

Edge Therapeutics, Inc.  
Form S-4  
December 21, 2018  
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As filed with the U.S. Securities and Exchange Commission on December 20, 2018

Registration No. 333-

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

Form S-4  
REGISTRATION STATEMENT

*UNDER  
THE SECURITIES ACT OF 1933*

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

<b>Delaware</b> (State or other jurisdiction of incorporation or organization) 300 Connell Drive, Suite 4000 Berkeley Heights, NJ 07922 (800) 208-3343	<b>2834</b> (Primary Standard Industrial Classification Code Number)	<b>26-4231384</b> (I.R.S. Employer Identification Number)
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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Brian A. Leuthner**  
President & Chief Executive Officer  
Edge Therapeutics, Inc.  
300 Connell Drive, Suite 4000  
Berkeley Heights, NJ 07922  
(800) 208-3343

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement and the satisfaction or waiver of all other conditions under the Merger Agreement described herein.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box:

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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  (Do not check if a smaller reporting company) 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 7(a)(2)(B) of the Securities Act.

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

#### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered <sup>(1)(2)</sup>	Proposed maximum offering price per share	Proposed maximum aggregate offering price <sup>(3)</sup>	Amount of registration fee <sup>(4)</sup>
Common stock, par value \$0.00033 per share	10,000,000	N/A	\$ 48.20	\$ 0.01

(1) Represents the maximum number of shares of common stock of Edge Therapeutics, Inc., or Edge, issuable to securityholders of PDS Biotechnology Corporation, or PDS, in the proposed merger described in the proxy statement/prospectus/information statement included herein, plus an additional amount of shares of common stock of Edge to ensure a sufficient number of shares are registered in the event that an adjustment to the exchange ratio occurs as required by the merger agreement. The amount of Edge common stock to be registered is based on the estimated number of shares of Edge common stock that are expected to be issued pursuant to the merger, after giving effect to the proposed reverse stock split, assuming a pre-split exchange ratio of 6.2315 shares of Edge common stock for each outstanding share of PDS common stock. The estimated exchange ratio

calculation contained herein is based upon Edge's capitalization immediately prior to the date of this proxy statement/prospectus/information statement, and will be adjusted to account for the issuance of any additional shares of Edge common stock prior to the closing of the merger.

- Pursuant to Rule 416 under the Securities Act of 1933, as amended, or Securities Act, there are also being
- (2) registered such additional shares of Edge common stock that may be issued because of events such as recapitalizations, stock dividends, stock splits and reverse stock splits, and similar transactions. Estimated solely for purposes of calculation of the registration fee in accordance with Rule 457(f) of the Securities Act. PDS is a private company and no market exists for its equity securities. PDS has accumulated a capital deficit; therefore, pursuant to Rule 457(f)(2) under the Securities Act, the proposed maximum offering price is one-third of the aggregate par value of PDS's capital stock being acquired in the proposed merger, which
  - (3) is calculated by taking one-third of the product of the par value of \$0.00001 and the maximum number of shares of PDS common stock that may be exchanged in the merger, or 14,607,307 shares of PDS common stock (computed as of December 18, 2018, the latest practicable date prior to the date of filing this registration statement, and inclusive of all shares of PDS common stock issuable upon conversion of any securities convertible into or exercisable for shares of PDS common stock).
  - (4) Determined in accordance with Section 6(b) of the Securities Act at a rate equal to \$121.20 per \$1,000,000 of the proposed maximum aggregate offering price.

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

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

**SUBJECT TO COMPLETION, DATED DECEMBER 20, 2018**

**PROPOSED MERGER**

**YOUR VOTE IS VERY IMPORTANT**

To the Stockholders of Edge Therapeutics, Inc. and PDS Biotechnology Corporation:

Edge Therapeutics, Inc., a Delaware corporation, or Edge, and Echos Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Edge, or Echos Merger Sub, and PDS Biotechnology Corporation, a Delaware corporation, or PDS, have entered into an Agreement and Plan of Merger and Reorganization, or Merger Agreement, pursuant to which Echos Merger Sub will merge with and into PDS, with PDS surviving the merger as a wholly-owned subsidiary of the combined company. These transactions are referred to herein collectively as the merger. Following the merger, Edge will be renamed PDS Biotechnology Corporation and is sometimes referred to herein as the combined company. The merger will result in a clinical-stage immuno-oncology biotechnology company developing novel product candidates for the potential treatment of early- and late-stage cancer, with a growing pipeline of next-generation cancer immunotherapies based on the proprietary, multi-functional Versamune® technology platform.

At the closing of the merger, (a) each outstanding share of capital stock of PDS, will be converted into the right to receive approximately [•] shares of Edge common stock, or the Exchange Ratio, subject to adjustment for any reverse stock split, and (b) each outstanding PDS stock option, whether vested or unvested, and warrant that has not previously been exercised prior to the effective time of merger will be converted into a stock option or warrant, as the case may be, to purchase approximately [•] shares of Edge common stock, subject to adjustment for any reverse stock split. This Exchange Ratio is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement. Under the Exchange Ratio formula in the Merger Agreement, as of immediately after the merger, the former PDS securityholders are expected to own approximately 70% of the aggregate number of shares of the common stock of the combined company issued and outstanding immediately following the closing of the merger, or the Post-Closing Shares, and the securityholders of Edge as of immediately prior to the closing of the merger are expected to own approximately 30% of the aggregate number of Post-Closing Shares. These percentages assume that the Exchange Ratio is not adjusted for net cash balances or otherwise, as described in the section titled The Merger Agreement below. For a more complete description of the Exchange Ratio please see the section titled The Merger Agreement-Exchange Ratio in this proxy statement/prospectus/information statement.

Shares of Edge common stock are currently listed on the Nasdaq Global Select Market under the symbol EDGE. Prior to the closing of the merger, Edge intends to file an initial listing application for the combined company with the Nasdaq Capital Market pursuant to its reverse merger rules. After the closing of the merger, the combined company expects to trade on the Nasdaq Capital Market under the symbol PDSB. On , 2018, the last trading day before the date of this proxy statement/prospectus/information statement, the closing sale price of Edge common stock was \$ per share.

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Edge is holding a special meeting of stockholders in order to obtain the stockholder approvals necessary to complete the merger and related matters. At the Edge special meeting, which will be held on \_\_\_\_\_, 2019 at \_\_\_\_\_, local time, at \_\_\_\_\_, unless postponed or adjourned to a later date, Edge will ask its stockholders, among other things, to approve the issuance of shares of Edge common stock as consideration in the merger, to approve an amendment to Edge's certificate of incorporation effecting a reverse stock split of Edge common stock at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS, and to approve an amendment to the Edge 2014 Equity Incentive Plan, each as described in this proxy statement/prospectus/information statement.

As described in this proxy statement/prospectus/information statement, certain PDS stockholders who in the aggregate own approximately [•]% of the outstanding shares of PDS common stock, and certain Edge stockholders who in the aggregate own approximately 5.8% of the outstanding shares of Edge common stock, are parties to support agreements with Edge and PDS, pursuant to which such stockholders have agreed to vote such shares in favor of approving certain of the transactions contemplated by the Merger Agreement, including the merger, and the issuance of shares of common stock pursuant to the Merger Agreement and the reverse stock split, respectively, subject to the terms of the support agreements. No meeting of PDS stockholders to adopt the Merger Agreement and approve the merger and related transactions will be held. Instead, all PDS stockholders will have the opportunity to vote to adopt the Merger Agreement and approve the merger and related transactions, by signing and returning to PDS a written consent following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the Securities and Exchange Commission. The holders of a sufficient number of shares of PDS common stock required to adopt the Merger Agreement and approve the merger and related transactions have agreed to adopt the Merger Agreement and approve the merger and related transactions via written consent. PDS stockholders, including those who are parties to support agreements, are requested to execute written consents providing such approvals.

