Edge Therapeutics, Inc.
Form 10-K
February 21, 2019

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

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to _____

Commission file number 001-37568

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

Delaware	26-4231384
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922
(Address of principal executive offices)

(800) 208-3343
(Registrant's telephone number)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K (§ 229.405 of this chapter) is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or

information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

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. Yes No

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates (without admitting that any person whose shares are not included in such calculation is an affiliate) of the registrant on June 30, 2018, was $32.3 million (based on the closing price for shares of the registrant’s common stock as reported on the Nasdaq Global Select Market on that date).

The number of shares of the registrant’s common stock, par value $0.00033 per share, outstanding as of February 14, 2019 was 31,509,822.

Edge Therapeutics, Inc.

FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2018

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual 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," "could," "expects," "intends," "plans," "anticipates," "believes," "e "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" contained in Item 1A of this 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 Annual Report and you should not place undue reliance on these forward-looking statements.

These forward-looking statements include, but are not limited to, statements about:

the expected benefits of and potential value created by the proposed merger among Edge Therapeutics, Inc., a Delaware corporation, or Edge, Echos Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Edge, or Merger Sub, and PDS Biotechnology Corporation, a Delaware corporation, or PDS, for the stockholders of Edge;

the likelihood of the satisfaction of certain conditions to the completion of the merger and whether and when the merger will be consummated;

Edge's ability to control and correctly estimate its operating expenses and its expenses associated with the merger;

the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings;

the plans to develop and commercialize additional products;

the attraction and retention of highly qualified personnel;

the ability to protect and enhance the combined company's products and intellectual property;

developments and projections relating to the combined company's competitors or industry;

the combined company's financial performance;

expectations concerning Edge's or PDS's relationships and actions with third parties;

future regulatory, judicial and legislative changes in Edge's or PDS's industry; and

other risks and uncertainties, including those listed under Item 1A. Risk Factors.

Any forward-looking statements in this Annual 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.

In this Annual Report, unless otherwise stated or the context otherwise indicates, references to “Edge,” “Edge Therapeutics,” “the Company,” “we,” “us,” “our” and similar references refer to Edge Therapeutics, Inc., a Delaware corporation.

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PART I

ITEM 1. Business

Pending Merger Agreement with PDS

On November 23, 2018, Edge, Merger Sub and PDS, a privately-held clinical-stage cancer immunotherapy company, entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into PDS, with PDS surviving the merger as the wholly-owned subsidiary of the combined company.

If the merger is completed, the business of Edge will become the business of PDS. If the merger is not completed, Edge will reconsider its strategic alternatives and may pursue one of the following courses of action, which Edge currently believes are the most likely alternatives if the merger with PDS is not completed:

Pursue another strategic transaction similar to the merger. Edge may resume its process of evaluating other companies interested in pursuing a strategic transaction with Edge and, if a candidate is identified, focus its attention on negotiating and completing such a transaction with such candidate.

Dissolve and liquidate its assets. If Edge is unable, or does not believe that it is able, to find a suitable candidate for another strategic transaction, Edge may dissolve and liquidate its assets. In the event of dissolution, Edge would be required to pay all of its debts and contractual obligations and to set aside certain reserves for potential future claims. If Edge dissolves and liquidates its assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to Edge's stockholders after paying Edge' debts and other obligations and setting aside funds for its reserves.

Overview

Edge is a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel therapies capable of transforming treatment paradigms in the management of medical conditions.

On March 28, 2018, Edge announced that a pre-specified interim analysis performed on data from the Day 90 visit of the first 210 subjects randomized and treated in the Phase 3 multi-center, randomized, double-blind, placebo-controlled, NEWTON 2 study of EG-1962 in adults with aneurysmal subarachnoid hemorrhage demonstrated a low probability of achieving a statistically-significant difference compared to the standard of care in the study's primary endpoint, if the study were to be fully enrolled. The independent Data Monitoring Committee, or the DMC, for the NEWTON 2 study recommended that the study be stopped based on this demonstration. The DMC also reported that there were no safety concerns attributed to EG-1962.

Based on the DMC recommendation, Edge decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study.

The NEWTON 2 study was designed to detect a 15% absolute improvement in favorable outcomes at Day 90 for the EG-1962 treatment group with a target enrollment of 374 subjects with WFNS grades 2-4 and an external ventricular drain, or EVD. Prior to discontinuation of the study, 289 subjects were randomized and 282 were treated. The final analysis showed that overall in the study's primary endpoint, 46% (64/138) of subjects treated with a single intraventricular injection of EG-1962 experienced a favorable outcome (a score of 6 to 8 on the extended Glasgow Outcome Scale, or GOSE) at Day 90, compared to 43% (62/144) of subjects treated with oral nimodipine. The GOSE is a clinically validated scale to assess recovery for patients who have suffered a brain injury.

In the NEWTON 2 study, at randomization, subjects were stratified by baseline severity as measured by the World Federation of Neurological Surgeons, or WFNS, grade. Results of a logistic regression analysis of Day 90 GOSE outcomes including interactions revealed a statistically significant treatment by WFNS group interaction (p=0.0381). In the pre-specified subgroup of subjects with WFNS grade 3 or 4 (i.e., severe aSAH subjects), 46% (32/69) of subjects treated with EG-1962 experienced a favorable outcome as measured by GOSE, compared to 32% (24/75) of subjects treated with oral nimodipine. While these results did not achieve statistical significance (as the NEWTON 2 study was not powered to provide statistical significance for subgroups), they suggest a clinically meaningful potential benefit for EG-1962 in subjects with WFNS grade 3 or 4. Further, these results are consistent with results from Edge's Phase 1/2 NEWTON study. In that study, EG-1962 demonstrated a similar efficacy trend in favorable outcome rate compared to oral nimodipine in severe aSAH subjects with WFNS grades 3 or 4, with 37% (10/27) of the subjects treated with EG-1962 experiencing a favorable outcome, compared to 23% (3/13) of the subjects treated with oral nimodipine.

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In the WFNS grade 2 subgroup (i.e., moderate aSAH subjects), favorable outcome rates from the NEWTON 2 study were inconsistent with those observed in the Phase 1/2 NEWTON study in both the EG-1962 and oral nimodipine treatment groups. In addition, the favorable response rate in the control group in NEWTON 2 was higher than, and inconsistent with, that reported in the medical literature.

Edge did not identify any safety concerns that would have halted the NEWTON 2 study or precluded further development of EG-1962. Notably, the incidence of vasospasm was significantly lower in the EG-1962 treatment group compared to the standard of care, oral nimodipine. In addition, there was a lower incidence of both mortality and hypotension in the EG-1962 treatment group.

Based on the overall findings of the NEWTON 2 study, Edge has explored whether any third party(ies) would be interested in acquiring rights to EG-1962. To date, there has been no significant interest expressed by any third party.

On April 17, 2018, the Edge Board of Directors, or the Edge Board, established a committee of convenience, the Transactions Committee, to explore strategic alternatives for Edge in order to maximize both near and long-term value for Edge shareholders, which might have included, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of Edge, a sale of stock, a strategic merger or other business combination transaction or other transaction between Edge and a third party.

In April 2018, the Edge Board retained Piper Jaffray & Co., or Piper Jaffray, to serve as its financial advisor in certain aspects of the strategic review process. Throughout the strategic alternatives review and selection process, Edge has continued to finance its operations with its existing cash. In addition, Edge has reduced the scope of its operations, including the size of its workforce, in order to preserve cash resources. Edge has ceased research and development on EG-1962, including the completion of the NEWTON 2 study, and all of Edge's other product candidates.

After a comprehensive review of strategic alternatives, on November 23, 2018, Edge, Merger Sub and PDS entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into PDS, with PDS surviving the merger as the wholly-owned subsidiary of the combined company. PDS is a private company with a growing pipeline of clinical-stage immunotherapies that are expected to treat various early-stage cancers, including head and neck cancer, cervical cancer, anal cancer, prostate cancer, breast cancer and other cancers. Following the merger, the combined company expects to focus on developing PDS's growing pipeline of next-generation cancer immunotherapies based on the proprietary, multi-functional Versamune® technology platform, the development of PDS0101 for the treatment of multiple human papilloma virus (HPV)-induced cancers, including cervical, anal and head and neck cancers, and multiple preclinical programs developing Versamune®-based cancer immunotherapies in combination with checkpoint inhibitors for various late-stage cancers.

Intellectual Property

The protection of Edge's product candidates, Edge's manufacturing methods, delivery systems and patient treatment protocols, and associated trade secrets and know-how are important to Edge's business. Edge has sought patent protection in the United States and internationally relating to EG-1962, a microparticulate formulation of nimodipine. Edge's policy is to seek, maintain and defend patent rights, whether developed internally or in-licensed, and to protect technologies, improvements and trade secrets that may be important to Edge's business.

Edge's commercial success will depend in part upon obtaining and maintaining patent and trade secret protection for Edge's product candidates, including components of Edge's proprietary formulations, methods of manufacturing Edge's product candidates, delivery systems, and methods of treating patients with Edge's product candidates, as well as successfully defending Edge's patent rights against third party challenges. Edge's ability to prevent or stop third parties

from making, using, selling, offering to sell or importing Edge's product candidates will depend in part upon whether Edge has valid and enforceable patent rights that cover the activities of third parties.

Patent Rights

Edge has been building Edge's patent portfolio. Where possible, Edge has pursued multi-tiered patent protection for Edge's product candidates and their manufacture, delivery and use. In addition to filing and prosecuting patent applications in the United States, Edge has filed counterpart patent applications in various countries and regions where Edge thinks such foreign filing is likely to be cost-effective.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which Edge files, the patent term is 20 years from the earliest date of filing of a non-provisional patent application, with up to an additional five-year patent term extension available for regulatory delay. In the United States, a patent's term may also be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office, or USPTO, in granting a patent. However, the term of a United States patent may be shortened, if the patent term for a patent is terminally disclaimed by its owner, over another patent.

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Patent Rights Associated with EG-1962

Edge wholly-owns one issued U.S. patent (expected to expire in 2029 if all maintenance fees are paid) directed to a method of treating a cerebral vasospasm in a human by administering a pharmaceutical composition via surgical injection into the subarachnoid space in a cistern closest to a cerebral artery at risk for vasospasm. Edge also has been granted patent protection for this invention in Australia (3), Canada, China, Germany, Great Britain, France, Switzerland, Spain, Israel, Japan, Korea (3), New Zealand (2) and Singapore.

Edge has wholly-owned patents (expected to expire in 2032 if all maintenance fees are paid) directed to a method of treating, and a microparticulate delivery system for treating, a delayed complication associated with brain injury where the brain injury includes interruption of at least one cerebral artery in Germany, Spain, France, United Kingdom, Italy and Hong Kong; a notice of allowance has issued in Israel.

Edge also has a wholly-owned U.S. patent (expected to expire in 2029 if all maintenance fees are paid) claiming a method of treating a cerebral artery in the subarachnoid space of a human at risk of interruption due to a brain injury by administering locally a microparticulate composition into a cerebral ventricle. Patent protection for these inventions has been granted in Australia, China, Switzerland, Germany, France, United Kingdom, Japan, New Zealand, Russia and Singapore.

Edge also has a wholly-owned U.S. patent (expected to expire in 2029 if all maintenance fees are paid) claiming a method for treating a delayed complication of a brain injury that deposits blood in a subarachnoid space of the brain, wherein the brain injury is mediated by decreased cerebral perfusion, comprising providing a flowable particulate composition comprising a microparticulate suspension containing a calcium channel antagonist and a pharmaceutically acceptable carrier comprising an agent that affects viscosity of the microparticulate suspension of claimed release characteristics, and a drug load of at least 40%; and administering the composition locally either intracisternally, intraventricularly or intrathecally. Patent protection for this invention has been granted in New Zealand and United Kingdom.

