,480 | 28,573,347 |
| Loss from operations | (10,903,454) | (10,276,792) | (35,843,480) | (28,573,347) |
| Other income (expense): | | | | |
| Other expense | - | (163,463) | - | (163,463) |
| Interest income | 214,064 | 56,082 | 479,297 | 148,272 |
| Interest expense | (592,089) | (375,089) | (1,591,998) | (717,263) |
| Net loss and comprehensive loss | (11,281,479) | (10,759,262) | (36,956,181) | (29,305,801) |
| Loss per share basic and diluted | \$ (0.37) | \$ (0.37) | \$ (1.23) | \$ (1.02) |
| Weighted average common shares outstanding basic and diluted | 30,852,514 | 28,896,941 | 30,091,640 | 28,848,842 |

See accompanying notes to the financial statements.

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EDGE THERAPEUTICS, INC.

Statements of Cash Flows

(Unaudited)

| | Nine Months Ended September 30, | |
|---|---------------------------------|------------------|
| | 2017 | 2016 |
| Cash flows from operating activities: | | |
| Net loss | \$ (36,956,181) | \$ (29,305,801) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 4,637,142 | 4,029,326 |
| Stock-based 401K company common match | 170,620 | - |
| Depreciation expense | 134,569 | 60,331 |
| Loss on disposal of fixed assets | - | 102,789 |
| Amortization of debt discount | 28,871 | 60,206 |
| Amortization of debt issuance costs | 81,306 | 63,699 |
| Non-cash interest expense | 274,530 | 82,357 |
| Changes in assets and liabilities: | | |
| Prepaid expenses and other assets | 627,848 | 633,513 |
| Accounts payable | (524,145) | (399,708) |
| Accrued expenses | 68,683 | (1,469,109) |
| Net cash used in operating activities | (31,456,757) | (26,142,397) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (160,751) | (339,410) |
| Net cash used in investing activities | (160,751) | (339,410) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of debt | 5,000,000 | 11,022,286 |
| Proceeds from exercise of stock options | 91,982 | 293,988 |
| Proceeds from exercise of warrants | 50,922 | 13,107 |
| Payments for issuance costs | - | (544,773) |
| Payments for debt issuance costs | - | (219,042) |
| Repayment of debt | - | (1,488,558) |
| Proceeds from issuance of common stock, net of issuance costs | 17,382,943 | - |
| Net cash provided by (used in) financing activities | 22,525,847 | 9,077,008 |
| Net increase (decrease) in cash | (9,091,661) | (17,404,799) |
| Cash and cash equivalents at beginning of period | 106,398,919 | 130,189,421 |
| Cash and cash equivalents at end of period | \$ 97,307,258 | \$ 112,784,622 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for: | | |
| Interest | \$ 1,172,979 | \$ 443,464 |

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Supplemental cash flow information:

| | | |
|--|-----------|------------|
| Accrued capital expenditures included in accrued expenses and accounts payable | \$ 18,084 | \$ 348,591 |
|--|-----------|------------|

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 critical care conditions. The Company’s product candidates utilize the Company’s 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, par value of \$0.00033 per share (“Common Stock”) 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. 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.

On April 21, 2017, the Company issued and sold 1,800,000 shares of Common Stock pursuant to a Subscription Agreement (the “Subscription Agreement”) with certain investors in a registered direct offering at a price of \$10.00 per share. The Company received approximately \$17.4 million in net proceeds after deducting a finder’s fee and other offering costs.

Note 2 – Summary of Significant Accounting Policies

(A) Unaudited interim financial statements:

The interim balance sheet at September 30, 2017, the statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2016, and cash flows for the nine months ended September 30, 2017 and 2016 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, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other future annual or interim period. The balance sheet as of December 31, 2016 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, 2016.

(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: rate of trial enrollment and the results of clinical testing and trial activities of the Company's product candidates, the Company's ability to manufacture its products or have its products manufactured, 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, manufacturing, marketing and other vendor 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) Patent costs:

The Company expenses patent costs as incurred and classifies such costs as general and administrative expenses in the accompanying statements of operations and comprehensive loss.