After careful consideration, the respective Edge and PDS boards of directors have unanimously approved the Merger Agreement and the transactions contemplated thereby, including the proposals referred to above (other than Brian Leuthner, Edge's President and Chief Executive Officer, who recused himself from the Edge board of directors vote). The Edge board of directors, or the Edge Board, unanimously recommends that its stockholders vote FOR each of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Equity Incentive Plan Proposal, each as is described in this proxy statement/prospectus/information statement, and the PDS board of directors, or the PDS Board, unanimously recommends that its stockholders sign and return the written consent indicating their approval of the merger and adoption of the Merger Agreement and related transactions to PDS.

**More information about Edge, PDS and the proposed transactions are contained in this proxy statement/prospectus/information statement. Edge and PDS urge you to read this proxy statement/prospectus/information statement carefully and in its entirety. IN PARTICULAR, YOU SHOULD CAREFULLY CONSIDER THE MATTERS DISCUSSED UNDER RISK FACTORS BEGINNING ON PAGE 25.**

Edge and PDS are excited about the opportunities the merger brings to both Edge and PDS stockholders, and thank you for your consideration and continued support.

Brian A. Leuthner  
President & Chief Executive Officer  
Edge Therapeutics, Inc.

Frank Bedu-Addo  
President & Chief Executive Officer  
PDS Biotechnology Corporation

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this proxy statement/prospectus/information statement. Any representation to the contrary is a criminal offense.**

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This proxy statement/prospectus/information statement is dated \_\_\_\_\_, 2019, and is first being mailed to Edge and PDS stockholders on or about \_\_\_\_\_, 2019.

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**EDGE THERAPEUTICS, INC.**  
**300 Connell Drive, Suite 4000**  
**Berkeley Heights, NJ 07922**  
**(800) 208-3343**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS**

**To Be Held On           , 2019**

Dear Stockholders of Edge:

On behalf of the board of directors of Edge Therapeutics, Inc., a Delaware corporation, or Edge, Edge is pleased to deliver this proxy statement/prospectus/information statement for the proposed merger between Edge and PDS, a Delaware corporation, or PDS, pursuant to which Echos Merger Sub, Inc., a wholly-owned subsidiary of Edge, will merge with and into PDS, with PDS surviving the merger as a wholly-owned subsidiary of the combined company. The special meeting of stockholders of Edge will be held on           , 2019 at           , local time           , at           , for the following purposes:

1. To consider and vote upon a proposal to approve the issuance of shares of Edge common stock pursuant to the Agreement and Plan of Merger and Reorganization, dated as of November 23, 2018, by and among Edge, Echos Merger Sub, Inc. and PDS, a copy of which is attached as *Annex A* to this proxy statement/prospectus/information statement, or the Stock Issuance Proposal;
2. To consider and vote upon an amendment to the certificate of incorporation of Edge to effect a reverse stock split of Edge common stock, at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS, the form of which is attached as *Annex B* to this proxy statement/prospectus/information statement, or the Reverse Stock Split Proposal; and
3. To consider and vote upon approving Amended and Restated Edge Therapeutics, Inc. 2014 Equity Incentive Plan, or the Restated Plan, the form of which is attached as *Annex C* to this proxy statement/prospectus/information statement, which, among other items, increases the number of shares Edge common stock available for grant under Edge's equity-based incentive compensation program, or the Equity Incentive Plan Proposal. If the Stock Issuance Proposal is not approved, the Equity Incentive Plan Proposal will be automatically withdrawn.

The Edge Board has fixed           , 2019 as the record date for the determination of stockholders entitled to notice of, and to vote at, the Edge special meeting and any adjournment or postponement thereof. Only holders of record of shares of Edge common stock at the close of business on the record date are entitled to notice of, and to vote at, the Edge special meeting. At the close of business on the record date, Edge had            shares of common stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of the holders of a majority of the shares of Edge common stock properly cast at the Edge special meeting, presuming a quorum is present, is required for approval of the Stock Issuance Proposal. The affirmative vote of the holders of a majority of the Edge common stock outstanding on the record date for the Edge special meeting is required for the approval of the Reverse Stock Split Proposal. No Edge Proposal is conditioned upon any other Edge Proposal.**

**Even if you plan to attend the Edge special meeting in person, Edge requests that you sign and return the enclosed proxy to ensure that your shares will be represented at the Edge special meeting if you are unable to attend.**

By Order of the Edge Board of Directors,

W. Bradford Middlekauff  
Senior Vice President, General Counsel and Secretary  
Berkeley Heights, NJ 07922

, 2019



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**THE EDGE BOARD HAS DETERMINED AND BELIEVES THAT EACH OF THE PROPOSALS OUTLINED ABOVE IS ADVISABLE TO, AND IN THE BEST INTERESTS OF, EDGE AND ITS STOCKHOLDERS AND HAS APPROVED EACH SUCH PROPOSAL. THE EDGE BOARD UNANIMOUSLY RECOMMENDS THAT EDGE STOCKHOLDERS VOTE FOR EACH OF THE STOCK ISSUANCE PROPOSAL AND THE REVERSE STOCK SPLIT PROPOSAL.**

**REFERENCES TO ADDITIONAL INFORMATION**

This proxy statement/prospectus/information statement incorporates important business and financial information about Edge that is not included in or delivered with this document. You may obtain this information without charge through the SEC website ([www.sec.gov](http://www.sec.gov)) or upon your written or oral request by contacting the Secretary of Edge Therapeutics, Inc., 300 Connell Drive, Suite 4000, Berkeley Heights, NJ 07922 or by calling (908) 242-3899.

**To ensure timely delivery of these documents, any request should be made no later than , 2019 to receive them before the special meeting.**

**For additional details about where you can find information about Edge, please see the section titled Where You Can Find More Information in this proxy statement/prospectus/information statement.**

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### **QUESTIONS AND ANSWERS ABOUT THE MERGER**

*Except where specifically noted, the following information and all other information contained in this proxy statement/prospectus/information statement does not give effect to the proposed reverse stock split of Edge common stock described in the Reverse Stock Split Proposal in this proxy statement/prospectus/information statement.*

The following section provides answers to frequently asked questions about the merger. This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

#### **Q: What is the merger?**

Edge Therapeutics, Inc., or Edge, and PDS Biotechnology Corporation, or PDS, have entered into an Agreement and Plan of Merger and Reorganization, dated November 23, 2018, or the Merger Agreement. The Merger Agreement contains the terms and conditions of the proposed business combination of Edge and PDS. Under the Merger Agreement, Echos Merger Sub, Inc., a wholly-owned subsidiary of Edge, will merge with and into PDS, with PDS surviving the merger as a wholly-owned subsidiary of the combined company. Following the merger, Edge will be renamed PDS Biotechnology Corporation and is referred to herein as the combined company. Subject to the terms and conditions of the Merger Agreement, at the effective time of the merger, or the Effective Time, (a) each outstanding share of capital stock of PDS (other than any shares held as treasury stock that will be cancelled), will be converted into the right to receive the number of shares of Edge common stock equal to the Exchange Ratio described below and (b) each outstanding PDS stock option, whether vested or unvested, and warrant that has not previously been exercised prior to the Effective Time will be assumed by Edge and converted into an option or warrant, as applicable, to purchase shares of Edge common stock, subject to adjustment for any reverse stock split, as described in the section titled "Treatment of PDS Stock Options and Warrants" below.