In addition to the foregoing, Edge has used Edge’s Precisa development platform, in collaboration with Evonik Industries, or Evonik, to seek to develop pharmaceutical compositions that contain particular polymorphic forms of nimodipine. Based on the collaboration, Edge co-owns, together with Evonik, two issued U.S. patents claiming a process for producing microparticles encapsulating a particular polymorphic form of nimodipine, a semisolid delivery system containing microparticles comprising the particular polymorphic form of nimodipine, and a method of treating a cerebral artery in a subarachnoid space at risk of interruption due to a brain injury using such a delivery system. These patents are expected to expire in 2033 if all maintenance fees are paid. Edge also co-owns, with Evonik, related patents granted in Australia, Canada, Japan, Korea, New Zealand and Singapore. The issued U.S. patents cover the microparticulate formulation used in the NEWTON study. Evonik, as successor to SurModics Pharmaceuticals, Inc., or SurModics, under Edge’s license agreement initially with SurModics, has granted Edge an exclusive, field-restricted, worldwide, royalty-bearing license under its patent rights together with enforcement rights against infringers, all pursuant to Edge’s license agreement with Evonik relating to the co-owned patent rights.

Manufacturing

Edge has no present intention to manufacture EG-1962 or any other product. Edge currently has (1) an amended and restated master formulation development agreement and (2) a manufacturing and supply agreement, each for EG-1962 and each with Oakwood Laboratories, or Oakwood, but no work is being performed under either agreement.

Competition

Edge has no current plans to further develop or commercialize its portfolio of products. However, to the extent the merger with PDS results in the further development of the candidates in its portfolio, potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Key competitive factors are likely to be efficacy, safety and tolerability profile, convenience of dosing, price and reimbursement. Many of these potential competitors have substantial financial, technical and human resources and significant experience in the discovery and development of product candidates, obtaining United States Food and Drug Administration, or FDA, approval and other regulatory approvals of products and the commercialization of those products. Further, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of competitors. Accordingly, competitors may be more successful in obtaining FDA approval for therapies and achieving widespread market acceptance. Competitors' products may also be more effective, or more effectively marketed and sold, than any product candidate that may be commercialized and may render Edge' therapies obsolete or non-competitive before development and commercialization expenses can be recovered.

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Government Regulation

Government authorities in the United States at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of new drugs.

A number of different regulatory agencies may be involved, depending on the product at issue, and the type and stage of activity. These include the FDA, the Drug Enforcement Administration, the Centers for Medicare and Medicaid Services, other federal agencies, state boards of pharmacy, state-controlled substance agencies and more.

U.S. Government Regulation

Drug Development Process

In the United States, the FDA is a primary regulator of drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. The process of obtaining regulatory approvals and other compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with applicable requirements at any time during the drug development process, approval process, or after approval, may subject Edge to adverse consequences and administrative or judicial sanctions, any of which could have a material adverse effect on Edge. These sanctions could include refusal to approve pending applications; withdrawal or restriction of an approval; imposition of a clinical hold or other limitation on research; warning letters; product seizures; total or partial suspension of development, production, or distribution; or injunctions, fines, disgorgement, or civil or criminal payments or penalties.

The process required before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal trials and formulation trials conducted according to Good Laboratory Practices, animal welfare laws and other applicable regulations;

submission to the FDA of an Investigational New Drug, or IND, application which must become effective before clinical trials (trials in human subjects) in the United States may begin, obtaining similar authorizations in other jurisdictions where clinical research will be conducted and maintaining these authorizations on a continuing basis throughout the time that trials are performed and new data are collected;

performance of adequate and well-controlled clinical trials according to Good Clinical Practices to demonstrate whether a proposed drug is safe and effective for its proposed intended use;

preparation and submission to the FDA of a marketing authorization application, such as a new drug application, or NDA, and submitting similar marketing authorization applications in other jurisdictions where commercialization will be pursued;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product will be produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity; and

FDA review and approval of the NDA or other marketing authorization application.

The development, testing and approval process requires substantial time, effort and financial resources, as well as bearing inherent risk that individual products will not exhibit relevant safety, effectiveness, or quality characteristics. Edge cannot be certain that any approvals for its product candidates will be granted on a timely basis, or with the

specific terms that Edge desires, if at all.

Foreign Regulation

In addition to regulations in the United States, Edge is subject to a variety of foreign regulations governing clinical trials, and governing any future distribution and commercial sales, if any, of Edge' products. Whether or not FDA approval is obtained for a drug candidate, the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, must approve commencement of clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

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Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunction, viral diseases or orphan medicinal products, and optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization based on the favorable scientific opinion of the European Medicines Agency that is valid for all European Union member states and the European Economic Area Countries (Norway, Iceland and Liechtenstein) through the EEA Treaty. The decentralized procedure provides for national approval to be granted in more than two or more member states based on an assessment of an application performed by the Member State leading the scientific evaluation, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether or not to approve the assessment report and related materials. If a member state does not accept the assessment of the reference member state on grounds relating to potential serious risk to public health, the points of disagreement are first referred to the coordination group on mutual recognition and decentralized procedures where all the member states are required to use their best endeavors to reach agreement on the action to be taken. If the Member States fail to reach an agreement within 60 days in the referral to the coordination group, the application will be referred to the European Medicines Agency for arbitration which will lead to a binding decision to be adopted by the European Commission.

The above overview describes the current drug approval framework in the European Union. In 2016, the United Kingdom voted to leave the European Union, commonly referred to as "Brexit". The Brexit implementation process is complex and ongoing. When finalized, Brexit may have implications on the drug approval framework in the European Union. The specifics of the potential impact of Brexit on the drug approval process are unclear at this time.

Employees

As of December 31, 2018, Edge had 10 full-time employees. Edge has no collective bargaining agreements with Edge's employees and has not experienced any work stoppages.

Corporate and Available Information

Edge was incorporated in Delaware in 2009. Edge completed the initial public offering of Edge's common stock in October 2015. Edge's common stock is currently listed on The Nasdaq Global Select Market under the symbol "EDGE." Edge is an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, and therefore Edge is currently subject to reduced public company reporting requirements.

Edge's principal executive offices are located at 300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922, and Edge's telephone number is (800) 208-3343.

You may find on Edge's website (http://www.edgetherapeutics.com) electronic copies of Edge's annual report on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K (and any amendments thereto) filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on Edge's website as soon as reasonably possible after they are filed with the Securities and Exchange Commission, or SEC. Edge's current charters for Edge's audit, compensation, and nominating and corporate governance committees and Edge's Code of Ethics are available on Edge's website as well. Any waiver of Edge's Code of Ethics may be made only by Edge's Board of Directors. You can read Edge's SEC filings over the internet at the SEC's web site at www.sec.gov.

ITEM 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes appearing elsewhere in this Annual Report, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and our future prospects would likely be materially and adversely affected. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

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Risks Related to the Merger

The ratio setting forth the number of shares of Edge common stock that will be issued in respect of each outstanding share of PDS capital stock, or the Exchange Ratio, is not adjustable based on the market price of Edge common stock so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

The Merger Agreement has set the Exchange Ratio for the PDS common stock, and the Exchange Ratio is only adjustable upward or downward based on increases or decreases in the number of shares of PDS's issued and outstanding capital stock and the number of shares of PDS common stock issuable upon the exercise of all issued and outstanding equity awards, increases or decreases the number of Edge's issued and outstanding common stock, if the cash balances at closing of either Edge or PDS fall outside a pre-determined range, and the proposed reverse stock split, prior to the closing of the merger. The Exchange Ratio will depend on the exact reverse stock split ratio that is ultimately mutually determined by Edge and PDS and certain changes in the capitalization of the two companies, as well as the cash balances of both companies relative to the agreed upon ranges. If there is a significant divergence in the cash balances of either company relative to the agreed upon ranges there could be a material change to Exchange Ratio, which would affect the stockholders of one party at the expense of the other party. The longer it takes to complete the merger, the greater the possibility there is for the Company's cash balances to fall outside of the range. Any changes in the market price of Edge common stock before the closing of the merger will not affect the number of shares PDS securityholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the closing of the merger the market price of Edge common stock declines from the market price on the date of the Merger Agreement, then PDS stockholders could receive merger consideration with substantially lower value. Similarly, if before the closing of the merger the market price of Edge common stock increases from the market price on the date of the Merger Agreement, then PDS stockholders could receive merger consideration with substantially more value for their shares of PDS common stock than the parties had negotiated for in the establishment of the Exchange Ratio. Because the Exchange Ratio does not adjust as a result of changes in the value of Edge common stock, for each one percentage point that the market value of Edge common stock rises or declines, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration issued to PDS stockholders.

Failure to complete the merger may result in Edge paying a termination fee or expenses to PDS and could harm the common stock price of Edge and future business and operations of each company.

If the merger is not completed, Edge and PDS are subject to the following risks:

if the Merger Agreement is terminated under certain circumstances and certain events occur, Edge will be required to pay PDS a termination fee of $1.75 million;

the price of Edge stock may decline and remain volatile; and

costs related to the merger, such as legal, accounting and investment banking fees which Edge and PDS estimate will total approximately $5.3 million, of which $3.5 million must be paid even if the merger is not completed.

In addition, if the Merger Agreement is terminated and the Edge Board determines to seek another business combination, there can be no assurance that Edge or PDS will be able to find a partner willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the merger.

If the conditions to the merger are not met, the merger may not occur.

Even if the proposals referred to herein are approved by the stockholders of Edge and PDS, specified other conditions must be satisfied or waived to complete the merger. These conditions are set forth in the Merger Agreement. Edge and PDS cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the merger may not occur or will be delayed, and Edge and PDS each may lose some or all of the intended benefits of the merger.

The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes or other causes.

In general, either Edge or PDS can refuse to complete the merger if there is a material adverse change affecting the other party between November 23, 2018, the date of the Merger Agreement, and the closing. However, certain types of changes do not permit either party to refuse to complete the merger, even if such change could be said to have a material adverse effect on Edge or PDS, including:

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any effect, change, event, circumstance or development in general economic or business conditions generally affecting the industries in which PDS or Edge operate;

any act of war, armed hostilities or terrorism;

any changes in financial, banking or securities markets;

the taking of any action required to be taken by the Merger Agreement;

any changes in accounting requirements or principles or any change in applicable laws, rules or regulations or the interpretation thereof;

any effect resulting from the announcement or pendency of the merger or any related transactions;

with respect to Edge, any change in the stock price or trading volume of Edge common stock; or

with respect to Edge, any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies.

If adverse changes occur and Edge and PDS still complete the merger, the combined company stock price may suffer. This in turn may reduce the value of the merger to the stockholders of Edge and PDS.

The combined company will need to raise additional capital by issuing securities or debt or through licensing arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or proprietary rights.

The combined company may be required to raise additional funds sooner than currently planned. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing or other strategic arrangements, it may be necessary to grant licenses on terms that are not favorable to the combined company or otherwise restrict its operations.

Certain Edge and PDS executive officers and directors have interests in the merger that are different from yours and that may influence them to support or approve the merger without regard to your interests.

Certain officers and directors of Edge and PDS will participate in arrangements that provide them with interests in the merger that are different from yours, including, among others, the continued service as officers and/or directors of the combined company, severance and retention benefits, the acceleration of stock options and continued indemnification.