(G) Stock-based compensation:

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

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

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

(H) Net loss per common share:

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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, Common Stock underlying the options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted average shares outstanding used to calculate both basic and diluted loss per common share are the same.

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

| | As of September 30, | |
|--|---------------------|-----------|
| | 2017 | 2016 |
| Stock options to purchase Common Stock | 6,387,495 | 5,166,511 |
| Warrants to purchase Common Stock | 376,682 | 544,705 |
| Total | 6,764,177 | 5,711,216 |

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(I) Accounting standards not yet adopted:

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, “Leases (Topic 842).” The new standard requires organizations that lease assets—referred to as “lessees”—to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases (see Note 7). 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.

(J) Accounting standards adopted:

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

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

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

There were no other material impacts to our consolidated financial statements as a result of adopting this updated standard.

Note 3 – Fair Value of Financial Instruments

There were no transfers between Levels 1, 2, or 3 during 2017 or 2016.

| | 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, 2017: (unaudited) | | | | |
| Cash and cash equivalents | \$ 97,307,258 | \$ 97,307,258 | \$ - | \$ - |
| As of December 31, 2016: | | | | |
| Cash and cash equivalents | \$ 106,398,919 | \$ 106,398,919 | \$ - | \$ - |

Note 4 – Accrued Expenses

Accrued expenses and other liabilities consist of the following:

| | As of September 30, 2017 | As of December 31, 2016 |
|--|-----------------------------|----------------------------|
| Accrued research and development costs | \$ 1,277,652 | \$ 654,795 |

| | | |
|---------------------------|--------------|--------------|
| Accrued professional fees | 183,864 | 366,394 |
| Accrued compensation | 1,417,420 | 1,866,255 |
| Accrued other | 382,046 | 319,434 |
| Deferred rent | 21,416 | 6,837 |
| Total | \$ 3,282,398 | \$ 3,213,715 |

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”). The Company was able to grant up to 1,350,412 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 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, subject to increases as hereafter described (the “Plan Limit”). On January 1, 2015 and each January 1 thereafter prior to the termination of the 2014 Equity Incentive Plan, pursuant to the terms of the 2014 Equity Incentive Plan, the Plan Limit was and shall be increased by the lesser of (x) 4% of the number of shares of Common Stock outstanding as of the immediately preceding December 31 and (y) such lesser number as the Board of Directors may determine in its discretion. On January 1, 2016 the Plan Limit was increased to 3,047,323 shares. As of January 1, 2017, the Plan Limit increased to 4,204,063 shares.

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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 March 1, 2017, the Company issued non-qualified options to purchase a total of 80,000 shares of Common Stock to its newly appointed Senior Vice President, Regulatory Affairs. The award was granted outside of the Company's 2014 Equity Incentive Plan and vests over four years with 25% vesting on February 28, 2018, which is one year following the employee's date of hire, and the remaining 75% vesting in 36 equal monthly installments thereafter, subject to the employee'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 the employee's stock option agreement. The foregoing grant award was made pursuant to the NASDAQ inducement grant exception as a material component of the employee's employment compensation. Together with the other inducement grants made by the Company, there are options covering an aggregate of 395,000 shares outstanding that were granted outside of the Plans.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|----------------------------------|--------------|---------------------------------|--------------|
| | 2017 | 2016 | 2017 | 2016 |
| | (unaudited) | | (unaudited) | |
| Stock-Based Compensation | | | | |
| Research and development | \$ 702,284 | \$ 567,452 | \$ 2,090,076 | \$ 1,609,683 |
| General and administrative | 868,630 | 665,579 | 2,547,066 | 2,419,643 |
| Total | \$ 1,570,914 | \$ 1,233,031 | \$ 4,637,142 | \$ 4,029,326 |

The fair value of options and warrants granted during the three months ended September 30, 2017 and 2016 was estimated using the Black-Scholes option valuation model utilizing the following assumptions:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|------------------------------------|----------------------------------|----------|---------------------------------|----------|
| | 2017 | 2016 | 2017 | 2016 |
| | Weighted | Weighted | Weighted | Weighted |
| | Average | Average | Average | Average |
| | (unaudited) | | (unaudited) | |
| Volatility | 86.98 | % 71.80 | % 88.82 | % 77.96 |
| Risk-Free Interest Rate | 1.83 | % 1.19 | % 1.89 | % 1.38 |
| Expected Term in Years | 6.03 | 6.07 | 5.99 | 6.02 |
| Dividend Rate | 0.00 | % 0.00 | % 0.00 | % 0.00 |
| Fair Value of Option on Grant Date | \$ 7.22 | \$ 6.78 | \$ 6.76 | \$ 5.24 |

