Edge Therapeutics, Inc.
Form S-3
October 21, 2016
TABLE OF CONTENTS

As filed with the Securities and Exchange Commission on October 21, 2016

Registration No. 333-

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

FORM S-3 REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**26-4231384**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

300 Connell Drive, Suite 4000
Berkeley Heights, NJ 07922
(800) 208-3343
(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

Brian A. Leuthner
President & Chief Executive Officer
Edge Therapeutics, Inc.
300 Connell Drive, Suite 4000
Berkeley Heights, NJ 07922
(800) 208-3343
(Name, address, including zip code and telephone number, including area code, of agent for service)

With copies to:

W. Bradford Middlekauff **Senior Vice President, General Counsel and Secretary** **Edge Therapeutics, Inc.** **300 Connell Drive, Suite 4000** **Berkeley Heights, NJ 07922** **(908) 242-3899**	**David S. Rosenthal, Esq.** **Dechert LLP** **1095 Avenue of the Americas** **New York, NY 10036** **(212) 698-3500**

Approximate date of commencement of proposed sale to the public:
From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.o

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 definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

(Check one):

Large accelerated filer	o	Accelerated filer	
Non-accelerated filer (Do not check if a smaller reporting company)	o	Smaller reporting company	o

TABLE OF CONTENTS

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per unit[1][2]	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[1]
Common Stock, $0.00033 par value per share[4][10]	—	—	—	—
Preferred Stock, $0.00033 par value per share[5][10]	—	—	—	—
Warrants[6][10]	—	—	—	—
Debt Securities[7][10]	—	—	—	—
Rights to purchase common stock, preferred stock, debt securities or units[8][10]				
Units[9][10]	—	—	—	—
TOTAL	$ 200,000,000	100 %	$ 200,000,000[11]	$ 23,180.00

(1) Not specified as to each class of securities to be registered pursuant to General Instruction II.D. to Form S-3.

(2) The proposed maximum offering price per unit will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o).

(4) Subject to note (11) below, there is being registered an indeterminate number of shares of common stock.

(5) Subject to note (11) below, there is being registered an indeterminate number of shares of preferred stock.

(6) Subject to note (11) below, there is being registered hereunder an indeterminate amount and number of warrants. The warrants may represent the right to purchase shares of common stock, shares of preferred stock or debt securities.

(7) Subject to note (11) below, there is being registered an indeterminate principal amount of debt securities, excluding accrued interest and accrued amortization of discount, if any, to the date of delivery.

(8) Subject to note (11) below, there is being registered an indeterminate number of rights that may represent a right to purchase common shares, preferred shares, debt securities or units.

(9) Subject to note (11) below, there is being registered an indeterminate number of units. Each unit will be issued under a unit agreement and will represent an interest in a combination of one or more of the securities registered hereunder.

(10) Subject to note (11) below, this registration statement also covers an indeterminate amount of securities as may be issued in exchange for, or upon conversion or exercise of, as the case may be, the shares of preferred stock or warrants registered hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. No separate consideration will be received for any securities registered hereunder that are issued in exchange for, or upon conversion of, as the case may be, the shares of preferred stock or warrants.

(11) In no event will the aggregate initial offering price of all securities issued from time to time pursuant to the prospectus contained in this registration statement exceed $200,000,000 or the equivalent thereof in one or more foreign currencies or foreign currency units. Such amount represents the offering price of any shares of common stock or shares of preferred stock, the principal amount of any debt securities issued at their stated principal amount, the issue price rather than the principal amount of any debt securities issued at an original issue discount, the issue price of any warrants, and the exercise price of any securities issuable upon the exercise of warrants. If

any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be equal to any such greater principal amount due at maturity, such aggregate principal amount not to exceed $200,000,000 less the value of securities previously issued hereunder. Any offering of securities denominated other than in United States dollars will be treated as the equivalent of United States dollars based on the exchange rate applicable to the purchase of such securities at the time of initial offering. The securities registered hereunder may be sold separately or as units with other securities registered hereunder.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

TABLE OF CONTENTS

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated October 21, 2016

PROSPECTUS

EDGE THERAPEUTICS, INC.