Furthermore, in connection with the closing of the merger, all unvested options to acquire shares of Edge common stock and Edge RSUs (including those held by Edge officers and the Edge Board members (including Edge RSUs for 10,000 shares of Edge common stock held by each of Robert Spiegel, M.D., FACP, and James J. Loughlin, who are expected to remain on the combined company's board of directors, and stock options for 220,607 and 64,286 shares of Edge common stock held by Dr. Spiegel and Mr. Loughlin, respectively)) will vest in full. The exercise price of all unvested stock option awards held by the Edge Board members and officers was above the trading price of Edge

common stock as of December 31, 2018. Additionally, the parties expect that Dr. Sol Barer will enter into a consulting arrangement in connection with serving as an advisor to the board of directors of the combined company.

In addition, certain of Edge's executive officers are expected to become executive officers of the combined company upon the closing of the merger. Specifically, Andrew Saik is expected to serve as Chief Financial Officer of the combined company, and W. Bradford Middlekauff is expected to serve as Senior Vice President, General Counsel and Secretary of the combined company. Additionally, James Loughlin and Robert Spiegel, each of whom is a current director of Edge, and Andrew Saik, the Chief Financial Officer of Edge, are expected to be designated to serve on the combined company's board of directors following the closing of the merger.

Additionally, certain of PDS's directors and executive officers are expected to become directors and executive officers of the combined company upon the closing of the merger. Specifically, Frank Bedu-Addo, Ph.D. is expected to serve as the Chief Executive Officer, Lauren Wood, MD is expected to serve as Chief Medical Officer and Gregory Conn, Ph.D. is expected to serve as the Chief Scientific Officer of the combined company. Additionally, each of Frank Bedu-Addo, Ph.D., DeLyle Bloomquist, Sir Richard Sykes and Gregory Freitag, each of whom is a current director of PDS, are expected to be designated to serve on the combined company's board of directors following the closing of the merger.

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In addition, certain of PDS's executive officers and directors and affiliates of PDS's directors currently hold shares of PDS common stock and preferred stock. Affiliates of certain PDS directors and certain executive officers of PDS will convert their unsecured subordinated convertible promissory notes into shares of PDS common stock prior to the closing of the merger pursuant to the note purchase agreement.

The market price of the combined company's common stock following the merger may decline as a result of the merger.

The market price of the combined company's common stock may decline as a result of the merger for a number of reasons including if:

investors react negatively to the prospects of the combined company's business and prospects from the merger;

the effect of the merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or

the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts.

Edge and PDS stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the merger, Edge and PDS securityholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the merger.

During the pendency of the merger, Edge and PDS may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede the ability of Edge and PDS to make acquisitions, subject, in the case of Edge, to certain exceptions relating to fiduciary duties, or complete other transactions that are not in the ordinary course of business pending the closing of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets or other business combination outside the ordinary course of business, with any third-party, subject to, in the case of Edge, certain exceptions. Any such transactions could be favorable to such party's stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Edge and PDS from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except, with respect to Edge, in certain circumstances where the Edge Board determines in good faith, after consultation with its financial advisor and outside legal counsel, that an unsolicited alternative takeover proposal constitutes or is reasonably likely to result in a superior takeover proposal. In addition, if Edge or PDS terminate the Merger Agreement under certain circumstances, including terminating because of a decision of a board of directors to recommend an alternative proposal, Edge would

be required to pay a termination fee of $1.75 million to the other party. These termination fees and reimbursement obligations described above may discourage third parties from submitting alternative takeover proposals to Edge and its stockholders, and may cause the Edge Board to be less inclined to recommend an alternative proposal.

The lack of a public market for PDS shares makes it difficult to determine the fair market value of the PDS shares, and PDS stockholders may receive consideration in the merger that is less than the fair market value of the PDS shares and/or Edge may pay more than the fair market value of the PDS shares.

PDS is privately held and its capital stock is not traded in any public market. The lack of a public market makes it extremely difficult to determine PDS's fair market value. Because the percentage of Edge equity to be issued to PDS stockholders was determined based on negotiations between the parties, it is possible that the value of the Edge common stock to be received by PDS stockholders will be less than the fair market value of PDS, or Edge may pay more than the aggregate fair market value for PDS.

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Risks Related to the Merger and Edge's Evaluation of Strategic Alternatives

If the merger is not completed, Edge may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed transaction with PDS, or at all, and Edge may be unable to reestablish an operating business. The Edge Board may decide to pursue a dissolution and liquidation of Edge. In such an event, the amount of cash available for distribution to Edge's stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

On March 28, 2018, Edge announced that an independent Data Monitoring Committee, or the DMC, for Edge's NEWTON 2 clinical trial for EG-1962 recommended that the NEWTON 2 study be stopped based on the DMC's conclusion that the study has a low probability of meeting its primary endpoint. Based on the DMC recommendation, Edge decided to discontinue the NEWTON 2 study and has taken steps to notify health authorities and clinical investigators participating in the study. Edge has ceased all further development of EG-1962 and Edge's other product candidates and has implemented operating cost reductions and organizational restructurings, including a reduction in Edge's workforce, to preserve Edge's cash resources. Edge's strategic focus shifted to the identification and evaluation of a range of potential strategic alternatives designed to maximize stockholder value.

In April 2018, Edge engaged Piper Jaffray as Edge's advisor to assist with the exploration of strategic alternatives. Edge devoted substantial time and resources to exploring such strategic alternatives.

To date, Edge's current assets consist primarily of cash, cash equivalents and marketable securities, Edge's clinical assets, Edge's listing on the Nasdaq Global Market and the Merger Agreement with PDS. While Edge has entered into the Merger Agreement with PDS, the closing of the merger with PDS may be delayed or may not occur at all and there can be no assurance that the merger will deliver the anticipated benefits Edge expects or enhance shareholder value.

If Edge is unable to consummate the merger with PDS, the Edge Board may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed merger with PDS. Attempting to complete an alternative transaction will be costly and time consuming, and Edge can make no assurances that such an alternative transaction would occur at all. Alternatively, the Edge Board may elect to continue operations to conduct another study of EG-1962 or decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to Edge's stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as Edge continues to fund its operations. In addition, if the Edge Board was to approve and recommend, and Edge's stockholders were to approve, a dissolution and liquidation of the company, Edge would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to Edge's stockholders. Edge's commitments and contingent liabilities may include severance obligations, regulatory and clinical obligations remaining under Edge's NEWTON 2 study, fees and expenses related to the merger and liabilities relating to investigations of or litigation against Edge and other various claims and legal actions. As a result of this requirement, a portion of Edge's assets may need to be reserved pending the resolution of such obligations. In addition, Edge may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, the Edge Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Edge common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

Failure to obtain stockholder approval for the proposed reverse stock split may result in the combined company being unable to obtain compliance with minimum bid price requirements for an initial listing on any Nasdaq market tier and may result in Edge common stock being delisted from the Nasdaq Global Select Market.

Edge is required pursuant to the terms of the Merger Agreement to submit to its stockholders a proposal to approve an amendment to its certificate of incorporation to authorize the Edge Board to effect a reverse stock split of all outstanding shares of its common stock, or the Reverse Stock Split Proposal. If the Reverse Stock Split Proposal is not approved by Edge's stockholders, the combined company will likely not be able to obtain compliance with the minimum bid price requirement for an initial listing on any Nasdaq market tier and, as a consequence, to the extent the merger is consummated under such circumstances, Nasdaq will immediately provide the combined company with written notification that the combined company's common stock will be delisted.

Upon receipt of such delisting letter, the combined company will likely appeal the determination to the Nasdaq hearings panel, or the Hearing Panel. If the combined company has not regained compliance with Nasdaq listing requirements prior to such hearing, and the Hearing Panel decides to continue with delisting of the combined company, the Hearing Panel's decision may be appealed to the Nasdaq Listing and Hearing Review Council but such appeal would not stay the delisting process.

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The issuance of shares of Edge common stock to PDS stockholders in the merger will dilute substantially the voting power of Edge's current stockholders.

If the merger is completed, each outstanding share of PDS common stock will be converted into the right to receive a number of shares of Edge common stock equal to the Exchange Ratio determined pursuant to the Merger Agreement. Immediately following the merger, Edge securityholders are expected to own approximately 30% of the outstanding capital stock of the combined company on a fully diluted basis, and PDS securityholders are expected to own approximately 70% of the outstanding capital stock of the combined company on a fully diluted basis. Accordingly, the issuance of shares of Edge common stock to PDS stockholders in the merger will reduce significantly the relative voting power of each share of Edge common stock held by Edge's current securityholders. Consequently, Edge securityholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger.

If the combined company after the merger is unable to realize the strategic and financial benefits currently anticipated from the merger, the Edge stockholders and the PDS stockholders will have experienced substantial dilution of their ownership interests in their respective companies without receiving the expected commensurate benefit, or receiving only part of the commensurate benefit to the extent the combined company is able to realize only part of the expected strategic and financial benefits currently anticipated from the merger.

The pendency of the merger could have an adverse effect on the trading price of Edge common stock and Edge's business, financial condition, results of operations or business prospects.

While there have been no significant adverse effects to date, the pendency of the merger could disrupt Edge's businesses in the following ways, including:

the attention of Edge's management may be directed toward the closing of the merger and related matters and may be diverted from the day-to-day business operations; and

third parties may seek to terminate or renegotiate their relationships with Edge as a result of the merger, whether pursuant to the terms of their existing agreements with Edge or otherwise.

Should they occur, any of these matters could adversely affect the trading price of Edge common stock or harm Edge's financial condition, results of operations or business prospects.

Stockholder litigation and regulatory inquiries and investigations are expensive and could harm Edge's business, financial condition and operating results and could divert management attention.

In the past, securities class action litigation and/or stockholder derivative litigation and inquiries or investigations by regulatory authorities have often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, such as the merger, or the announcement of negative events, such as negative results from clinical trials. Edge is currently and may in the future be the target of this type of litigation as a result of changes in Edge's stock price, past transactions, results of clinical trials or other matters. Any stockholder litigation and/or regulatory investigations against Edge, whether or not resolved in Edge's favor, could result in substantial costs and divert Edge's management's attention from other business concerns, which could adversely affect Edge's business and cash resources and Edge's ability to consummate a potential strategic transaction or the ultimate value Edge's stockholders receive in any such transaction.

Edge is substantially dependent on Edge's remaining employees to facilitate the consummation of a strategic transaction.

On May 1, 2018, Edge announced that it planned to reduce its workforce by 29 to a total of eight full-time employees. Edge's ability to successfully complete a strategic transaction depends in large part on Edge's ability to retain certain of its remaining personnel. Despite Edge's efforts to retain these employees, one or more may terminate their employment with Edge on short notice. The loss of the services of any of these employees could potentially harm Edge's ability to consummate the merger, to run Edge's day-to-day operations, as well as fulfill Edge's reporting obligations as a public company.

There is no assurance that the proposed merger will be completed in a timely manner or at all. If the merger is not consummated, Edge's business could suffer materially and its stock price could decline.

The closing of the proposed merger is subject to a number of closing conditions, including the approval by Edge's stockholders of the issuance of shares of Edge common stock pursuant to the Merger Agreement and the proposed reverse stock split of Edge common stock and other customary closing conditions. If the conditions are not satisfied or waived, the merger will not occur or will be delayed.

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If the proposed merger is not consummated, Edge may be subject to a number of material risks, and Edge's business and stock price could be adversely affected, as follows:

Edge has incurred and expects to continue to incur significant expenses related to the proposed merger even if the merger is not consummated;

Edge could be obligated to pay PDS a termination fee of up to $1.75 million under certain circumstances pursuant to the Merger Agreement;

the market price of Edge common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed; and

Edge may not be able to pursue an alternate merger transaction if the proposed merger with PDS is not completed.