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

| | Number | Weighted | Weighted Average | Aggregate |
|--|-----------|----------------|------------------|-----------------|
| | of Shares | Average | Remaining | Intrinsic Value |
| | | Exercise Price | Contractual | |
| | | | Life in Years | |
| Options outstanding at December 31, 2016 | 5,316,511 | \$ 5.84 | | |
| Granted | 1,165,400 | 9.16 | | |
| Exercised | (30,666) | 3.00 | | |

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| | | | | |
|---|-----------|---------|------|---------------|
| Forfeited | (63,750) | 8.21 | | |
| Options outstanding at September 30, 2017 | 6,387,495 | \$ 6.44 | 7.32 | \$ 27,951,302 |
| Vested and expected to vest at September 30, 2017 | 6,387,495 | \$ 6.44 | 7.32 | \$ 27,951,302 |
| Exercisable at September 30, 2017 | 3,898,218 | \$ 5.02 | 6.40 | \$ 22,525,438 |

At September 30, 2017 there was approximately \$13,553,683 of unamortized stock compensation expense, which is expected to be recognized over a remaining average vesting period of 2.56 years.

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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, 2017 and December 31, 2016.

At December 31, 2016, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$69.5 million which expire between 2029 and 2036. At December 31, 2016, the Company had federal research and development credits carryforwards of approximately \$1.3 million and an orphan drug credit carryover of approximately \$11.4 million. The Company may be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company’s capital during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

At December 31, 2016, the Company had approximately \$26.2 million of State of New Jersey NOL’s which expire between 2030 and 2035. At December 31, 2016, the Company had approximately \$0.6 million of the State of New Jersey research development credits carryforwards. The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net loss carryforwards. In 2016, the Company sold \$19,196,765 of State of New Jersey NOL’s and \$257,222 of State of New Jersey R&D Credits for \$1,845,986.

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, 2016, there were no uncertain positions. The Company’s U.S. federal and state net operating losses have occurred since its inception in 2009 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. In September 2017, the IRS concluded auditing the Company's 2015 tax year resulting in a no change letter. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the nine months ended September 30, 2017 and 2016.

Note 7 – Commitments and Contingencies

Evonik

The Company entered into an agreement with SurModics Pharmaceuticals, Inc. (“SurModics”) in October 2010, which was subsequently amended in 2015, 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 (as amended, the “Evonik Agreement”). This agreement was later transferred to Evonik Industries AG (“Evonik”) when it purchased substantially all the assets of SurModics.

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

EG-1962, based on a mid-single digit percentage of net sales, regardless of whether or not such products are manufactured by Evonik. The Evonik Agreement provides for the reduction of these royalties in certain circumstances.

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

Oakwood Amended and Restated Master Formulation Development Agreement

On June 30, 2017, the Company entered into an Amended and Restated Master Formulation Development Agreement (the "Restated Development Agreement") with Oakwood Laboratories, L.L.C. ("Oakwood"), pursuant to which Oakwood will continue to provide the Company with certain drug formulation development and non-commercial manufacturing services for EG-1962, the Company's lead product candidate, in accordance with project plans to be entered into from time to time. Oakwood is currently performing process engineering, optimization and other scale up activities for the Company and is currently the sole manufacturer of EG-1962 used in Edge's ongoing NEWTON 2 Phase 3 pivotal trial for EG-1962.

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Under the Restated Development Agreement, the Company agreed to pay Oakwood to perform services under agreed upon project plans and to pay Oakwood up to an aggregate of \$4.50 million upon the achievement of various regulatory milestones, but no later than April 1, 2019. In July 2017, the Company paid \$1.5 million of such amount in connection with entering into the Restated Development Agreement. The remaining payments are subject to acceleration in the event that the Company closes an equity or similar financing in excess of a predetermined amount ahead of the achievement of the regulatory milestones and April 1, 2019.