Under the Exchange Ratio formula in the Merger Agreement, as of immediately after the merger and assuming no adjustments for net cash balances as provided for in the Merger Agreement, the former PDS securityholders are expected to own approximately 70% of the aggregate number of shares of common stock of the combined company immediately following the Effective Time, the Post-Closing Shares, and the securityholders of Edge as of immediately prior to the merger are expected to own approximately 30% of the aggregate number of Post-Closing Shares. The Exchange Ratio will be fixed prior to closing to reflect Edge's and PDS's capitalization as of immediately prior to such time.

#### **Q: What will happen to Edge if, for any reason, the merger does not close?**

If, for any reason, the merger does not close, the Edge Board may elect to, among other things, attempt to complete another strategic transaction like the merger, attempt to sell or otherwise dispose of the various assets of Edge or continue to operate the business of Edge. If the Stock Issuance Proposal is not approved but the Reverse Stock Split Proposal is approved, the Edge board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 in order to satisfy Edge's continued listing requirements on the Nasdaq Global Select Market. Edge may be unable to identify and complete an alternative strategic transaction or continue to operate the business due to limited cash availability, and it may be required to dissolve and liquidate its assets. In such case, Edge would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Edge and setting aside funds for reserves.

#### **Q: Why are the companies proposing to merge?**

A: Edge and PDS believe that the combined company will have several potential advantages, including: (i) an immunotherapy pipeline with multiple product candidates that have demonstrated promising efficacy and safety results in pre-clinical and early-stage clinical studies, (ii) an efficient expected path to potential

commercialization, (iii) operational synergies, (iv) a combined management team with experience in immuno-oncology and public company management and (v) a board of directors with experience in immuno-oncology and public company governance.

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Following the merger, the combined company will focus on developing PDS's Versamun® platform for next generation immune-oncology products that are effective and safe across a broad range of cancer types.

For a more complete discussion of Edge's and PDS's reasons for the merger, please see the section titled "The Merger—Edge Reasons for the Merger" and "The Merger—PDS Reasons for the Merger."

### **Q: Why am I receiving this proxy statement/prospectus/information statement?**

You are receiving this proxy statement/prospectus/information statement because you have been identified as a stockholder of Edge or PDS as of the applicable record date, and you are entitled, as applicable, to vote at the

**A:** Edge stockholder meeting to approve among other things the issuance of shares of Edge common stock pursuant to the Merger Agreement and reverse stock split, or sign and return the PDS written consent to adopt the Merger Agreement and approve the transactions contemplated thereby. This document serves as:

- a proxy statement of Edge used to solicit proxies for its special meeting of stockholders;
- a prospectus of Edge used to issue shares of Edge common stock in exchange for shares of PDS common stock in the merger; and
- an information statement of PDS used to solicit the written consent of its stockholders for the adoption of the Merger Agreement and the approval of the merger and related transactions.

### **Q: What is required to consummate the merger?**

To consummate the merger, Edge stockholders must approve the issuance of shares of Edge common stock

**A:** pursuant to the Merger Agreement and the reverse stock split. In addition, PDS stockholders must adopt the Merger Agreement and approve the merger and the transactions contemplated thereby.

The approval of the issuance of Edge common stock pursuant to the Merger Agreement by the stockholders of Edge requires the affirmative vote of the holders of a majority of the shares of Edge common stock properly cast at the Edge special meeting, presuming a quorum is present at the meeting. The approval of the reverse stock split requires the affirmative vote of the holders of a majority of the Edge common stock outstanding on the record date for the Edge special meeting.

The adoption of the Merger Agreement and the approval of the merger and related transactions by the stockholders of PDS requires the affirmative vote of the holders of a majority of the outstanding shares of PDS common stock.

In addition to the requirement of obtaining such stockholder approval and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

The approval of the reverse stock split is required to avoid the delisting of Edge common stock from the Nasdaq Global Select Market. Therefore, if Edge's stockholders do not approve the Reverse Stock Split Proposal to effect the reverse stock split upon the closing of the merger, Edge has been advised that The Nasdaq Stock Market LLC will commence delisting proceedings immediately following the closing of the merger. If the Stock Issuance Proposal is not approved but the Reverse Stock Approval is approved, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on the Nasdaq Global Select Market.

Certain PDS stockholders including certain directors and executive officers who in the aggregate own approximately 82% of the outstanding shares of PDS common stock, and certain Edge stockholders including certain directors and executive officers who in the aggregate own approximately 5.8% of the outstanding shares of Edge common stock, are parties to support agreements with Edge and PDS pursuant to which such stockholders have agreed to vote for the adoption of the Merger Agreement and the merger and for the issuance of Edge common stock in the merger pursuant to the Merger Agreement and the reverse stock split, respectively, pursuant to the terms of the support agreements. In addition, following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC and pursuant to the conditions of the Merger Agreement, PDS

stockholders who are party to the support agreements will each execute written consents approving the merger and related transactions. The holders of a sufficient number of shares of PDS common stock

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required to adopt the Merger Agreement have agreed to adopt the Merger Agreement via written consent. PDS stockholders, including those who are parties to support agreements, are requested to execute written consents providing such approvals. For a more detailed discussion of the support agreements see the section titled Agreements Related to the Merger-Support Agreements and Written Consent.

For a more complete description of the closing conditions under the Merger Agreement, please see the section titled The Merger Agreement—Conditions to the Closing of the Merger.

**Q: What will PDS securityholders receive in the merger?**

**A:** As a result of the merger, PDS securityholders will become entitled to receive shares of Edge common stock equal to approximately 70% of the aggregate number of Post-Closing Shares.

For a more complete description of what PDS securityholders will receive in the merger, please see the sections titled Market Price and Dividend Information and The Merger Agreement—Merger Consideration.

**Q: What will Edge securityholders receive in the merger?**

**A:** Edge securityholders will not receive any new securities in the merger, but will instead retain ownership of their shares of Edge common stock equal to approximately 30% of the aggregate number of Post-Closing Shares.

**Q: Who will be the directors of the combined company following the merger?**

**A:** Upon the closing of the merger, the combined company's board of directors is expected to be composed of seven directors. Three of the directors will be designated by Edge, and four of the directors will be designated by PDS and will be as follows:

<b>Name</b>	<b>Current Principal Affiliation</b>
Frank Bedu-Addo, PhD. <sup>(2)</sup>	President & Chief Executive Officer, PDS
Brian A. Leuthner <sup>(1)</sup>	President & Chief Executive Officer, Edge
De Lyle W. Bloomquist <sup>(2)</sup>	Former President, Global Chemicals Business for Tata Chemicals Ltd.
Gregory Freitag, J.D., CPA <sup>(2)</sup>	General Counsel, SVP Business Development, AxoGen, Inc.
James Loughlin <sup>(1)</sup>	Former Partner, KPMG LLP
Robert Spiegel, M.D., FACP <sup>(1)</sup>	Former Chief Medical Officer, Schering-Plough Research Institute
Sir Richard Sykes <sup>(2)</sup>	Former Chief Executive Officer and Chairman of GlaxoWellcome

(1) Edge designee

(2) PDS designee

In addition, Sol J. Barer, Ph.D., current chairman of the board of directors of Edge, Chairman of the board of directors at Teva Pharmaceutical Industries Ltd. and who previously spent 24 years at Celgene as, among other positions, President, COO and CEO, as well as its Executive Chairman and Chairman, is expected to serve as an advisor to the board of directors of the combined company.