Risks Related to Development and Regulatory Approval

Edge may not be able to successfully develop or obtain regulatory approval for EG-1962 or any other product candidate.

Edge has ceased all research and development activities for EG-1962 and its other product candidates. Edge currently has no drug products for sale and may never be able to develop marketable drug products. If Edge were to resume research and development activities, EG-1962 will require substantial additional clinical development, testing, and regulatory approval before Edge will be permitted to commence its commercialization. No clinical studies have been undertaken with respect to Edge's only other product candidates, EG-1964 and EG-1965. If Edge were to resume research and development activities, the clinical studies of Edge's product candidates will be, and the manufacturing and marketing of Edge's product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where Edge intends to investigate and, if approved, market any product candidate. If Edge were to resume research and development activities, before obtaining regulatory approvals for the commercial sale of any product candidate, Edge would have to successfully meet a number of critical developmental milestones. For example, for EG-1962, these would include:

providing adequate and well-controlled data that the product candidate is safe and effective and shows a significant benefit over the active comparator in patients for the intended indication;

demonstrating that the product candidate formulation is reproducible and can meet the relevant release specifications for each market Edge intends to commercialize in; and

completing the development and scale-up to permit manufacture of Edge's product candidates in commercial quantities and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain.

If Edge were to resume research and development activities, Edge may not be able to finalize the design or formulation of any product candidate. In addition, if Edge were to resume research and development activities, Edge may select components, solvents, excipients or other ingredients to include in its product candidates that have not previously been used in approved pharmaceutical products, which may require Edge to perform additional studies and may delay clinical testing and regulatory approval of its product candidates. If Edge were to resume research and development activities, Edge may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period, and may not be able to

commercialize and earn revenue from any products candidates. Moreover, even if a product candidate can be approved, it could be blocked by competitor patents or exclusivities.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are inherently unpredictable, and, to the extent Edge resumes research and development activities, if Edge's product candidates are subject to multiple cycles of review or Edge is ultimately unable to obtain regulatory approval for its product candidates, Edge's business will be substantially harmed. In addition, the regulatory approval processes can delay clinical trials, which can jeopardize the ability to generate revenues from the sale of products.

Of the large number of drugs in development in the United States, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Edge has ceased all research and development activities for EG-1962 and its other product candidates but to the extent that Edge resumes research and development activities, Edge will not be permitted to market any of product candidates in the United States or in other global markets unless and until Edge receives approval of an NDA from the FDA or the requisite approval from such other global regulatory authorities. Successfully completing clinical studies and obtaining approval of an NDA is complex, lengthy, and expensive. The FDA or a comparable foreign regulatory authority may delay, limit or deny approval of product candidates for many reasons, including, among others:

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disagreement with, or disapproval of, the design of, procedures for, or implementation of, clinical trials;

the inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

disagreement with the sufficiency of the final content and data included in a marketing application;

feedback from the FDA or a comparable foreign regulatory authority on results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol;

a decision by the FDA or a comparable foreign regulatory authority to suspend or terminate clinical trials at any time for safety issues or for any other reason;

challenges in meeting regulatory requirements to commence clinical trials in countries outside the United States;

failure to conduct the trial in accordance with regulatory requirements;

failure to demonstrate that the product candidate provides an overall benefit to risk or significant enough improvement over the comparator in the proposed indication;

failure of the product candidate to demonstrate efficacy at the level of statistical significance required for approval;

a negative interpretation of the data from preclinical studies or clinical trials;

deficiencies in the manufacturing processes or failure of third party manufacturing facilities to effectively and consistently manufacture product or to pass FDA pre-approval facility inspection;

failure to demonstrate adequate and reproducible product stability to support product commercialization;

failure to adequately demonstrate process performance qualification prior to product commercialization;

inability to validate analytical and microbiological methods consistent with industry and government agency expectations; or

changes in governmental regulations or administrative actions.

Further, if Edge were to resume research and development activities and experiences delays in the completion of, or termination of, any clinical trial of product candidates, the commercial prospects of those product candidates will be harmed, and Edge’s ability to generate product revenues will be delayed or may not happen at all, which circumstances may significantly harm Edge’s business, financial condition and prospects.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials and non-head-to-head analysis (e.g., historical comparisons) may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Many companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, failure by the study drug to demonstrate sufficiently improved efficacy over a comparator arm, or adverse safety profiles, notwithstanding

promising results in earlier trials. If Edge were to resume research and development activities, Edge's future clinical trials may not be successful.

To the extent Edge were to resume research and development activities, even if a product candidate receives regulatory approval, it may still face future development and regulatory challenges and any approved products will be subject to extensive post-approval regulatory requirements.

To the extent Edge were to resume research and development activities and in the future obtains regulatory approval for a product candidate, Edge would be subject to extensive ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of Edge's product candidates, these regulatory authorities may require labeling changes or, depending on the nature of the safety information, establishment of a Risk Evaluation and Mitigation Strategy, impose significant restrictions on a product's indicated uses or marketing, impose ongoing requirements for potentially costly post-approval studies or post-market surveillance, cause a recall or even move to withdraw the marketing approval for the product.

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In addition, manufacturers of therapeutic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with applicable regulations, including a focused pre-approval inspection in connection with any regulatory submission for approval. If Edge or a regulatory agency discover previously unknown problems with a product, such as problems with the facility where the product is manufactured, a regulatory agency may take regulatory actions against the manufacturing facility or Edge, leading to a product recall or withdrawal, or suspension of manufacturing.

If Edge, Edge's product candidates or the manufacturing facilities for Edge's product candidates fail to comply with applicable regulatory requirements, Edge's ability to commercialize Edge's products and generate revenue may be significantly limited.

Advertising and promotion of any product candidate that obtains approval in the United States may be heavily scrutinized by the FDA, including the Office of Prescription Drug Promotion, the Department of Justice, or the DOJ, the Department of Health and Human Services, Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of products for unapproved (or off-label) uses, may be subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, engaging in impermissible promotion of products, including for off-label uses, can also subject companies to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company can promote or distribute a drug product. These false claims statutes include the False Claims Act, or FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid, and other federal and state healthcare programs. If Edge does not lawfully promote any approved products, Edge may become subject to such litigation and, if Edge is not successful in defending against such actions, those actions may have a material adverse effect on Edge's business, financial condition and results of operations.

Failure to obtain regulatory approval in international jurisdictions would prevent Edge's product candidates from being marketed abroad.

To the extent Edge were to resume research and development activities, and in the future obtains regulatory approval for a product candidate, in order to market and sell Edge's products in the EU, Canada, Japan and other international jurisdictions, Edge would have to obtain separate and distinct marketing approvals and comply with the respective regulatory requirements of each of these jurisdictions. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval, but can involve additional testing or safety surveillance. Edge may need to partner with third parties in order to obtain regulatory approvals outside the United States. Approval by the FDA does not necessarily guarantee approval by regulatory authorities in other countries or jurisdictions. Nor does the approval by one regulatory authority outside the United States ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Edge may not be able to file for marketing approvals and may not receive necessary approvals to commercialize Edge's products in any market. If Edge is unable to obtain approval of any product candidates by regulatory authorities in the EU, Canada, and other international jurisdictions, the commercial prospects of those product candidates may be significantly diminished and Edge's

business prospects could dramatically decline.

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Risks Related to Edge's Business and Industry

To the extent Edge were to resume research and development activities, Edge's future success will depend on Edge's ability to attract, retain and motivate qualified personnel.

Edge does not have the resources or the required expertise to develop any of its potential product candidates. To the extent Edge were to seek to resume research and development activities, because of the specialized scientific nature of Edge's business, it would need to hire additional qualified scientific personnel. The competition for qualified personnel in the pharmaceutical field is intense and, as a result, Edge may be unable to attract qualified personnel necessary for the future development of Edge's business.

The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render Edge's technologies and products obsolete or uncompetitive.

If Edge were to resume research and development activities, there is no assurance that Edge's product candidates will be the most effective, the safest, the first to market, or the most economical to make or use. The introduction of competitive therapies as alternatives to any of Edge's product candidates could dramatically reduce the value of those development projects or chances of successfully commercializing those product candidates, which could have a material adverse effect on Edge's long-term financial success.

Edge's business and operations would suffer in the event of system failures.

Despite the implementation of security measures, the servers of Edge's cloud-based computing providers and other systems, and those of other third parties on which Edge relies, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in Edge's operations, it could result in a material disruption of Edge's drug development programs if Edge were to resume research and development activities. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in Edge's regulatory approval efforts and significantly increase Edge's costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to Edge's data or applications, or inappropriate disclosure of confidential or proprietary information, Edge could incur liability and the further development of Edge's product candidates could be delayed.

Any future collaborators may compete with Edge or have interests which conflict with Edge's. This may restrict any future research and development efforts.

If Edge were to resume research and development activities, large pharmaceutical companies with whom Edge may seek to collaborate may have internal programs or enter into collaborations with Edge's competitors for products addressing the same medical conditions targeted by Edge's technologies. Thus, such collaborators may pursue alternative technologies or product candidates in order to develop treatments for the diseases or disorders targeted by Edge's collaborative arrangements. Such collaborators may pursue these alternatives either on their own or in collaboration with others, including Edge's competitors. Depending on how other product candidates advance, a corporate partner may slow down or abandon its work on Edge's product candidates or terminate its collaborative arrangement with Edge in order to focus on these other prospects.

If any conflicts arise, Edge's future collaborators may act in their own interests, which may be adverse to Edge. In addition, in Edge's future collaborations, Edge may be required to agree not to conduct any research that is competitive with the research conducted under Edge's future collaborations. Edge's future collaborations may have the effect of limiting the areas of research that Edge may pursue. Edge's collaborators may be able to develop products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Business disruptions could seriously harm Edge's financial condition and increase Edge's costs and expenses.

Edge's operations could be subject to natural disasters, power shortages, telecommunications failures, water shortages, fires, medical epidemics and other manmade disasters or business interruptions, for which Edge or they are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm Edge's financial condition and increase Edge's costs and expenses.

Edge's employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on Edge's business.

Edge is exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to Edge. Edge has adopted, implemented, and is enforcing a code of conduct, or Code of Conduct, and other compliance-based policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions Edge takes to detect and prevent this activity, such as employee training on enforcement of the Code of Conduct and other policies and procedures, may not be effective in controlling unknown or unmanaged risks or losses or in protecting Edge from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against Edge, and Edge is not successful in defending itself or asserting Edge's rights, those actions could have a significant impact on Edge, including the imposition of significant fines or other sanctions.

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Risks Related to Edge's Intellectual Property

If Edge is unable to protect Edge's intellectual property rights, Edge's competitive position could be harmed.

If Edge were to resume research and development activities, Edge will depend on its ability to protect its proprietary technology. Edge relies on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. If Edge were to resume research and development activities, Edge's success will depend in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to Edge's proprietary technology and products.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of Edge's patents are highly uncertain.

The steps Edge has taken to police and protect Edge's proprietary rights may not be adequate to preclude misappropriation of Edge's proprietary information or infringement of Edge's intellectual property rights, both inside and outside the United States. The rights already granted under any of Edge's currently issued/granted patents and those that may be granted under future issued/granted patents may not provide Edge with the proprietary protection or competitive advantages Edge may seek in the future. If Edge is unable to obtain and maintain patent protection for Edge's technology and products, or if the scope of the patent protection obtained is not sufficient, Edge's competitors could develop and commercialize technology and products similar or superior to Edge's, and Edge's ability to successfully commercialize Edge's technology and products may be adversely affected.

Although Edge has a number of issued/granted patents, the issuance/grant of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and issued/granted patents that Edge owns or has licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit Edge's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for Edge's technology and products.