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

The term of the Restated Development Agreement continues until the expiration or termination of the Supply Agreement, unless earlier terminated (the “Term”). The Company has the right to terminate project plans upon the occurrence of various circumstances described in the Restated Development Agreement. In the event that the Company terminates the most recent project plan prior to completion (including due to the Company’s decision to discontinue the development or commercialization of EG-1962), the Company must pay to Oakwood a termination fee. Either party has the right to terminate the Restated Development Agreement upon sixty (60) days written notice for failure by the other party to cure a material breach during the applicable cure period. The Company can terminate the Restated Development Agreement immediately upon notice to Oakwood if Oakwood’s annual financial audit report required to be provided to the Company contains any going concern or similar qualification or if Oakwood fails to maintain a pre-determined working capital ratio. Either party may also terminate the Restated Development Agreement immediately in the event of certain failures with regard to validation of the manufacturing process and other specified regulatory failures.

Oakwood Manufacturing and Supply Agreement

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

Pursuant to the Supply Agreement, the price per unit of EG-1962 to be purchased by the Company is based on the expected commercially usable units per batch. In addition, the Company has agreed to pay Oakwood milestone payments that could total up to an aggregate of \$2.25 million upon the achievement of certain development and regulatory milestones.

The Company will have no minimum order requirement under the Supply Agreement until the third (3rd) year following commercial launch of EG-1962. Beginning in the third year following commercial launch and continuing until the fifth year following commercial launch, the Company will be required to (x) order, at a minimum, the greater of (a) five (5) batches and (b) fifty percent (50%) of the aggregate vials of EG-1962 purchased by the Company from all sources in such year (such greater amount being the “Minimum Order Commitment”) or (y) pay a catch-up price to Oakwood based on the amount of EG-1962 actually ordered by the Company during the applicable time period.

The term of the Supply Agreement will continue (unless earlier terminated) until three (3) years following commercial launch of EG-1962. Thereafter, the Supply Agreement will automatically renew for additional two (2)-year periods unless Edge provides notice of non-renewal at least twelve (12) months prior to the end of the then-current term. The Supply Agreement will also terminate automatically upon the termination of the Restated Development Agreement for any reason. Following the first anniversary of the commercial launch of EG-1962, either party may terminate upon

two (2) years written notice. Further, either party may terminate the Supply Agreement upon a material breach by the other party that fails to be cured in the applicable cure period.

The Company may terminate the Supply Agreement immediately upon notice to Oakwood in the event that (a) any regulatory authority requires or causes the withdrawal of EG-1962 from the market or (b) the Company ceases to develop or commercialize EG-1962; provided, that in the latter case of termination prior to completion of the most recent project plan attached to the Restated Development Agreement, the Company must pay to Oakwood a termination fee.

Employment Agreements

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

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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.

Rent expense is recognized on a straight line basis where there are escalating payments, and was approximately \$152,026 and \$82,163 for the three months ended September 30, 2017 and 2016, respectively and \$450,700 and \$196,322 for the nine months ended September 30, 2017 and 2016, 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, 2017:

| | |
|---------------------------------|--------------|
| Year ended December 31, | |
| 2017 (remaining) | \$ 149,021 |
| 2018 | 602,461 |
| 2019 | 604,541 |
| 2020 | 603,371 |
| 2021 | 530,384 |
| 2022 and after | - |
| Total minimum payments required | \$ 2,489,778 |

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 term loan of \$3,000,000 was funded on January 29, 2015. Both the first and second term loans were due to mature on March 1, 2018. The Company elected not to draw the third term loan of \$4.0 million, the availability of which expired on June 30, 2015. Initially, the loan 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 base rate on the loan was lowered 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 the 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 loan otherwise became due and payable, the Company was also required to make a payment 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 the Amended Loan Agreement, the Company may borrow up to \$20,000,000. At closing, the Company borrowed \$15,000,000 of the amount available for draw under the Amended Loan Agreement (and received proceeds net of the amount then outstanding under the Original Loan Agreement, fees and expenses). On May 23, 2017, the Company elected to draw down the second tranche of \$5 million. 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 on the loan as of June 30, 2017 was 9.15%. Pursuant to the terms of the Amended Loan Agreement, the Company will make interest-only payments until