**Q: Who will be the executive officers of combined company immediately following the merger?**

**A:** Upon the closing of the merger, the executive management team of the combined company is expected to be composed of the following:

<b>Name</b>	<b>Title</b>
Frank Bedu-Addo, PhD.	Chief Executive Officer
Brian A. Leuthner	President
Gregory Conn, PhD.	Chief Scientific Officer
Andrew Saik	Chief Financial Officer

Lauren Wood, M.D.

Chief Medical Officer

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**Q: What are the intended U.S. federal income tax consequences of the merger to PDS United States stockholders?**

Each of Edge and PDS intends that the merger qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code. In general, the material tax consequences to U.S. Holders (as defined herein) of PDS common stock are expected to be as follows:

- Each PDS stockholder should not generally recognize gain or loss upon the exchange of PDS common stock for Edge common stock pursuant to the merger, except to the extent of cash received in lieu of a fractional share of Edge common stock as described below; and
- Each PDS stockholder should recognize gain or loss to the extent any cash received in lieu of a fractional share of Edge common stock exceeds or is less than the basis of such fractional share.

However, there are many requirements that must be satisfied in order for the merger to be treated as a reorganization under Section 368(a) of the Code, some of which are based upon factual determinations, and the reorganization treatment could be affected by actions taken after the merger. If the merger failed to qualify as a reorganization under Section 368(a) of the Code, the PDS stockholders generally would recognize the full amount of gains and losses realized on the exchange of their PDS common stock in the merger.

Tax matters are very complicated, and the tax consequences of the merger to a particular PDS stockholder will depend on such stockholder's circumstances. Accordingly, you should consult your tax advisor for a full understanding of the tax consequences of the merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For more information, please see the section titled *The Merger—Certain Material U.S. Federal Income Tax Consequences of the Merger*.

**Q: Do persons involved in the merger have interests that may conflict with mine as an Edge stockholder?**

Yes. In considering the recommendation of the Edge Board with respect to issuing shares of Edge common stock pursuant to the Merger Agreement and the other matters to be acted upon by Edge stockholders at the Edge special meeting, Edge stockholders should be aware that certain members of the Edge Board and executive officers of Edge have interests in the merger that may be different from, or in addition to, interests they have as Edge stockholders.

Edge has entered into employment agreements, stock option agreements and restricted stock unit agreements with its executive officers that provide them with cash severance payments and acceleration of certain of their outstanding equity awards in the event their employment is terminated without cause or for good reason in connection with a change in control. Based on the terms of these employment agreements, Edge's executive officers whose employment with Edge will end in connection with the merger will be contractually entitled to these severance payments and benefits. Additionally, all outstanding equity awards held by Edge's executive officers will accelerate fully and vest upon the closing of the merger. As of the date of this proxy statement/prospectus/information statement, Edge's executive officers held stock options to purchase an aggregate of [•] shares of Edge common stock with a weighted average exercise price of \$[•] per share (all of which are out of the money based on the closing price of Edge common stock as of [•], 2018) and held unvested restricted stock units covering [•] shares of Edge common stock. Based on data available as of the date of this proxy statement/prospectus/information statement, Edge's executive officers would be entitled to receive a total of approximately \$[•] (collectively, not individually) in cash severance payments if their employment was terminated by Edge without cause or by them for good reason, in either case, in connection with the closing of the merger. For more information, please see the sections titled *The Merger—Interests of the Edge Directors and Executive Officers in the Merger*.

Edge's non-employee directors hold restricted stock units totaling 80,000 shares of Edge common stock and hold stock options to purchase an aggregate of 2,546,089 shares of Edge common stock with a weighted average exercise price of \$4.72 per share as part of Edge's non-employee director compensation program. These stock options will by their terms vest in full upon the closing of the merger, including restricted stock units of 20,000 shares of Edge common stock and stock options for 240,607 and 64,286 shares of Edge common stock held by James Loughlin and Robert



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Spiegel, M.D., FACP, respectively, each of whom is expected to remain on the combined company's board of directors. [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

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the combined company.] [In addition, Dr. Barer, as chairman of the transactions committee of the Edge Board, will receive a one-time cash payment of \$[•] for his service on such committee, and each of [•] and [•], the other members of the transactions committee, will receive \$[•] for service on such committee.] For more information, please see the section titled "The Merger-Interests of the Edge Directors and Executive Officers in the Merger." ]

**Q: Do persons involved in the merger have interests that may conflict with mine as a PDS stockholder?**

Yes. In considering the recommendation of the PDS Board with respect to approving the merger and related transactions by written consent, PDS stockholders should be aware that certain members of the PDS Board and executive officers of PDS have interests in the merger that may be different from, or in addition to, interests they have as PDS stockholders. All of PDS's executive officers have options to purchase shares of PDS common stock which will vest and convert into options to purchase a number of shares of Edge common stock determined by the exchange ratio, rounding any resulting fractional shares down to the nearest whole share, certain of PDS's directors and executive officers are expected to become directors and executive officers of Edge upon the closing of the merger and all of PDS's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement. For more information, please see the section titled "The Merger—Interests of the PDS Directors and Executive Officers in the Merger."

**Q: As an Edge stockholder, how does the Edge Board recommend that I vote?**

**A:** After careful consideration, the Edge Board unanimously recommends that Edge stockholders vote:

- **FOR** the Stock Issuance Proposal to consider and vote upon the issuance of shares of Edge common stock pursuant to the Merger Agreement;
- **FOR** the Reverse Stock Split Proposal to consider and vote upon the amendment to the certificate of incorporation of Edge to effect a reverse stock split of Edge common stock, at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS; and
- **FOR** the Equity Incentive Plan Proposal to consider and vote to approve the Restated Plan, which, among other items, increases the number of shares of Edge common stock available for grant under Edge's equity-based incentive compensation program.

Except as stated below, no Edge Proposal is contingent upon any other Edge Proposal. Therefore, if the Stock Issuance Proposal is not approved but the Reverse Stock Split Approval is approved, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on the Nasdaq Global Select Market. However, if the Merger is not consummated, the Equity Incentive Plan Proposal will be automatically withdrawn.

**Q: Why is Edge proposing the Equity Incentive Plan Proposal?**

The Restated Plan, which would become effective following the consummation of the merger, is intended to maintain and strengthen Edge's ability to attract and retain key employees, directors, consultants and certain other individuals providing services to Edge and to motivate them to remain focused on long-term stockholder value.

**Q: As a PDS stockholder, how does the PDS Board recommend that I vote?**

After careful consideration, the PDS Board recommends that the PDS stockholders execute the written consent indicating their votes in favor of the adoption of the Merger Agreement and the approval of the merger and the transactions contemplated thereby.