Protecting against the unauthorized use of Edge's patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of Edge's intellectual property rights, even in relation to issued/granted patent claims, and proving any such infringement may be even more difficult.

Edge could be required to incur significant expenses to obtain Edge's intellectual property rights, and Edge cannot ensure that Edge will obtain meaningful patent protection for its products.

The patent prosecution process is expensive and time-consuming, and Edge or any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, if Edge were to resume research and development activities, it is also possible that Edge or Edge's licensors will fail to identify patentable aspects of further inventions made in the course of Edge's development and commercialization activities before they are publicly disclosed, making it too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of Edge's patents or narrow the scope of Edge's patent protection. The laws of foreign countries may not protect Edge's rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change.

Obtaining and maintaining Edge's patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and Edge's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued/granted patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If Edge or Edge's licensors fail to maintain the patents and patent applications covering any of Edge's product candidates, Edge's competitors might be able to enter the market, which would have a material adverse effect on Edge's business.

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Edge may become involved in lawsuits to protect or enforce Edge's intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe Edge's patents or misappropriate or otherwise violate Edge's intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend Edge's intellectual property rights, to protect Edge's trade secrets or to determine the validity and scope of Edge's own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming and results can be uncertain. Many of Edge's current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than Edge can. Accordingly, despite Edge's efforts, Edge may not be able to prevent third parties from infringing upon or misappropriating Edge's intellectual property, particularly in certain parts of the world. Litigation could result in substantial costs and diversion of management resources, which could harm Edge's business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, Edge is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that Edge's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of Edge's patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Edge's confidential information could be compromised by disclosure during this type of litigation. If any of these occur, Edge's business could be materially and adversely affected.

From time to time Edge may need to rely on licenses to proprietary technologies, which may be difficult, expensive or not possible to obtain or Edge may lose certain licenses which may be difficult or not possible to replace.

If Edge were to resume research and development activities, Edge may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market Edge's product candidates. If Edge is unable to timely obtain these licenses on commercially reasonable terms and maintain these licenses, Edge's ability to commercially market Edge's product candidates may be inhibited or prevented, which could have a material adverse effect on Edge's business, results of operations, financial condition and cash flows.

Third parties may initiate legal proceedings alleging that Edge is infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of Edge's business.

If Edge were to resume research and development activities, Edge's commercial success will depend upon Edge's ability to develop, manufacture, market and sell Edge's product candidates, and to use Edge's proprietary technologies without infringing the proprietary rights of third parties. Edge may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to Edge's products and technology, including interference (for patents with an effective date before March 16, 2013) and various post grant proceedings before the USPTO, and opposition proceedings at other patent offices. Third parties may assert infringement claims against Edge based on existing patents or patents that may be granted in the future. In the event a third party were to assert an infringement claim against Edge and Edge were ultimately found to infringe the third party's intellectual property rights, Edge could be required to obtain a license from such third party to continue developing and commercializing Edge's products and technology. However, Edge may not be able to obtain an appropriate license on commercially reasonable terms or at all. Even if Edge is able to obtain a license, it may be non-exclusive, thereby giving Edge's competitors access to the same technologies licensed to Edge. Edge could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, Edge could be found liable for monetary damages. A finding of infringement could prevent Edge from commercializing Edge's product candidates or force Edge to cease some of Edge's business operations, which could materially harm Edge's business. Any claims by third parties that Edge has misappropriated their confidential information or trade secrets could have a similar negative impact on Edge's business.

Edge’s trade secrets are difficult to protect.

Confidentiality agreements with employees and others may not adequately prevent disclosure of Edge’s trade secrets and other proprietary information and may not adequately protect Edge’s intellectual property.

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If Edge were to resume research and development activities, Edge's success will depend upon the skills, knowledge and experience of Edge's scientific and technical personnel, Edge's consultants and advisors as well as Edge's partners, licensors and contractors. Because Edge operates in a highly competitive technical field of drug discovery, Edge relies in part on trade secrets to protect Edge's proprietary technology and processes. However, trade secrets are difficult to protect. Edge enters into confidentiality and invention assignment agreements with Edge's employees and certain of Edge's corporate partners, consultants, sponsored researchers and other advisors. These agreements generally require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party by Edge during the course of the receiving party's relationship with Edge. These confidentiality and assignment agreements may be breached and may not effectively assign intellectual property rights to Edge.

Edge's trade secrets also could be independently discovered by competitors, in which case Edge would not be able to prevent use of such trade secrets by Edge's competitors. The enforcement of a claim alleging that a party illegally obtained and was using Edge's trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain meaningful trade secret protection could adversely affect Edge's competitive position.

Edge may be subject to claims that Edge's employees or consultants have wrongfully used or disclosed alleged trade secrets of their former employers or other third parties.

Many of Edge's employees and consultants were previously employed at other biotechnology or pharmaceutical companies, including Edge's competitors or potential competitors. Some of these employees, including each member of Edge's senior management, and consultants executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although Edge tries to ensure that Edge's employees and consultants do not use the proprietary information or know-how of others in their work for Edge, Edge may be subject to claims that Edge or these employees and consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or consultant's former employer. Edge is not aware of any threatened or pending claims related to these matters or concerning the agreements with Edge's senior management, but in the future, litigation may be necessary to defend against such claims. If Edge fails in defending any such claims, in addition to paying monetary damages, Edge may lose valuable intellectual property rights or personnel. Even if Edge is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property disputes could cause Edge to spend substantial resources.

Even if resolved in Edge's favor, litigation or other legal proceedings relating to intellectual property claims may cause Edge to incur significant expenses. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of Edge's common stock. Such litigation or proceedings could substantially increase Edge's operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Edge may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of Edge's competitors may be able to sustain the costs of such litigation or proceedings more effectively than Edge can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Edge's ability to compete in the marketplace.

Edge may not be able to protect Edge's intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of Edge's product candidates throughout the world could be prohibitively expensive.

Competitors may use Edge's technologies in jurisdictions where Edge has not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where Edge has patent protection, but where enforcement is not as strong as that in the United States. These products may compete with any of Edge's future products, to the extent Edge resumes research and development activities, in jurisdictions where Edge does not have any issued/granted patents and Edge's patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for Edge to stop the infringement of Edge's patents or marketing of competing products in violation of Edge's proprietary rights generally. Proceedings to enforce Edge's patent rights in foreign jurisdictions could result in substantial cost and divert Edge's efforts and attention from other aspects of Edge's business and will have uncertain outcomes.

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Risks Related to Edge's Financial Position and Capital Needs

Edge has incurred significant losses since Edge's inception and anticipates that Edge will continue to incur losses for the foreseeable future.

Edge is a clinical-stage biotechnology company. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. Edge has not generated any revenue from product sales to date, and Edge continues to incur expenses related to Edge's ongoing operations. As a result, Edge is not profitable and has incurred losses in each period since inception in 2009. For the years ended December 31, 2018 and December 31, 2017, Edge reported a net loss of $40.9 million and $50.9 million, respectively.

Edge expects to continue to incur losses for the foreseeable future. Edge may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect Edge's business. Edge's prior losses and expected future losses have had and will continue to have an adverse effect on Edge's stockholders' (deficit) equity and working capital.

Edge has not generated any revenues since inception and may never become profitable.

Edge has not generated any revenues since Edge's inception. If Edge were to resume research and development activities, even if Edge is able to successfully achieve regulatory approval for any product candidates, Edge does not know when any of these products will generate revenue for Edge, if at all.

If Edge were to resume research and development activities, Edge will require additional capital to fund Edge's operations and if Edge fails to obtain necessary financing, Edge will not be able to complete the development and commercialization of Edge's product candidates.

Edge's operations have consumed substantial amounts of cash since inception. If Edge were to resume research and development activities, Edge will require additional capital for the further development and commercialization of Edge's product candidates.

Under such circumstances Edge cannot be certain that additional funding will be available on acceptable terms, or at all. If Edge is unable to raise additional capital in sufficient amounts or on terms acceptable to Edge, Edge may have to significantly delay, scale back or discontinue the development or commercialization of one or more of Edge's products or product candidates or one or more of Edge's other research and development initiatives.

Raising additional capital may cause dilution to Edge's stockholders, restrict Edge's operations or require Edge to relinquish rights to Edge's technologies or product candidates.

If Edge were to resume research and development activities, Edge may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that Edge raises additional capital through the sale of equity or convertible debt securities, Edge's then-existing stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of then-existing stockholders. Debt financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of Edge's then-existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on Edge's ability to incur additional debt, limitations on Edge's ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact Edge's ability to conduct Edge's business and may result in liens being placed on Edge's assets and intellectual property. If Edge were to default on such indebtedness, Edge could lose such assets and intellectual

property. If Edge raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, Edge may have to relinquish valuable rights to Edge's product candidates, or grant licenses on terms that are not favorable to Edge.

Risks Related to Ownership of Edge's Common Stock

The trading market in Edge's common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the Nasdaq Global Select Market.

Prior to Edge's initial public offering, or IPO, there was no market for shares of Edge's common stock. Since Edge's initial listing on the Nasdaq Global Select Market on October 1, 2015, the trading market in Edge's common stock has been limited and substantially less liquid than the average trading market for companies quoted on the Nasdaq Global Select Market. The quotation of Edge's common stock on the Nasdaq Global Select Market does not assure that a meaningful, consistent and liquid trading market currently exists. Edge cannot predict whether a more active market for Edge's common stock will develop in the future. An absence of an active trading market could adversely affect Edge's stockholders' ability to sell Edge's common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for Edge's common stock may be limited and such lack of visibility may have a depressive effect on the market price for Edge's common stock. As of December 31, 2018, approximately 41% of Edge's outstanding shares of common stock was held by Edge's officers, directors, beneficial owners of 5% or more of Edge's capital stock and their respective affiliates, which adversely affects the liquidity of the trading market for Edge's common stock, inasmuch as federal securities laws restrict sales of Edge's shares by these stockholders under certain circumstances. If Edge's affiliates continue to hold their shares of common stock, there will be limited trading volume in Edge's common stock, which may make it more difficult for investors to sell their shares or increase the volatility of Edge's stock price.

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If Edge fails to continue to meet all applicable Nasdaq Global Select Market requirements and Nasdaq determines to delist Edge's common stock, the delisting could adversely affect the market liquidity of Edge's common stock and the market price of Edge's common stock could decrease.

Edge's common stock is listed on The Nasdaq Global Select Market. In order to maintain Edge's listing, Edge must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that Edge is not characterized as a "public shell company." Edge has received written notice from Nasdaq stating that, at present, Edge is not in compliance with the audit committee requirements for continued listing on The Nasdaq Global Select Market, because Edge currently has an audit committee comprised of two members. If Edge does not regain compliance with audit committee requirements in a timely manner, Nasdaq will provide written notification to Edge that Edge's securities will be subject to delisting. In addition, Edge has received written notice from Nasdaq stating that, at present, Edge is not in compliance with the bid price requirements for Edge's common stock because the bid price for Edge's common stock had closed below $1.00 per share for 30 consecutive business days. If Edge does not regain compliance with the bid price requirements in a timely manner, Nasdaq will provide written notification to Edge that Edge's securities will be subject to delisting.

Nasdaq has notified Edge that, in connection with the Merger, Edge will be required to submit a new listing application and meet Nasdaq's initial listing requirements, as opposed to Nasdaq's more lenient continued listing requirements. Edge cannot provide any assurance that it will meet the initial listing requirements at the closing of the Merger. If the merger is consummated, the combined company following such transaction will need to meet Nasdaq's initial listing standards. If Edge is unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist Edge's common stock from The Nasdaq Global Select Market or other of Nasdaq's trading markets. If Edge's common stock is delisted for any reason, it could reduce the value of Edge's common stock and its liquidity.