March 1, 2018, and on that date begin to repay the principal balance of the loan in 24 equal monthly payments of principal and interest through the scheduled maturity date of 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 Amended Loan Agreement, in March 2018, the Company must make a payment 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 loan otherwise becomes due and payable, under the Amended Loan Agreement the Company must also make a payment of \$900,000, which is equal to 4.5% of the total amounts available under the Amended Loan Agreement. In addition, if the Company prepays the term loan (i) during the first year following the initial closing, the Company must pay a prepayment charge equal to 2% of the amount being prepaid, (ii) during the second year following the closing, the Company must pay a prepayment charge equal to 1% of the amount being prepaid, and (iii) after the second year following the closing, the Company must pay a prepayment charge equal to 0.5% of the amount being prepaid.

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The 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 the Company's 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, 2017 were as follows:

| Year Ending in December 31: | (000's) |
|-----------------------------|----------|
| 2017 (remaining) | \$- |
| 2018 | 7,882 |
| 2019 | 10,287 |
| 2020 | 1,831 |
| Total | \$20,000 |

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, 2017 approximates the carrying amount.

Note 9 – Subsequent Events

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

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 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, 2016 (the "Annual Report") filed with the SEC on March 2, 2017. 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," "continues" 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;

the potential for success of competing products that are or become available for the indications we are pursuing or may in the future pursue;

our ability, within the expected timeframes, to announce the results of such studies and trials, 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 expectations with respect to the performance of third parties, including contract manufacturers, collaborators, and other third party partners or vendors;

the size of the potential markets for our product candidates and our ability to serve those markets;

the anticipated rate and degree of market acceptance of our product candidates for any indication once approved;

our ability to obtain additional financing;

the accuracy of our estimates regarding expenses, future revenues, capital requirements and the length of time existing cash resources will last;

our use of the net proceeds from our initial public offering ("IPO") of common stock, our sales of shares in a registered direct offering and future financings, if any; 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 critical care conditions. Our initial product candidates target acute, life-threatening neurological and other conditions for which we believe the approved existing therapies, if any, are inadequate.

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 high concentrations 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, through a novel delivery mechanism that enables targeted and sustained drug exposure while potentially avoiding 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 Food and Drug Administration, or FDA, for the treatment of patients with subarachnoid hemorrhage. The European Commission has granted orphan drug designation to EG-1962 for treatment of aSAH.

In preparation for a potential launch of EG-1962, as our health economic outcome research progresses, we continue to gain a better understanding regarding the economic burden of aSAH, how physicians currently use oral nimodipine to treat their patients, and the potential size of the United States market for EG-1962. Of the approximately 35,000 SAH patients in the United States each year, a subset is comprised of aSAH patients. At the Neurocritical Care Society meeting in October 2017, we presented new retrospective, claims-based health economic data showing aSAH per patient hospital charges represent a high economic burden for U.S. hospitals. The analysis also showed that the aSAH patient population currently being studied in the NEWTON 2 study had the highest per patient hospital charges and experienced the longest hospitalizations among all aSAH patients. Specifically, these are patients who require an external ventricular drain (EVD), and undergo either neurosurgical clipping or endovascular coiling for repair of their aneurysm. We are continuing to better understand the SAH population, its treatment costs, and current utilization of oral nimodipine in patients with a brain hemorrhage.

In July 2016, we commenced the Phase 3 NEWTON 2 study for EG-1962. NEWTON 2 is a 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 aSAH. The primary endpoint of the NEWTON 2 study is the proportion of subjects with a favorable clinical outcome (a score of 6 – 8 on the extended Glasgow Outcome Scale, or GOSE) at day 90. The key secondary endpoint is the subject's score on the Montreal Cognitive Assessment Scale. We expect the results of an interim analysis of NEWTON 2 to be available in early 2018. Depending on the results of the interim analysis, the study may continue to full data readout after 374 patients have completed the study, in which case we expect the results of the study to be available in late 2018. The results of the NEWTON 2 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 for the treatment of aSAH. In the United States, we plan to submit an NDA for EG-1962 using the FDA Section 505(b)(2) regulatory pathway.