$200,000,000

Common Stock
Preferred Stock
Debt Securities
Rights to Purchase Common Stock, Preferred Stock, Debt Securities or Units
Warrants
Units

We may offer and sell from time to time our shares of common stock, shares of preferred stock, debt securities, warrants and rights to purchase shares of common stock or preferred stock, debt securities or units, as well as units that include any of these securities. We may sell any combination of these securities in one or more offerings with an aggregate initial offering price of up to $200,000,000.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference herein or therein before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is listed on The NASDAQ Global Select Market under the symbol EDGE. On October 20, 2016, the last reported sale price for our common stock was $10.95 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on The NASDAQ Global Select Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

Investing in our securities involves risks. See Risk Factors beginning on page 5.

We may sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement. In addition, the underwriters, if any, may over- allot a portion of the securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 21, 2016.

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $200,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus, together with the information incorporated herein by reference as described under the heading Incorporation of Certain Information by Reference.

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus, the accompanying prospectus supplement or related free writing prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus, the accompanying supplement to this prospectus and any related free writing prospectus, if any, do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus, the accompanying supplement to this prospectus or any related free writing prospectus, if any, constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference therein is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered or the applicable securities are sold on a later date.

TABLE OF CONTENTS

SUMMARY

This summary highlights selected information from this prospectus and the documents incorporated herein by reference and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing in our securities discussed under Risk Factors beginning on page 5 of this prospectus, the information incorporated herein by reference, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. All references in this prospectus to we, us, our, Edge, the Company and similar designations refer to Edge Therapeutics, Inc. and its consolidated subsidiaries, unless otherwise indicated or as the context otherwise requires.

Our Business

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 rare, acute, life-threatening 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 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, through a novel delivery mechanism that enables targeted and sustained drug exposure while potentially avoiding dose-limiting systemic side effects associated with currently available formulations of nimodipine. EG-1962 has been granted orphan drug designation and Fast Track designation by the U.S. Food and Drug Administration (the FDA) for the treatment of patients with subarachnoid hemorrhage, and the European Commission granted orphan drug designation of EG-1962 for the treatment of patients with aneurysmal subarachnoid hemorrhage.

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

In July 2016 we commenced the Phase 3 NEWTON 2 study for EG-1962. 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 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 GOSE) at day 90. The key secondary endpoint is the subject s score on the Montreal Cognitive Assessment scale, or MoCA. We expect the results of an interim analysis to be completed in early 2018 with the results of the full study to be available in late 2018.

We have also initiated a study of the safety, pharmacokinetics and clinical outcomes of EG-1962 administered directly into the basal cisterns of the brain in patients with aSAH who do not receive an external-ventricular drain (EVD) but remain at risk for delayed neurological complications following surgical repair of a ruptured aneurysm. This study is a US multicenter, randomized, controlled, open-label study in which 9 patients are expected to receive EG-1962 via

intracisternal administration and 3 patients are expected to receive standard of care oral nimodipine. We expect data to be available from this study during 2017.

In addition to EG-1962, we are using our Precisa development platform to develop additional product candidates targeting other acute, serious conditions where limited or no effective therapies currently exist. We are developing our second product candidate, EG-1964, as a potential prophylactic treatment in the management of chronic subdural hematoma, or cSDH, to prevent recurrent bleeding on the surface of the brain. A cSDH is a

1

TABLE OF CONTENTS

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

Corporate Information

Our principal corporate offices are located at 300 Connell Drive, Suite 4000 and our telephone number is (800) 208-3343. We were incorporated in Delaware in 2009. Our internet address is *www.edgetherapeutics.com*. The information found on our internet site is not part of this prospectus.

Securities We May Offer

We may offer shares of our common stock and preferred stock, various series of debt securities, warrants and rights to purchase shares of common stock or preferred stock, debt securities or units, as well as units to purchase any of such securities, from time to time under this prospectus, together with any applicable prospectus supplement and related free writing prospectus, at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate principal amount or aggregate offering price;
- maturity, if applicable;
-