Market volatility may affect Edge's stock price and the value of Edge's stockholders' investment.

The trading price of Edge's common stock, similar to other biotechnology companies, is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond Edge's control, including, among others:

regulatory actions with respect to Edge;

the recruitment or departure of key personnel;

announcements by Edge or Edge's competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

regulatory or legal developments in the United States and other countries;

developments or disputes concerning patent applications, issued/granted patents or other proprietary rights;

the level of Edge's expenses;

actual or anticipated changes in estimates as to financial results;

variations in Edge's financial results or those of companies that are perceived to be similar to Edge;

fluctuations in the valuation of companies perceived by investors to be comparable to Edge;

share price and volume fluctuations attributable to inconsistent trading volume levels of Edge's shares;

announcement or expectation of additional financing efforts;

sales of Edge's common stock by Edge, Edge's insiders or Edge's other stockholders;

market conditions in the pharmaceutical and biotechnology sectors; and

general economic, industry and market conditions.

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In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of Edge's common stock, regardless of Edge's actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of Edge's common stock.

Future sales of a substantial number of shares of Edge's common stock in the public market or other issuances of Edge's common stock or rights to purchase common stock, including pursuant to equity incentive plans could result in additional dilution of the percentage ownership of Edge's stockholders and could cause Edge's stock price to fall.

Edge's stock price could also decline as a result of sales of a large number of shares of Edge's common stock, including shares issuable upon exercise of stock options and warrants, or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for Edge to sell equity securities in the future at a time and at a price that Edge deems appropriate.

As of December 31, 2018, the holders of up to 3,290,905 shares, or 10.4%, of Edge's common stock outstanding, will have rights, subject to some conditions, to require Edge to file registration statements covering the sale of their shares or to include their shares in registration statements Edge may file for itself or other stockholders. Once Edge registers the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market.

In addition, in the future, Edge may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements, or otherwise. Any such issuance could result in substantial dilution to Edge's then-existing stockholders and could cause Edge's stock price to decline.

Future issuances of Edge's common stock or rights to purchase common stock, including pursuant to Edge's equity incentive plans, could result in additional dilution of the percentage ownership of Edge's stockholders and could cause Edge's stock price to fall.

Any future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and warrants to purchase 7,632,383 shares of common stock as of December 31, 2018 and any additional shares issued in connection with acquisitions, if any, may result in material dilution to Edge's then-existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of Edge's common stock.

Edge's principal stockholders and management own a significant percentage of Edge's stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2018, Edge's executive officers, directors, holders of 5% or more of Edge's capital stock and their respective affiliates beneficially owned approximately 41% of Edge's outstanding voting stock (assuming no exercise of outstanding stock options). These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of Edge's organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for Edge's common stock that Edge's then-existing stockholders' may feel are in their best interest. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their

common stock, and might affect the prevailing market price for Edge's common stock.

Some provisions of Edge's charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of Edge by others, even if an acquisition would be beneficial to Edge's stockholders and may prevent attempts by Edge's stockholders to replace or remove Edge's current management.

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Provisions in Edge's amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire Edge or increase the cost of acquiring Edge, even if doing so would benefit Edge's stockholders, or remove Edge's current management. These provisions include:

authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of Edge's stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders;

establishing a staggered board of directors; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by Edge's stockholders to replace or remove Edge's current management by making it more difficult for stockholders to replace members of Edge's board of directors, who are responsible for appointing the members of Edge's management. Because Edge is incorporated in Delaware, Edge is governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring Edge or merging with Edge whether or not it is desired by or beneficial to Edge's stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of Edge's amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for Edge's stockholders to receive a premium for their shares of Edge's common stock, and could also affect the price that some investors are willing to pay for Edge's common stock.

Because Edge does not anticipate paying any cash dividends on Edge's capital stock in the foreseeable future, capital appreciation, if any, will be Edge's stockholders' sole source of gain.

Edge has never declared or paid cash dividends on Edge's capital stock. Edge currently intends to retain all of Edge's future earnings, if any, to finance Edge's business. In addition, any future debt agreements may preclude Edge from paying dividends. As a result, capital appreciation, if any, of Edge's common stock will be Edge's stockholders' sole source of gain for the foreseeable future.

Edge is an "emerging growth company" and Edge intends to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in Edge's common stock being less attractive to investors.

Edge is an "emerging growth company," as defined in the JOBS Act, and Edge intends to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in Edge's periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote

on executive compensation and stockholder approval of any golden parachute payments not previously approved. Edge cannot predict if investors will find Edge's common stock less attractive because Edge will rely on these exemptions. Edge may take advantage of these reporting exemptions until Edge is no longer an emerging growth company, which could potentially be for up to five years after the date of Edge's IPO, which occurred on October 1, 2015. If investors find Edge's common stock less attractive as a result of Edge's reduced reporting requirements, there may be a less active trading market for Edge's common stock and Edge's stock price may be more volatile. Edge may also be unable to raise additional capital as and when Edge needs it.

If Edge fails to maintain an effective system of internal control over financial reporting in the future, Edge may not be able to accurately report Edge's financial condition, results of operations or cash flows, which may adversely affect investor confidence in Edge and, as a result, the value of Edge's common stock.

The Sarbanes-Oxley Act requires, among other things, that Edge maintain effective internal controls for financial reporting and disclosure controls and procedures. Edge's annual report on Form 10-K includes a report by management on, among other things, the effectiveness of Edge's internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by Edge's management in Edge's internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from Edge's independent registered public accounting firm on the effectiveness of Edge's internal control over financial reporting. However, for as long as Edge remains an emerging growth company as defined in the JOBS Act, Edge intends to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

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Edge's compliance with Section 404 requires that Edge incur additional accounting expense and management efforts. Edge currently does not have an internal audit group. Edge may not be able to complete any required Section 404 evaluation, testing and remediation in a timely fashion. During the evaluation and testing process, if Edge identifies one or more material weaknesses in Edge's internal control over financial reporting, Edge will be unable to assert that Edge's internal control over financial reporting is effective. Edge cannot assure Edge's stockholders that there will not be material weaknesses or significant deficiencies in Edge's internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit Edge's ability to accurately report Edge's financial condition, results of operations or cash flows. If Edge is unable to conclude that Edge's internal control over financial reporting is effective, or if Edge's independent registered public accounting firm determines Edge has a material weakness or significant deficiency in Edge's internal control over financial reporting, Edge could lose investor confidence in the accuracy and completeness of Edge's financial reports, the market price of Edge's common stock could decline, and Edge could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in Edge's internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict Edge's future access to the capital markets.

Edge's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Edge's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by Edge in reports Edge files or submits under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Edge believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in Edge's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to the Combined Company

If the merger with PDS closes, the combined company will be subject to additional risks, including each of those described below.

The combined company's stock price is expected to be volatile, and the market price of its common stock may drop following the merger.

The market price of the combined company's common stock following the merger could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

the ability of the combined company or its partners to develop product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;

the ability of the combined company or its partners to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;

failure of any of the combined company's product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;

failure by the combined company to maintain its existing third-party license, manufacturing and supply agreements;

failure by the combined company or its licensors to prosecute, maintain, or enforce its intellectual property rights;

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changes in laws or regulations applicable to the combined company's product candidates;

any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;

adverse regulatory authority decisions;

introduction of new or competing products by its competitors;

failure to meet or exceed financial and development projections the combined company may provide to the public;

the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by the combined company or its competitors;

disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined company's ability to obtain intellectual property protection for its technologies;

additions or departures of key personnel;

significant lawsuits, including intellectual property or stockholder litigation;

if securities or industry analysts do not publish research or reports about the combined company, or if they issue an adverse or misleading opinions regarding its business and stock;

changes in the market valuations of similar companies;

general market or macroeconomic conditions;

sales of its common stock by the combined company or its stockholders in the future;

trading volume of the combined company's common stock;

adverse publicity relating to the combined company's markets generally, including with respect to other products and potential products in such markets;

changes in the structure of health care payment systems; and

period-to-period fluctuations in the combined company's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation.

Edge and PDS do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings, if any, to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be your sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing stockholders of Edge and PDS sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after legal restrictions on resale lapse, the trading price of the common stock of the combined company could decline. Based on shares outstanding as of December 31, 2018 and shares expected to be issued upon the closing of the merger, the combined company is expected to have outstanding a total of approximately 101 million shares of common stock (prior to giving effect to the proposed reverse stock split) immediately following the closing of the merger. Approximately 36 million of such shares of common stock (prior to giving effect to the proposed reverse stock split) will be freely tradable, without restriction, in the public market. Approximately 65 million of such shares of common stock (prior to giving effect to the proposed reverse stock split) will be held by directors, executive officers of the combined company and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements.

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If the ownership of the combined company common stock is highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company stock price to decline.

Executive officers and directors of the combined company and their affiliates are expected to beneficially own or control approximately 59.6% of the outstanding shares of the combined company common stock following the closing of the merger. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the combined company, even if such a change of control would benefit the other stockholders of the combined company. The significant concentration of stock ownership may adversely affect the trading price of the combined company's common stock due to investors' perception that conflicts of interest may exist or arise.

Because the merger will result in an ownership change under Section 382 of the Code for Edge, pre-merger U.S. net operating loss carryforwards and certain other tax attributes will be subject to limitations.

As of December 31, 2018, Edge had federal and state net operating loss carryforwards, or NOLs, of $128.6 million and $27.2 million, respectively, due to prior period losses. If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's U.S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state and foreign tax laws. Edge believes that it may have already undergone one or more ownership changes prior to the merger. The merger will also result in an ownership change for Edge and, accordingly, Edge's U.S. net operating loss carryforwards and certain other tax attributes will be subject to limitations on their use after the merger.

Changes in tax laws and regulations or in the combined company's operations may impact the combined company's effective tax rate and may adversely affect the combined company's business, financial condition and operating results.

Changes in tax laws in any jurisdiction in which combined company operates, or adverse outcomes from any tax audits that the combined company may be subject to in any such jurisdictions, could result in an unfavorable change in Edge's effective tax rate, which could adversely affect Edge's business, financial condition, and operating results.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The changes included in the Tax Act are broad and complex. The impact of these changes on how the combined company's earnings are taxed include, among other items, (i) reducing the U.S. federal corporate tax rate from 35% to 21%; (ii) repealing the corporate alternative minimum tax and changing how existing credits can be utilized; (iii) temporarily providing for elective immediate expensing for certain depreciable property; (iv) creating a new limitation on the deductibility of interest expense; and (v) changing rules related to uses and limitations of net operating losses created in tax years beginning after December 31, 2017. Edge and PDS continue to evaluate the Tax Act and its impact on the combined company's businesses. It is possible that the Tax Act will be subject to further changes either in a technical corrections bill or entirely new legislation. The overall impact of the Tax Act also depends on the future interpretations and regulations that may be issued by U.S. tax authorities. Edge expects there will be further guidance provided by these authorities potentially having a material adverse effect on the combined company's financial condition or results of operations. The impact of broad proposals or of regulatory issuances on the combined company's business can vary substantially depending upon the specific changes or further guidance made and how the changes or guidance are implemented by the authorities.

Anti-takeover provisions under Delaware law could make an acquisition of the combined company more difficult and may prevent attempts by the combined company stockholders to replace or remove the combined company management.