Our Phase 1/2 clinical study of EG-1962, which we refer to as our NEWTON study, met its primary and secondary endpoints of safety, tolerability, defining the maximum tolerated dose and pharmacokinetics. The results of the principal exploratory efficacy endpoint from the 90-day follow-up demonstrated that 59% (27 of 46) of patients treated with EG-1962 experienced a favorable clinical outcome (a score of 6-8 on the GOSE) versus 28% (5 of 18) of patients treated with the standard of care oral nimodipine. At the final assessment, of the 46 patients treated with EG-1962, 28% (13 of 46) of patients achieved the highest clinical outcome score (GOSE=8, Upper Good Recovery) versus 6% (1 of 18) patients treated with the standard of care oral nimodipine.

A Phase 1 study of the safety, pharmacokinetics and clinical outcomes of EG-1962 administered intracisternally, or directly into the basal cisterns of the brain, is open for enrollment for patients with aSAH who do not receive an external ventricular drain but remain at risk for delayed neurological complications following surgical repair of a ruptured aneurysm. This study is a 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 current approved therapies exist. We are developing our second product candidate, EG-1964, as treatment for chronic subdural hematoma, or cSDH. 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, bleeding in the subdural space typically recurs in 3% to 33% of patients at which point another costly and risky surgical intervention is required. EG-1964 contains aprotinin, a serine protease inhibitor. Aprotinin works by slowing the breakdown of blood clots. We are in the process of formulating EG-1964 to deliver aprotinin directly to the subdural space by way of a single administration at the time of initial neurosurgical intervention with sustained drug exposure over approximately 30 days. If approved, we expect that EG-1964 can become the standard of care as a treatment in the management of cSDH. We intend to complete formulation development activities and commence non-clinical studies of EG-1964 in 2017. Based on the results of those studies, in 2018, we may submit to the FDA and potentially other country health authorities a request for authorization to investigate a new drug in human clinical studies, known as an Investigational New Drug Application, for EG-1964.

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 studies and raising capital.

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We have never been profitable and have incurred net losses in each year since inception. Our net losses were \$37.0 million and \$29.3 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had an accumulated deficit of approximately \$138.0 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 at least the next several years. 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, or we enter into outbound licensing or future collaboration agreements. 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 our 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, 2017, we had \$97.3 million in cash and cash equivalents.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenue

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

Research and Development

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

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Comparison of the Three Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the three months ended September 30, 2017 and 2016:

| | Three Months Ended September 30, | | Increase (Decrease) | | |
|-------------------------------------|----------------------------------|--------------|---------------------|-----|---|
| | 2017 | 2016 | \$ | % | |
| | (in thousands) | | | | |
| Operating expenses: | | | | | |
| Research and development expenses | \$ 6,913 | \$ 6,725 | \$ 188 | 3 | % |
| General and administrative expenses | 3,990 | 3,552 | 438 | 12 | % |
| Total operating expenses | 10,903 | 10,277 | 626 | 6 | % |
| Loss from operations | (10,903) | (10,277) | (626) | 6 | % |
| Other expense | - | (163) | 163 | 100 | % |
| Interest (expense), net | (378) | (318) | (60) | 19 | % |
| Net loss and comprehensive loss | \$ (11,281) | \$ (10,758) | \$ (523) | 5 | % |

Research and Development Expenses

Research and development (R&D) expenses increased to \$6.9 million in the three months ended September 30, 2017 from \$6.7 million for the same period in 2016. The increase of \$0.2 million in 2017 was primarily attributable to an increase in external expenses for clinical study costs of \$0.1 million and an increase in internal R&D personnel and departmental costs of \$0.1 million.

General and Administrative Expenses

General and administrative expenses increased to \$4.0 million in the three months ended September 30, 2017 from \$3.6 million for the same period in 2016. The \$0.4 million increase was due primarily to increases in personnel costs of \$0.3 million, legal and professional fees of \$0.3 million and a decrease in other expenses of \$0.2 million.

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Other Expense

Other expense in 2016 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 Expense, net

Interest expense, net increased primarily due to interest expense for our loan of \$0.2 million partially offset by an increase in interest income from interest earned on our cash and cash equivalents of \$0.1 million.