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**Q: What risks should I consider in deciding whether to vote in favor of the issuance of shares of Edge common stock pursuant to the Merger Agreement or to execute and return the written consent approving the Merger Agreement and the transactions contemplated thereby, as applicable?**

**A:** You should carefully review this proxy statement/prospectus/information statement, including the section titled Risk Factors, which sets forth certain risks and uncertainties related to the merger, risks and uncertainties to which the combined company's business will be subject, and risks and uncertainties to which each of Edge and PDS, as an independent company, is subject.

**Q: When do you expect the merger to be consummated?**

**A:** The merger is anticipated to close as soon as possible after the Edge special meeting is held on , 2019, but Edge cannot predict the exact timing. For more information, please see the section titled The Merger Agreement-Conditions to the Closing of the Merger.

**Q: What do I need to do now?**

**A:** Edge and PDS urge you to read this proxy statement/prospectus/information statement carefully, including its annexes, and to consider how the merger affects you.

If you are an Edge stockholder, you may provide your proxy instructions in one of two different ways. First, you can mail your signed proxy card in the enclosed return envelope. Second, you may also provide your proxy instructions via the Internet by following the instructions on your proxy card or voting instruction form. Please provide your proxy instructions only once, unless you are revoking a previously delivered proxy instruction, and as soon as possible so that your shares can be voted at the special meeting of Edge stockholders.

If you are a PDS stockholder, you may execute and return your written consent to PDS in accordance with the instructions provided.

**Q: What happens if I do not return a proxy card or otherwise provide proxy instructions, as applicable?**

**A:** If you are a stockholder of record and you return a signed proxy card without marking any selections, your shares will be voted **FOR** each of the Stock Issuance Proposal, the Reverse Stock Split Proposal and the Equity Incentive Plan Proposal.

If you do not give instruction to your broker, your broker can vote your Edge shares with respect to discretionary items but not with respect to non-discretionary items. It is anticipated that the Stock Issuance Proposal and Equity Incentive Plan Proposal will be a non-discretionary items. On non-discretionary items for which you do not give your broker instructions, the Edge shares will be treated as broker non-votes. Broker non-votes will not be considered to be shares entitled to vote at the meeting and will not be counted as having been voted on the applicable proposal. The Reverse Stock Split Proposal is a matter on which a broker or other nominee are generally empowered to vote, and therefore, limited or no broker non-votes are expected with respect to those proposals.

**Q: May I vote in person at the special meeting of stockholders of Edge?**

If your shares of Edge common stock are registered directly in your name with the Edge transfer agent, you are considered to be the stockholder of record with respect to those shares, and the proxy materials and proxy card are being sent directly to you by Edge. If you are an Edge stockholder of record, you may attend the special meeting of Edge stockholders and vote your shares in person. Even if you plan to attend the Edge special meeting in person, Edge requests that you sign and return the enclosed proxy to ensure that your shares will be represented at the Edge special meeting if you are unable to attend. If

**A:** your shares of Edge common stock are held in a brokerage account or by another nominee, you are considered the beneficial owner of shares held in street name, and the proxy materials are being forwarded to you by your broker or other nominee together with a voting instruction card. As the beneficial owner, you are also invited to attend the special meeting of Edge stockholders. Because a beneficial owner is not the stockholder of record, you may not vote these shares in person at the Edge special meeting unless you obtain a proxy from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the meeting.



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**Q: When and where is the special meeting of Edge stockholders being held?**

The special meeting of Edge stockholders will be held at \_\_\_\_\_, at \_\_\_\_\_ local time, on \_\_\_\_\_, 2019. Subject to  
**A:** space availability, all Edge stockholders as of the record date, or their duly appointed proxies, may attend the meeting. Since seating is limited, admission to the meeting will be on a first-come, first-served basis.

**Q: If my Edge shares are held in \_\_\_\_\_ street name by my broker, will my broker vote my shares for me?**

Unless your broker has discretionary authority to vote on certain matters, your broker will not be able to vote your shares of Edge common stock on matters requiring discretionary authority without instructions from you. Brokers  
**A:** are not expected to have discretionary authority to vote for the Stock Issuance Proposal and Equity Incentive Plan Proposal. To make sure that your vote is counted, you should instruct your broker to vote your shares, following the procedures provided by your broker. Brokers are expected to have discretionary authority to vote for the Reverse Stock Split Proposal.

**Q: May I change my vote after I have submitted a proxy or provided proxy instructions?**

Edge stockholders of record, other than those Edge stockholders who are parties to support agreements, may change their vote at any time before their proxy is voted at the Edge special meeting in one of three ways. First,  
**A:** an Edge stockholder of record can send a written notice to the Secretary of Edge stating that it would like to revoke its proxy. Second, an Edge stockholder of record can submit new proxy instructions either on a new proxy card or via the Internet. Third, an Edge stockholder of record can attend the Edge special meeting and vote in person. Attendance alone will not revoke a proxy. If an Edge stockholder of record or a stockholder who owns Edge shares in \_\_\_\_\_ street name has instructed a broker to vote its shares of Edge common stock, the stockholder must follow directions received from its broker to change those instructions.

**Q: Who is paying for this proxy solicitation?**

Edge and PDS will share equally the costs of printing and filing this proxy statement/prospectus/information statement and proxy card. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Edge common stock for the forwarding of solicitation materials to the  
**A:** beneficial owners of Edge common stock. Edge and PDS will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Edge has engaged D.F. King & Co., Inc. to assist in the solicitation of proxies and provide related advice and informational support, for a service fee, plus customary disbursements, which are not expected to exceed \$15,000 in total, which shall be borne by Edge.

**Q: Who can help answer my questions?**

If you are an Edge stockholder and would like additional copies, without charge, of this proxy  
**A:** statement/prospectus/information statement or if you have questions about the merger, including the procedures for voting your shares, you should contact Edge's proxy solicitor:

D.F. King & Co., Inc.  
(800) 967-5074 (toll free)  
(212) 269-5550 (collect)

If you are a PDS stockholder and would like additional copies, without charge, of this proxy statement/prospectus/information statement or if you have questions about the merger, including the procedures for voting your shares, you should contact:

PDS Biotechnology Corporation  
303B College Road East  
Princeton, New Jersey 08540  
Attention: Chief Executive Officer

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### **PROSPECTUS SUMMARY**

*This summary highlights selected information from this proxy statement/prospectus/information statement and may not contain all of the information that is important to you. To better understand the merger, the proposals being considered at the Edge special meeting and the PDS stockholder actions that are the subject of the written consent, you should read this entire proxy statement/prospectus/information statement carefully, including the Merger Agreement and the other annexes to which you are referred to herein. For more information, please see the section titled *Where You Can Find More Information*.*

#### **The Parties**

##### ***Edge Therapeutics, Inc.***

300 Connell Drive, Suite 4000  
Berkeley Heights, NJ 07922  
(800) 208-3343

Edge Therapeutics, Inc., or Edge, is a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel, hospital-based therapies capable of transforming treatment paradigms for the management of acute, life-threatening conditions.

##### ***PDS Biotechnology Corporation***

303B College Road East  
Princeton, New Jersey 08540  
(609) 423-1450

PDS Biotechnology Corporation, or PDS, is a private company with a growing pipeline of clinical-stage immunotherapies to treat various early-stage and late-stage cancers, including head and neck cancer, cervical cancer, anal cancer, prostate cancer, breast cancer and other cancers.