Because the combined company will be incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with the combined company. Although Edge and PDS believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the combined company's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined company's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

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ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our corporate headquarters consists of approximately 20,410 square feet of office space located at 300 Connell Drive, Berkeley Heights, New Jersey, that we occupy under a 63 month lease which ends in November of 2021. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms.

ITEM 3. Legal Proceedings

From time to time in the ordinary course of our business, we are subject to claims, legal proceedings and disputes.

On April 23, 2018, a purported securities class action complaint was filed against Edge, Brian Leuthner (Edge's President and Chief Executive Officer) and Andrew Saik (Edge's Chief Financial Officer) in the United States District Court for the District of New Jersey, captioned Sanfilippo v. Edge Therapeutics, Inc., Case No. 2:18-cv-8236. The complaint alleged that Edge, Mr. Leuthner and Mr. Saik violated Section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements concerning Edge's business, operations and prospects by failing to disclose that Edge's developmental product EG-1962 allegedly would likely fail a futility analysis. The complaint also asserted a "control" person claim against Mr. Leuthner and Mr. Saik pursuant to Section 20(a) of the Exchange Act. The complaint was brought on behalf of all purchasers of Edge's common stock between December 27, 2017, and March 27, 2018, and sought unspecified damages. On December 7, 2018, the court appointed Sam Kirkpatrick and Amos Bakouple lead plaintiffs for the putative class and appointed the firm Glancy, Prongay & Murray LLP lead counsel for the putative class. On February 14, 2019, the lead plaintiffs voluntarily dismissed the action, without prejudice, as to all defendants.

Edge and the Edge Board have been named as defendants in two individual lawsuits and two putative class action lawsuits regarding the potential merger, each of which alleges that the registration statement on Form S-4 (Registration No. 333-228937) filed by the Edge on December 21, 2018 omitted material information with respect to the proposed transaction, which rendered the registration statement on Form S-4 false or misleading. The case captioned Michael Condon v. Edge Therapeutics et al., case no. 2:19-cv-00152, or the Condon Action, was filed on January 4, 2019 in the United States District Court for the District of New Jersey. The case captioned Adam Franchi et al. v. Edge Therapeutics et al., case no. 1:19-cv-00058-UNA, or the Franchi Action, was filed on January 9, 2019 in the United States District Court for the District of Delaware. The case captioned Jeffrey L. Prince v. Edge Therapeutics et al., case no. 1:19-cv-00280, or the Prince Action, was filed on January 10, 2019 in the United States District Court for the Southern District of New York. The case captioned Brian Foldenauer et al. v. Edge Therapeutics et al., case no. 1:19-cv-00280, or the Foldenauer Action, was filed on January 22, 2019 in the United States District Court for the District of Delaware.

The causes of action set forth in each of the Condon Action, the Franchi Action, the Prince Action and the Foldenauer Action are (i) a claim against Edge and the Board for violations of Section 14(a) of the Exchange Act, as well as (ii) a claim against the Board for violations of Section 20(a) of the Exchange Act. In the Franchi Action, PDS was also named as a defendant in respect of the claim regarding violations of Section 20(a) of the Exchange Act. In each case, the plaintiffs seek, among other things, injunctive relief, rescissory damages, and an award of attorneys' fees and expenses.

Edge has voluntarily accepted service of process in the Franchi Action and Prince Action, but has not yet been served with process in the Condon Action or the Foldenauer Action. On January 18, 2019, the plaintiffs in the Prince Action

filed a motion for a preliminary injunction barring any stockholder vote on the proposed merger until revised disclosures are made to Edge's stockholders, and withdrew the motion for a preliminary injunction on February 1, 2019. Edge believes the litigation is without merit and in any event has been rendered moot by amendment no. 1 to the Registration Statement on S-4 filed by Edge on January 25, 2019 and subsequent disclosures. This litigation remains in the initial pleadings phase.

ITEM 4. Mine Safety Disclosures

Not applicable.

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PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Market Information

On October 1, 2015, our common stock began trading on the Nasdaq Global Market under the symbol "EDGE". Prior to that time, there was no public market for our common stock. Shares sold in our initial public offering on October 1, 2015 were priced at $11.00 per share.

On February 14, 2019, the closing price for our common stock as reported on the Nasdaq Global Market was $0.39. The following table sets forth the high and low sales prices per share of our common stock as reported on the Nasdaq Global Market for the period indicated.

Year Ended December 31, 2018	High	Low
Fourth Quarter	$1.09	$0.31
Third Quarter	$1.10	$0.70
Second Quarter	$1.28	$0.87
First Quarter	$17.47	$1.18

Year Ended December 31, 2017	High	Low
Fourth Quarter	$11.16	$9.07
Third Quarter	$11.51	$9.20
Second Quarter	$10.72	$8.81
First Quarter	$12.99	$7.62

Stockholders

As of February 14, 2019, there were 36 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Use of Proceeds from Registered Securities

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 invested the net proceeds in short-term, investment-grade, interest-bearing cash equivalents.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS AS OF DECEMBER 31, 2018

Plan category	(A) Number of securities to be issued upon exercise	(B) Weighted-average exercise price of outstanding options, warrants	(C) Number of securities remaining available for future issuance under equity compensation plans (excluding securities

	of outstanding options, warrants and rights	and rights ($)	reflected in column (A))
Equity compensation plans approved by security holders	7,238,787	5.41	136,228
Equity compensation plans not approved by security holders	315,003	8.35	-
Total	7,553,787	5.68	136,228

ITEM 6. Selected Financial Data

We are a smaller reporting company; as a result, we are not required to report selected financial data disclosures as required by Item 301 of Regulation S-K.

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ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Annual Report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report.

The Company is a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel therapies capable of transforming treatment paradigms in the management of medical conditions. On March 28, 2018, the Company announced that a pre-specified interim analysis performed on data from the Day 90 visit of the first 210 subjects randomized and treated in the Phase 3 multi-center, randomized, double-blind, placebo-controlled NEWTON 2 study of EG-1962 in adults with aneurysmal subarachnoid hemorrhage demonstrated a low probability of achieving a statistically significant difference compared to the standard of care in the study's primary endpoint, if the study were to be fully enrolled. The independent Data Monitoring Committee ("DMC") for the NEWTON 2 study recommended that the study be stopped based on this demonstration. The DMC also reported that there were no safety concerns attributed to EG-1962. Based on the DMC recommendation, the Company decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study.

On April 30, 2018, the Company announced that it was exploring strategic alternatives that might have included, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of the Company, a sale of stock, a strategic merger or other business combination transaction or other transaction between the Company and a third party. The Company retained Piper Jaffray & Co. to serve as the financial advisor to its Board of Directors in certain aspects of the process. The Company has reduced the scope of its operations, including the size of its workforce, in order to preserve its cash resources.

After a comprehensive review of strategic alternatives, on November 23, 2018, the Company, Merger Sub and PDS entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into PDS, with PDS surviving the merger as the wholly-owned subsidiary of the combined company. PDS is a private company with a growing pipeline of clinical-stage immunotherapies that are expected to treat various early-stage cancers, including head and neck cancer, cervical cancer, anal cancer, prostate cancer, breast cancer and other cancers. Following the merger, the combined company expects to focus on developing PDS's growing pipeline of next-generation cancer immunotherapies based on the proprietary, multi-functional Versamune® technology platform, the development of PDS0101 for the treatment of multiple human papilloma virus (HPV)-induced cancers, including cervical, anal and head and neck cancers, and multiple preclinical programs developing Versamune®-based cancer immunotherapies in combination with checkpoint inhibitors for various late-stage cancers.

The Company has never been profitable and has incurred net losses in each year since inception. The Company's net losses were $40.9 million, and $50.9 million for the years ended December 31, 2018 and 2017 respectively. As of December 31, 2018, the Company had an accumulated deficit of $192.8 million. From the Company's inception, it has devoted substantially all of its efforts to business planning, engaging regulatory, manufacturing and other technical consultants, acquiring operating assets, planning and executing clinical trials and raising capital. The Company's future operations are highly dependent on the success of its transaction with PDS. The Company has ceased research and development on EG-1962, including the completion of the NEWTON 2 study, and all of its other product candidates.

Furthermore, the Company expects to incur additional costs associated with operating as a public company. Accordingly, at least until the Company can generate significant revenue from product sales, the Company will seek to fund its operations through public or private equity or debt financings or other sources. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all.

As of December 31, 2018, the Company had $34.6 million in cash and cash equivalents.

Financial Operations Overview

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 Expenses

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.

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The following table summarizes our research and development expenses incurred for the periods indicated (in thousands):

	Year Ended December 31,	
	2018	2017
EG-1962 product candidate	$9,504	$22,075
EG-1964 product candidate	5	640
Pipeline	188	371
Internal Operating Expenses	6,372	11,226
Total	$16,069	$34,312

Following the DMC's recommendation that the NEWTON 2 Trial for EG-1962 be stopped, we decided to discontinue the NEWTON 2 study and took steps to notify health authorities and clinical investigators participating in the study. We have ceased all further research and development activities for EG-1962 and suspended research for our other product candidates and implemented operating cost reductions and organizational restructurings, including a reduction in the our workforce, to preserve our cash resources and better align the organization with our current operating plan.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, business development and support functions. Other general and administrative expenses include travel expenses, professional fees for auditing, tax and legal services and facility-related costs.

The following table summarizes our general and administrative expenses incurred for the periods indicated (in thousands):

	Year Ended December 31,	
	2018	2017
General and administrative expenses	$14,291	$17,655

As was mentioned in "Research and Development Expenses" above, we have implemented operating cost reductions and organizational restructurings, including a reduction in the Company's workforce, to preserve its cash resources and better align the organization with its current operating plan.

Restructuring Expenses

Restructuring expenses consist of charges related our company reorganization including severance, financial advisor fees, legal fees and retention compensation. Restructuring expenses amounted to $9.9 million for the year ended 2018.

Impairment charges

Impairment charges reflects the charge to the write-down of machinery and equipment no longer needed as a consequence of ceasing research and development on EG-1962.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

Interest Expense

Interest expense consists of interest expense on our borrowings under the Amended Loan Agreement with Hercules. The loan was repaid in full in June 2018.

Critical Accounting Policies and Significant Judgments 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.

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While our significant accounting policies are described in the notes to our financial statements appearing in this Annual Report, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Income Taxes

We file U.S. federal income tax returns and New Jersey state tax returns. Our deferred tax assets are primarily comprised of federal and state tax net operating losses and tax credit carryforwards and are recorded using enacted tax rates expected to be in effect in the years in which these temporary differences are expected to be utilized. At December 31, 2018, we had federal net operating loss, or NOL, carryforwards of approximately $101.5 million, which expire at various dates between 2029 and 2038, and $27.1 million generated in 2018 will have an indefinite carryforward period. At December 31, 2018, we had federal research and development credits carryforwards of approximately $2.3 million and Orphan Drug credit of approximately $24.4 million. We 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 our value immediately before the ownership change, changes to our capital during a specified period prior to the change, and the federal published interest rate. Although we have not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

On December 22, 2017, H.R. 1 (also known as the Tax Cuts and Jobs Act (the “Tax Act”)) was signed into law. Among its numerous changes to the Internal Revenue Code, the Tax Act reduces U.S. federal corporate tax rate to 21%. As a result, the most significant impact on its consolidated financial statements was the reduction of approximately $13.6 million for the deferred tax assets related to net operating losses and other assets. Such reduction was offset by changes to the Company’s valuation allowance as of December 31, 2017. We previously provided a provisional estimate of the effect of the Tax Act in our financial statements. In the fourth quarter of 2018, we completed our analysis to determine there was no additional effect of the Tax Act as of December 31, 2018.

Accrued Clinical Expenses

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones.

When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred.