Comparison of the Nine Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended September 30, | | Increase (Decrease) | |
|-------------------------------------|---------------------------------|--------------|---------------------|-------|
| | 2017 | 2016 | \$ | % |
| | (in thousands) | | | |
| Operating expenses: | | | | |
| Research and development expenses | \$ 23,478 | \$ 18,047 | \$ 5,431 | 30 % |
| General and administrative expenses | 12,365 | 10,527 | 1,838 | 17 % |
| Total operating expenses | 35,843 | 28,574 | 7,269 | 25 % |
| Loss from operations | (35,843) | (28,574) | (7,269) | 25 % |
| Other expense | - | (163) | 163 | 100 % |
| Interest (expense), net | (1,113) | (568) | (545) | 96 % |
| Net loss and comprehensive loss | \$ (36,956) | \$ (29,305) | \$ (7,651) | 26 % |

Research and Development Expenses

Research and development (R&D) expenses increased to \$23.5 million in the nine months ended September 30, 2017 from \$18.0 million for the same period in 2016. The increase of \$5.4 million in 2017 was primarily attributable to an increase in external expenses for clinical studies of \$4.2 million and additional internal R&D personnel and departmental costs of \$1.2 million.

General and Administrative Expenses

General and administrative expenses increased to \$12.4 million in the nine months ended September 30, 2017 from \$10.5 million for the same period in 2016. The \$1.8 million increase was due primarily to increases in personnel costs of \$0.9 million, employee separation costs of \$0.3 million, professional fees of \$0.4 million and \$0.2 million in other expenses.

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Other Expense

Other expense in 2016 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 Expense, net

Interest expense, net increased primarily due to interest expense for our loan of \$0.8 million offset by an increase in interest income from interest earned on our cash and cash equivalents of \$0.3 million.

Liquidity and Capital Resources

Since our inception and through September 30, 2017, we have raised aggregate net proceeds of \$207.9 million to fund our operations, primarily \$82.8 million from the sale of Common Stock, \$87.5 million from the sale of preferred stock, par value of \$0.00033 per share ("Preferred Stock"), \$17.4 million net proceeds from a registered direct common stock offering and \$20.0 million from a loan. As of September 30, 2017, we had total cash and cash equivalents of \$97.3 million as compared to \$106.4 million as of December 31, 2016. The \$9.1 million decrease in total cash was due primarily to increased funding of operations, which mainly consisted of research and development activities and general and administrative expenses offset by proceeds from a registered direct common stock offering and 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, 2017.

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

We have no committed sources of capital. Therefore, 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.

Hercules Loan and Security 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 the Amended Loan Agreement, we may borrow up to \$20.0 million. At closing, we borrowed \$15.0 million of the amount available for draw under the Amended Loan Agreement (and received proceeds net of the amount then outstanding under the Original Loan Agreement, fees and expenses). On May 23, 2017, we elected to draw down the second tranche of \$5 million. 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 on the loan as of March 31, 2017 was 9.15%. Pursuant to the terms of the Amended Loan Agreement, we will make interest-only payments until March 1, 2018, and on that date begin to repay the principal balance of the loan in 24 equal monthly payments of principal and interest through the scheduled maturity date of 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 Amended Loan Agreement, in March 2018, we must make a payment 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 loan otherwise becomes due and payable, under the Amended Loan Agreement we must also make a payment of \$900,000, which is equal to 4.5% of the total amounts available under the Amended Loan Agreement. In addition, if we prepay the term loan (i) during the first year following the initial closing, we must pay a prepayment charge equal to 2% of the amount being prepaid, (ii) during the second year following the closing, we must pay a prepayment charge equal to 1% of the amount being prepaid, and (iii) after the second year following the closing, we must pay a prepayment charge equal to 0.5% of the amount being prepaid.

The 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 our 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.