##### ***Echos Merger Sub, Inc.***

300 Connell Drive, Suite 4000  
Berkeley Heights, NJ 07922  
(800) 208-3343

Echos Merger Sub, Inc., or Merger Sub, is a wholly-owned subsidiary of Edge and was formed solely for the purposes of carrying out the merger.

#### **The Merger**

If the merger is consummated, Merger Sub will merge with and into PDS, with PDS surviving the merger as a wholly-owned subsidiary of the combined company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the merger, or the Effective Time, (a) each outstanding share of capital stock of PDS (other than any shares held as treasury stock that will be cancelled) will be converted into the right to receive a number of shares of Edge common stock equal to [•], or the Exchange Ratio, plus any cash paid in lieu of fractional shares; (b) each outstanding PDS warrant that is not exercised

prior to the Effective Time will be assumed by Edge, *provided, however*, that from and after the Effective Time, the PDS warrants will be exercisable into that number of shares of common stock of the Parent equal to (i) the Exchange Ratio multiplied by (ii) the number of shares of common stock of PDS into which such PDS warrant is exercisable as of immediately prior to the effective time, at an exercise price per share equal to (A) the exercise price per share of PDS common stock under the existing warrant divided by (B) the Exchange Ratio; and (c) each PDS stock option will fully vest and be assumed by Edge and converted into an option to purchase, on the same terms and conditions, a number of shares of Edge common stock equal to the product of (i) the number of shares of PDS common stock subject to such option, multiplied by (ii) the Exchange Ratio, at an exercise price per share of Edge common stock equal to (A) the exercise price per share of the PDS common stock subject to such option divided by (B) the Exchange Ratio. Prior to the closing, the Edge Board shall adopt resolutions to provide that (i) each unexpired and unexercised Edge option, whether vested or unvested, shall be accelerated in full, with each unexercised Edge option remaining outstanding

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immediately after the Effective Time in accordance with its terms and (ii) each outstanding and unvested Edge restricted stock unit, or Edge RSU, shall be accelerated in full effective as of immediately prior to the Effective Time and settled within five days after the Effective Time (with settlement to be one share of Edge common stock for each share of Edge common stock underlying such Edge RSU). The Exchange Ratio is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement.

Under the Exchange Ratio formula in the Merger Agreement, as of immediately after the merger and assuming no adjustments for cash balances as provided for in the Merger Agreement, the former PDS securityholders are expected to own approximately 70% of the Post-Closing Shares, and the securityholders of Edge as of immediately prior to the merger are expected to own approximately 30% of the aggregate number of Post-Closing Shares. This Exchange Ratio will be fixed prior to closing to reflect Edge's and PDS's capitalization as of immediately prior to such time. These percentages assume that the Exchange Ratio is not adjusted for net cash balances or otherwise, as described in the section titled "The Merger Agreement-Merger Consideration" below. For a more complete description of the Exchange Ratio please see the section titled "The Merger Agreement-Exchange Ratio" in this proxy statement/prospectus/information statement.

The closing of the merger will occur no later than the second business day after the last of the conditions to the merger has been satisfied or waived, or at another time as Edge and PDS agree. Edge and PDS anticipate that the closing of the merger will occur promptly after the Edge special meeting. However, because the merger is subject to a number of conditions, neither Edge nor PDS can predict exactly when the closing will occur or if it will occur at all. After the closing of the merger, the name of the combined company will be changed from Edge Therapeutics, Inc. to PDS Biotechnology Corporation.

### **Reasons for the Merger**

On April 30, 2018, Edge announced that it was exploring strategic alternatives that included 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 transactions or other transactions between Edge and a third party. Edge retained Piper Jaffray & Co., or Piper Jaffray, to serve as its financial advisor in certain aspects of the process. After a comprehensive review of strategic alternatives, on November 26, 2018, Edge announced the signing of a definitive merger agreement with PDS. Following the merger, the combined company will 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.

In reaching its unanimous decision (other than Brian Leuthner, who recused himself from the Edge Board vote) to approve the Merger Agreement and the transactions contemplated thereby, the Edge Board considered a number of factors, including, among others, the following:

- the historical and current information concerning Edge's business, financial performance, financial condition, operations, management and competitive position, the prospects of Edge and its product candidates, the nature of the biotechnology industry generally, including financial projections of Edge under various scenarios and its short- and long-term strategic objectives;
- that PDS's proprietary platform, as well as its immunotherapies pipeline, which includes clinical stage candidates that may address sizeable market opportunities, provide new medical benefits for patients and returns for investors;



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- that the merger would provide existing Edge stockholders a significant opportunity to participate in the potential growth of the combined company following the merger;
- that the combined company is expected to be led by an experienced senior management team and a board of directors with representation from each of the current boards of directors of Edge and PDS;
- that the Phase 3, NEWTON 2 study of EG-1962 demonstrated a low probability of achieving a statistically-significant difference compared to the standard of care in the study's primary endpoint and the resulting discontinuation of the NEWTON 2 study; and

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- the terms of the Merger Agreement and associated transactions, including the relative percentage ownership of Edge securityholders and PDS securityholders immediately following the closing of the merger, the reasonableness of the fees and expenses related to the merger and the likelihood that the merger will be completed.

For more information on the Edge Board's reasons for the transaction, see the section titled "The Merger—Edge Reasons for the Merger."

In reaching its unanimous decision to approve the Merger Agreement and the related transactions, the PDS Board considered a number of factors, including, among others, the following:

- the potential increased access to sources of capital at a lower cost and a broader range of investors to support PDS's commercialization efforts than it could otherwise obtain if it continued to operate as a privately held company;
- the ability to access institutional investors who may otherwise be unable to invest in a privately-held company;
- the potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- the PDS board of director's belief that no alternatives to the merger were reasonably likely to create greater value for the PDS stockholders after reviewing the various strategic options to enhance stockholder value that were considered by the PDS Board;
- the expectation that the merger with Edge would be a more time- and cost-effective means to access capital than other options considered;
- the cash resources of the combined company expected to be available at the closing of the merger, including Edge's cash balance of \$[ ] million as of [ ], 2018;
- the fact that shares of Edge common stock issued to PDS stockholders will be registered on a Form S-4 registration statement by Edge and will become freely tradable;
- the belief that increased visibility as a public company would provide access to additional strategic partnering transactions; and
- the expectation that the merger will be treated as a reorganization for U.S. federal income tax purposes, with the result that the PDS stockholders will not recognize taxable gain or loss for U.S. federal income tax purposes upon the exchange of PDS common stock for Edge common stock pursuant to the merger.

For more information on the PDS Board's reasons for the transaction, see the section titled "The Merger—PDS Reasons for the Merger."

### **Opinion of the Financial Advisor to the Edge Board**

The Edge Board engaged Piper Jaffray to provide financial advisory and investment banking services in connection with the Edge Board's consideration and evaluation of certain potential strategic alternatives. On November 23, 2018, Piper Jaffray rendered its oral opinion to the Edge Board (which was subsequently confirmed in writing by delivery of Piper Jaffray's written opinion dated November 23, 2018) to the effect that, as of November 23, 2018, and based upon and subject to the various assumptions and limitations set forth therein, the Exchange Ratio was fair, from a financial point of view, to Edge.