As of December 2018, we have agreed with our clinical research organization on the final wind-down costs of our EG-1962 study and have recorded the expense in 2018.

Stock-based Compensation

We estimate the fair value of our stock-based option awards to employees and non-employees using the Black-Scholes option-pricing model, which requires the input of assumptions, including: (1) the expected volatility of our stock, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends. In accordance with FASB ASC 505, we re-measure the fair value of non-employee stock-based compensation as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered. We believe that all stock options issued under our stock option plans meet the criteria of “plain vanilla” stock options. The expected term of the options outstanding was determined using the “simplified” method as prescribed by Staff Accounting Bulletin, No. 107, Share Based Payment. The risk-free interest rate is based on U.S. Treasury notes with remaining terms similar to the expected term of the option. The volatility was based on a representative group of small publicly traded drug development companies. The dividend yield assumption is zero since we have never paid cash dividends and have no present intention to pay cash dividends.

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The fair value of options granted for the periods indicated was estimated using the Black-Scholes option valuation model utilizing the following assumptions:

	Year Ended December 31,	
	2018 Weighted Average	2017 Weighted Average
Volatility	86.33%	88.87%
Risk-Free Interest Rate	2.23%	1.88%
Expected Term in Years	6.00	6.00
Dividend Rate	0.00%	0.00%
Fair Value of Option on Grant Date	$5.08	$ 6.93

Basic and Diluted Net Loss Per Share of Common Stock

We compute basic and diluted net loss per share of common stock 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, unvested RSUs 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.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	Year Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
	(in thousands)			
Operating expenses:				
Research and development expenses	$16,069	$34,312	$(18,243)	(53)%
General and administrative expenses	14,291	17,655	(3,364)	(19)%
Restructuring expenses	9,914	–	9,914	100%
Impairment charges	2,823	–	2,823	100%
Total operating expenses	43,097	51,967	(8,870)	(17)%
Loss from operations	(43,097)	(51,967)	8,870	(17)%
Interest income (expense), net	(553)	(1,479)	926	(63)%
Loss before income taxes	(43,650)	(53,446)	9,796	(18)%
Benefit for income taxes	2,782	2,586	196	8%
Net loss and comprehensive loss	$(40,868)	$(50,860)	$9,992	(20)%

Research and Development Expenses

Research and development expenses decreased to $16.1 million in the year ended December 31, 2018 from $34.3 million for the same period in 2017. The decrease of $18.2 million in 2018 was primarily attributable to a decrease in external expenses for the clinical studies of $13.4 million and R&D internal department costs of $4.8 million resulting from the discontinuance of the clinical studies and reduction in force.

General and Administrative Expenses

General and administrative expenses decreased to $14.3 million in the year ended December 31, 2018 from $17.7 million for the same period in 2017. The $3.4 million decrease was due primarily to decreases in personnel costs of $0.8 million, facilities $0.2 million, travel $0.2 million, marketing of $1.1 million and legal and professional fees of $1.1 million.

Restructuring Expenses

Restructuring expenses amounted to $9.9 million for the year ended December 31, 2018, related to the previously announced discontinuance of the NEWTON 2 study. The components consisted of $4.4 million for severance benefits, $2.3 million for financial advisory fees, $1.4 million for legal fees and $1.8 million for retention compensation.

Impairment Charges

The charge in 2018 reflects the impairment charge to the write-down of machinery and equipment no longer needed as a consequence of ceasing research and development on EG-1962.

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Interest Income and Expense, net

Interest income and expense, net decreased primarily due to reduced interest expense for our loan of $0.7 million resulting from paying off the loan in June 2018 offset by an increase in interest income from interest earned on our cash and cash equivalents of $0.2 million.

Benefit for Income Taxes

Benefit for income taxes increased as a result of selling additional New Jersey Net Operating Losses in 2018 as compared to 2017.

Liquidity and Capital Resources

Since our inception and through December 31, 2018, 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, $17.4 million net proceeds from a registered direct common stock offering and $20.0 million from a loan. As of December 31, 2018, we had total cash and cash equivalents of $34.6 million as compared to $88.1 million as of December 31, 2017. The $53.5 million decrease in total cash and cash equivalents was due to repayment of debt totaling $20.9 million and to the funding of operations, which mainly consisted of research and development activities and general and administrative expenses offset by proceeds from exercise of stock options.

On October 6, 2015, we completed the IPO of our common stock for aggregate gross proceeds of $92.5 million. We received $82.8 million in net proceeds after deducting underwriting discounts and commissions and other offering costs of $9.7 million. In connection with the IPO, all preferred stock was converted into common stock. There is no preferred stock outstanding as of December 31, 2018.

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

In April 2018, we announced that we plan to explore strategic alternatives for the Company in order to maximize both near and long-term value for our shareholders, which might have included, without limitation, an acquisition of another company, acquisitions or in-licensing of products or product candidates, technologies or other assets, the sale of all or substantially all of the assets of the Company, a sale of stock, a strategic merger or other business combination transaction or other transaction between the Company and a third party. In April 2018, the Edge Board retained Piper to serve as its financial advisor in certain aspects of the strategic review process. Throughout the strategic alternatives process, we have financed our operations with our existing cash. Our ability to continue to support our operations is dependent, in the near-term, upon managing our cash resources as we pursue such strategic alternatives. We have ceased research and development on EG-1962, other than the wind-down of the NEWTON 2 study, and all of our other product candidates.

On November 23, 2018, Edge, Merger Sub and PDS, a privately-held clinical-stage cancer immunotherapy company, entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into PDS, with PDS surviving the merger as the wholly-owned subsidiary of the combined company.

If the merger is completed, the business of Edge will become the business of PDS. If the merger is not completed, Edge will reconsider its strategic alternatives and may pursue one of the following courses of action, which Edge currently believes are the most likely alternatives if the merger with PDS is not completed:

Pursue another strategic transaction similar to the merger. Edge may resume its process of evaluating other companies interested in pursuing a strategic transaction with Edge and, if a candidate is identified, focus its attention on negotiating and completing such a transaction with such candidate.

Dissolve and liquidate its assets. If Edge is unable, or does not believe that it is able, to find a suitable candidate for another strategic transaction, Edge may dissolve and liquidate its assets. In the event of dissolution, Edge would be required to pay all of its debts and contractual obligations and to set aside certain reserves for potential future claims. If Edge dissolves and liquidates its assets, there can be no assurance as to the amount or timing of available cash that will remain for distribution to Edge' stockholders after paying Edge' debts and other obligations and setting aside funds for its reserves.

Hercules Loan and Security 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. ("Hercules"). Pursuant to the Amended Loan Agreement, the Company was able to 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. Pursuant to the Amended Loan Agreement, in March 2018, the Company made a payment of $90,000, which is equal to 1.5% of the total amounts funded under the Original Loan Agreement.

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In June 2018, the Company paid off its entire outstanding debt under the Amended Loan Agreement. The payment consisted of $20.0 million for the principal amount, an additional $0.9 million in back-end fees and $0.1 million in accrued and unpaid interest.

As of June 30, 2018, there were no future principal payments due under the Amended Loan Agreement.

Cash flows

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

	Year Ended December 31,	
	2018	2017
Net cash used in operating activities	$(33,153)	$(40,697)
Net cash used in investing activities	–	(188)
Net cash (used in) provided by financing activities	(20,269)	22,554
Net decrease in cash	$(53,422)	$(18,331)

Net Cash Used in Operating Activities

Net cash used in operating activities was $33.2 million and $40.7 million for the years ended December 31, 2018 and 2017, respectively. The decrease in cash used in operating activities of $7.5 million was primarily due to the reduction of operating activities as compared to the prior year.

Net Cash Used in Investing Activities

Net cash used in investing activities in 2017 relates entirely to purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash used in financing activities of $20.3 million for the year ended December 31, 2018 was due to the repayment of debt and debt fees totaling $21.0 million offset by receipt of net proceeds from exercise of stock options of $0.7 million.

Net cash provided by financing activities of $22.6 million for the year ended December 31, 2017 was primarily due to the receipt of net proceeds from the issuance of common stock of $17.4 million and debt of $5.0 million.

Operating Capital Requirements

Our future capital requirements are difficult to forecast. We expect that our research and development expenses will decrease significantly due to the discontinuation of the NEWTON 2 study for EG-1962 and further research and development activities for EG-1962 and our other product candidates, at least until the strategic review process is complete.

We believe that our existing cash and cash equivalents as of December 31, 2018 will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our

available capital resources sooner than we currently expect. Our future capital requirements are difficult to forecast and will depend on many factors, including:

our ability to timely consummate the merger with PDS;

the costs incurred in defending the class action civil litigation;

the costs incurred in responding to disruptive actions by activist stockholders;

the timing and nature of any strategic transactions that we undertake;

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personnel-related expenses, including salaries, benefits, severance, stock-based compensation expense and other compensation costs related to implementing our restructuring plan;

the scope and nature of activities we may pursue to advance clinical development for our product candidates, if any; and

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

Please see the section titled “Risk Factors” elsewhere in this Annual Report for additional risks associated with our operations.

Contractual Obligations and Commitments

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

As of December 31, 2018	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	$1,739	$605	$1,134	$ –	$ –
Total contractual obligations	$1,739	$605	$1,134	$ –	$ –

This table above does not include (a) any milestone payments related to contingent events which may become payable to third parties under our license agreements should we elect to conduct further development and potential commercialization of EG-1962, as the timing and likelihood of such payments are not known and may not occur at all, 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. Following the discontinuation of the NEWTON 2 trial for EG-1962, we have ceased all research and development efforts related to EG-1962 and suspended our other product candidates. As such, unless we resume such development activities, it is unlikely that we will have any additional milestones or royalty obligations to Evonik in the future.

Under 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 $4.5 million. In July 2017 and April 2018, the Company paid $1.5 million and $0.5 million, respectively, of such aggregate amount in connection with entering into the Restated

Development Agreement. The remaining $2.5 million was payable no later than April 1, 2019. The remaining payment was discounted to $2.375 million pursuant to an accelerated payment agreement entered into in August 2018. As of September 30, 2018, there are no remaining payments under the Restated Development Agreement. 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.

Following the discontinuation of the NEWTON 2 trial for EG-1962, we have ceased all research and development efforts related to EG-1962 and our other product candidates. As such, we may terminate the Supply Agreement immediately upon notice to Oakwood (which will also result in the automatic termination of the Restated Development Agreement); provided, that if we choose to do so prior to completion of the most recent project plan attached to the Restated Development Agreement, we must pay to Oakwood a termination fee. While certain of our milestone payments to Oakwood will remain outstanding (including the termination fee in the event the Restated Development Agreement is terminated), unless we resume such development activities for EG-1962, it is unlikely that we will be required to pay additional milestone or royalty payments to Oakwood in the future pursuant to the Restated Development Agreement or the Supply Agreement.

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JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

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 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. 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 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a—15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer and effected by the Edge Board, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles.

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived, operated, tested and monitored, can provide only reasonable, not absolute, assurance that the objectives of the control system are met because of inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. As a result of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (the 2013 Framework). Management, under the supervision and with the participation of the principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 and concluded that it was effective.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption.

Changes in Internal Control over Financial Reporting

There were no significant changes to our internal control over financial reporting that occurred during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

Not applicable.

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PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Board of Directors

All of our current directors bring to the Edge Board executive leadership experience from their service as executives and/or directors of our Company and/or other entities. The biography of each of the Edge Board members below contains information regarding the person's business experience, director positions held currently or at any time during the last five years, and the experiences, qualifications, attributes and skills that caused the nominating and corporate governance committee and the Edge Board to determine that the person should serve as a director, given our business and structure.

Name