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Cash flows

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

| | Nine Months Ended September 30, | |
|---|---------------------------------|--------------|
| | 2017 | 2016 |
| Net cash used in operating activities | \$ (31,457) | \$ (26,143) |
| Net cash used in investing activities | (161) | (339) |
| Net cash provided by financing activities | 22,526 | 9,077 |
| Net decrease in cash | \$ (9,092) | \$ (17,405) |

Net Cash Used in Operating Activities

Net cash used in operating activities was \$31.5 million and \$26.1 million for the nine months ended September 30, 2017 and 2016, respectively. The increase in cash used in operating activities of \$5.4 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 for the nine months ended September 30, 2017 was due to the receipt of net proceeds of \$17.4 million from a registered direct common stock offering and \$5.0 million from issuance of debt.

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.

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, 2017, will be sufficient to meet our anticipated cash requirements through the full data readout of the NEWTON 2 trial of EG-1962 for the treatment of aSAH, which is anticipated to occur in late 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. Moreover, if circumstances are favorable, we may seek to secure additional capital opportunistically. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the initiation, progress (including rate of enrollment), 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 for EG-1962, 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;

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

the effect of competing technological and market developments;

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

the cost of establishing manufacturing, 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” elsewhere in this Annual Report for additional risks associated with our substantial capital requirements.

We will need to raise additional capital and may seek collaborations in the future in order to further 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.

Contractual Obligations and Commitments

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

| As of September 30, 2017 | Total | Less than one year | 1-3 Years | 3-5 Years | More than 5 Years |
|-------------------------------|----------------|-----------------------|-----------|-----------|----------------------|
| | (in thousands) | | | | |
| Debt principal and interest | \$22,762 | \$ 7,183 | \$ 15,579 | \$ - | \$ - |
| Operating lease obligations | 2,490 | 600 | 1,208 | 682 | - |
| Total contractual obligations | \$25,252 | \$ 7,783 | \$ 16,787 | \$ 682 | \$ - |

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

The Evonik Agreement provides for the reduction of royalties in certain circumstances.

Under the Oakwood Restated Development Agreement (the “Restated Development Agreement”), we agreed to pay Oakwood to perform services under agreed upon project plans and to pay Oakwood up to an aggregate of \$4.50 million upon the achievement of various milestones, but no later than April 1, 2019. In July 2017, we paid \$1.5 million of such amount in connection with entering into the Restated Development Agreement. Certain of these payments are subject to acceleration in the event that we close an equity or similar financing in excess of a predetermined amount ahead of the achievement of the regulatory milestones and April 1, 2019. In addition, the Restated Development Agreement calls for us to pay royalties on sales of certain products based on a low single digit percentage of net sales of EG-1962, regardless of the manufacturer or supplier thereof.

Pursuant to the Oakwood Commercial Supply Agreement, the price per unit of EG-1962 to be purchased by us is based on the expected commercially usable units per batch. In addition, we have agreed to pay Oakwood milestone payments that could total up to an aggregate of \$2.25 million upon the achievement of certain development and regulatory milestones.

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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.

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, 2017 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Off-balance Sheet Arrangements

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

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ITEM 3: Quantitative and Qualitative Disclosure about Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve principal, while at the same time maximizing the income we receive from our cash and marketable securities without significantly increasing risk. As of September 30, 2017, we had cash equivalents of \$97.3 million that were held in a non-interest-bearing money operating account and an institutional U.S. Treasury money market fund. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are comprised of U.S. Treasury and Treasury backed repurchase agreements.

ITEM 4: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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, 2016.

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, 2017.

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 of 1933, or 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.

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EXHIBIT INDEX

| Exhibit Number | Exhibit Description |
|----------------|--|
| <u>3.1</u> | Eighth Amended and Restated Certificate of Incorporation of Edge Therapeutics, Inc. (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein). |
| <u>3.2</u> | Second Amended and Restated Bylaws of Edge Therapeutics, Inc. (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on October 6, 2015, and incorporated by reference herein). |
| <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 purposes 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.

* Confidential Treatment has been requested with respect to certain portions of this Exhibit. Omitted portions have been filed separately with the SEC.

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SIGNATURES

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

Edge Therapeutics, Inc.

November 1, 2017 By: /s/ Brian A. Leuthner
Brian A. Leuthner
President and Chief Executive Officer
(Principal Executive Officer)

November 1, 2017 By: /s/ Albert N. Marchio II
Albert N. Marchio II
Chief Accounting Officer
(Principal Accounting Officer)