**Piper Jaffray's opinion was directed to the Edge Board, and only addressed the fairness, from a financial point of view, to Edge of the Exchange Ratio and did not address any other aspect or implication of the merger. The summary of Piper Jaffray's opinion in this proxy statement/prospectus/information statement is qualified in its entirety by reference to the full text of its written opinion, which is included as Annex D to this proxy statement/prospectus/information statement and sets forth the assumptions made, procedures followed, matters considered and limitations on the scope of the review undertaken by Piper Jaffray in preparing its opinion. However, neither Piper Jaffray's written opinion nor the summary of its**



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**opinion and the related analyses set forth in this proxy statement/prospectus/information statement is intended to be, and they do not constitute, a recommendation to any Edge stockholder as to how such stockholder should act or vote with respect to the merger or any other matter.**

See *Annex D* and the section of this proxy statement/prospectus/information statement entitled *The Merger—Opinion of the Financial Advisor to the Edge Board*.

### **Overview of the Merger Agreement and Agreements Related to the Merger Agreement**

#### ***Merger Consideration***

At the closing of the merger:

- each outstanding share of capital stock of PDS (other than any shares held as treasury stock that will be cancelled) will be converted into the right to receive approximately [•] shares of Edge common stock, plus any cash paid in lieu of fractional shares, subject to adjustment for any reverse stock split;
- each outstanding PDS warrant that is not exercised will be assumed by Edge, *provided, however*, that from and after the Effective Time, the PDS warrants will be exercisable into that number of shares of common stock of the Parent equal to (i) the Exchange Ratio multiplied by (ii) the number of shares of common stock of PDS into which such PDS warrant is exercisable as of immediately prior to the effective time, at an exercise price per share equal to (A) the exercise price per share of PDS common stock under the existing warrant divided by (B) the Exchange Ratio; and
- each PDS stock option will fully vest and be assumed by Edge and converted into an option to purchase, on the same terms and conditions, a number of shares of Edge common stock equal to the product of (i) the number of shares of PDS common stock subject to such option, multiplied by (ii) the Exchange Ratio, at an exercise price per share of Edge common stock equal to (A) the exercise price per share of the PDS common stock subject to such option divided by (B) the Exchange Ratio.

Immediately after the merger, based on the Exchange Ratio, PDS securityholders will own approximately 70% of the outstanding capital stock of the combined company, and Edge securityholders will own approximately 30% of the outstanding capital stock of the combined company. The Exchange Ratio is an estimate only and the final Exchange Ratio will be determined pursuant to a formula described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement. Adjustments to the Exchange Ratio are described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement.

The Merger Agreement does not include a price-based termination right. Accordingly, the market value of the shares of Edge common stock issued pursuant to the Merger Agreement will depend on the market value of the shares of Edge common stock at the time the merger closes and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement. On December [•], 2018, the last trading day before the date of this proxy statement/prospectus/information statement, the closing sale price of Edge common stock was \$[ ] per share.

#### ***Treatment of Edge Stock Options and Edge RSUs***

Prior to the closing, the Edge Board will adopt resolutions to provide that (i) each unexpired and unexercised Edge option, whether vested or unvested, shall be accelerated in full, with each unexercised Edge option remaining outstanding immediately after the effective time of the merger in accordance with its terms and (ii) each outstanding and unvested Edge RSU, shall be accelerated in full effective as of immediately prior to the Effective Time and settled within five days after the Effective Time (with settlement to be one share of Edge common stock for each share of Edge common stock underlying such Edge RSU). The number of shares of Edge common stock underlying such

options and Edge RSUs and the exercise prices for such options will be appropriately adjusted to reflect Edge's proposed reverse stock split, if consummated. The terms governing options to purchase shares of Edge common stock will otherwise remain in full force and effect following the closing of the merger.

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### ***Treatment of PDS Stock Options and Warrants***

#### *Stock Options*

At the effective time of the merger, each PDS option will fully vest and will be assumed by Edge and converted into an option to purchase, on the same terms and conditions, a number of shares of Edge common stock equal to the product of (a) the number of shares of PDS common stock subject to such option, multiplied by (b) the Exchange Ratio, at an exercise price per share of Edge common stock equal to (i) the exercise price per share of the PDS common stock subject to such option divided by (ii) the Exchange Ratio.

#### *Warrants*

At the effective time of the merger, each PDS warrant that is not exercised prior to the effective time shall be assumed by Edge, *provided, however*, that from and after the effective time, such PDS warrants shall be exercisable into that number of shares of common stock of Edge equal to (a) the Exchange Ratio multiplied by (b) the number of shares of common stock of PDS into which such PDS warrant is exercisable as of immediately prior to the effective time, at an exercise price per share equal to (i) the exercise price per share of the common stock of PDS under the existing PDS warrant divided by (ii) the Exchange Ratio.

#### *Permitted Bridge Financing*

After the date of the Merger Agreement but prior to the effective time of the merger, PDS may issue, in a single transaction or a series of transactions, or a Permitted Bridge Financing, (a) shares of the common stock of PDS, in which event such shares shall be included in the calculation of the outstanding shares of PDS used to calculate the Exchange Ratio, or PDS Outstanding Shares, (b) PDS warrants, in which event the PDS warrants shall be included in the calculation of PDS Outstanding Shares to the extent provided in such definition and/or (c) convertible promissory notes, which promissory notes shall convert into either shares of (i) common stock of PDS prior to the closing, in which case such shares shall be included in the calculation of PDS Outstanding Shares or (ii) common stock of PDS immediately after the closing, in which case such shares shall be deducted from the calculation of the shares issued to the stockholders of PDS at the closing. In no event shall the aggregate proceeds of the Permitted Bridge Financing exceed \$3,000,000 without the prior written consent of Edge.

#### ***Conditions to the Closing of the Merger***

To consummate the merger, a majority of shares of Edge common stock present in person or represented by proxy at a stockholder meeting at which a quorum is present must approve the issuance of shares of Edge common stock pursuant to the Merger Agreement.

The PDS stockholders holding a majority of shares of common stock (voting as a single class) must approve and adopt the Merger Agreement and the transactions contemplated thereby, including the merger.

In addition to obtaining such stockholder approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

#### ***Non-Solicitation***

Each of Edge and PDS have agreed that, subject to certain exceptions, neither they nor any of their respective subsidiaries will authorize or permit any of their or their subsidiaries' directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives to, directly or indirectly:

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- solicit, initiate or knowingly encourage, induce or facilitate the communication, making, submission or announcement of, any acquisition proposal or acquisition inquiry, each as defined in the Merger Agreement and as defined in the section titled "The Merger Agreement—Non-Solicitation" below;
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or an acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- subject to certain exceptions, approve, endorse or recommend an acquisition proposal;

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- execute or enter into any letter of intent or any contract contemplating or otherwise relating to any acquisition transaction, as defined in the Merger Agreement and as defined in the section titled "The Merger Agreement—Non-Solicitation" below; or
- publicly propose to do any of the above.

However, before obtaining the Edge stockholder approval required to consummate the merger, Edge may furnish nonpublic information regarding such party to, and may enter into discussions or negotiations with, any person in response to a bona fide written acquisition proposal, which the Edge Board determines in good faith, after consultation with Edge's financial advisor and outside legal counsel, constitutes or is reasonably likely to result in a superior offer, as defined in the Merger Agreement and as defined in the section titled "The Merger Agreement—Non-Solicitation" below, and is not withdrawn, if:

- neither Edge nor any of its directors, officers, employees, agents, attorneys, accountants, investment bankers, advisors and representatives has breached the non-solicitation provisions of the Merger Agreement described above;
- the Edge Board concludes in good faith based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of the Edge Board under applicable law;
- Edge receives from the third-party an executed confidentiality agreement containing provisions (including nondisclosure provisions, use restrictions, non-solicitation provisions and no hire provisions) at least as favorable to such party as those contained in the confidentiality agreement between Edge and PDS; and
- substantially contemporaneously with furnishing of nonpublic information to a third-party, Edge furnishes the same information to the other party to the extent not previously furnished.

If either Edge or PDS receives an acquisition proposal or acquisition inquiry at any time during the period between November 23, 2018, and earlier to occur of (a) the Effective Time and (b) termination of the Merger Agreement, then such party must promptly, and in no event later than one business day after becoming aware of such acquisition proposal or acquisition inquiry, advise the other party orally and in writing of such acquisition proposal or acquisition inquiry, including the identity of the person making or submitting the acquisition proposal or acquisition inquiry and the material terms thereof. Each of Edge and PDS must keep the other reasonably informed with respect to the status and material terms of any such acquisition proposal or acquisition inquiry and any material modification or proposed material modification thereto.

### ***Termination of the Merger Agreement***

Either Edge or PDS can terminate the Merger Agreement under certain circumstances, which would prevent the merger from being consummated.

### ***Termination Fees***

If the Merger Agreement is terminated under certain circumstances and certain other events occur, Edge will be required to pay PDS a termination fee of \$1.75 million. Moreover, if Edge fails to pay any termination fee when due, then it will be required to pay interest on and reasonable fees and expenses incurred in connection with the collection of such overdue amount in addition to the \$1.75 million termination fee.

### ***Support Agreements and Written Consent***

#### ***PDS***

Certain PDS stockholders are party to a support agreement with Edge, Echos Merger Sub and PDS pursuant to which, among other things, each such stockholder agreed, solely in his, her or its capacity as a PDS stockholder, to vote all of



his, her or its shares of PDS common stock in favor of the adoption and approval of the Merger Agreement and the transactions contemplated thereby and to acknowledge that the adoption and approval of the Merger Agreement is irrevocable. In addition, these PDS stockholders agreed not to, directly or indirectly, knowingly take any action that PDS is not permitted to take under the non-solicitation provisions of the Merger Agreement. The parties to these support agreements with Edge, Echos Merger Sub and PDS are:

- Frank Bedu-Addo

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- Asklepios Capital LLC
- Indiana 21st Century Fund, L.P.
- NetScientific plc
- DeLyle Bloomquist
- Sir Richard Sykes
- Ian Postlethwaite
- Gregory Freitag
- Gregory Conn, Ph.D.
- Michael King, MBA

The stockholders of PDS that are party to a support agreement with Edge consist of the holders of a majority of the shares of PDS common stock and each outstanding on the record date and entitled to vote thereon (voting as a single class).

Therefore, holders of the number of shares of PDS common stock required to approve and adopt the Merger Agreement and approve the merger and related transactions are contractually obligated to approve and adopt the Merger Agreement. Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part and pursuant to the Merger Agreement, stockholders of PDS holding a sufficient number of shares to approve and adopt the Merger Agreement and thereby approve the merger and related transactions will execute written consents providing for such adoption and approval.

*Edge*

Certain Edge stockholders are party to a support agreement with Edge, Echos Merger Sub and PDS pursuant to which, among other things, each of such stockholders agreed, solely in his or her capacity as a stockholder, to vote all of his or her shares of Edge common stock in favor of the approval of the issuance of shares of Edge common stock pursuant to the Merger Agreement and the reverse stock split of Edge common stock. In addition, these Edge stockholders agreed not to, directly or indirectly, knowingly take any action that Edge is not permitted to take under the non-solicitation provisions of the Merger Agreement. The parties to these support agreements with Edge, Echos Merger Sub and PDS are:

- Brian A. Leuthner
- Andrew Saik
- Herbert J. Faleck, D.O.
- W. Bradford Middlekauff
- Alyssa J.S. Wyant
- Sol Barer, Ph.D.
- Liam Ratcliffe, M.D., Ph.D.
- Robert Spiegel, M.D.
- R. Loch Macdonald, M.D., Ph.D.
- Isaac Blech
- Rosemary Crane
- James Loughlin

The stockholders of Edge that are party to a support agreement with Edge, Echos Merger Sub and PDS consist of the holders of an aggregate of 1,822,915 shares of Edge common stock, representing 5.8% of the outstanding shares of Edge common stock as of September 30, 2018. These stockholders are solely comprised of the executive officers and directors of Edge.

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***Lock-up Agreements***

*PDS*

As a condition to the closing of the merger, PDS’s directors, executive officers and principal stockholders, who will beneficially hold 82% of the combined company’s capital stock immediately following the closing of the merger, will enter into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of PDS common stock prior to the closing of the merger, and the combined company’s common stock thereafter, for 180 days following the Effective Time in the case of directors and officers continuing with the combined company, and 90 days in the case of directors and officers who will not remain with the combined company.

*Edge*

As a condition to the closing of the merger, Edge’s directors and officers will enter into lock-up agreements, pursuant to which such parties will agree not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of Edge’s capital stock prior to the closing of the merger, and the combined company’s common stock thereafter, for 180 days following the Effective Time.

**Management Following the Merger**

Effective as of the closing of the merger, the combined company’s executive officers are expected to be composed of members of the following current Edge and PDS management teams:

<b>Name</b>	<b>Position(s)</b>
Frank Bedu-Addo, Ph.D.	Chief Executive Officer, Director
Brian A. Leuthner	President, Director
Gregory Conn, Ph.D.	Chief Scientific Officer
Andrew Saik	Chief Financial Officer
Lauren Wood, M.D.	Chief Medical Officer

***Transition Services Agreement***

Edge and PDS may enter into a transition services agreement, pursuant to which Edge may provide PDS with certain clinical and manufacturing consulting services prior to the expected closing of the merger. Edge and PDS expect that, if such an agreement is reached, it will be on arm’s-length terms, subject to mutual agreement of the parties on the scope of consulting services and the related terms of any agreement.

**The Edge Special Meeting**

The special meeting of stockholders of Edge will be held on \_\_\_\_\_, 2019 at \_\_\_\_\_, local time, at \_\_\_\_\_, for the following purposes:

- to consider and vote upon a proposal to approve the issuance of shares of Edge common stock in connection with merger, or the Stock Issuance Proposal;
- to consider and vote upon the amendment to the certificate of incorporation of Edge to effect a reverse stock split of Edge common stock, at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge

stockholders, determined solely by the Edge Board following the special meeting, or the Reverse Stock Split Proposal; and

- to transact such other business as may properly come before the Edge special meeting or any adjournment or postponement thereof.

Collectively the proposal above are referred to as the Edge Proposals. On each matter to be voted upon, stockholders have one vote for each share of Edge common stock owned as of \_\_\_\_\_, 2019. Votes will be counted by the inspector of election. The following table summarizes vote requirements and the effect of abstentions and broker non-votes.

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<b>Proposal Number</b>	<b>Proposal Description</b>	<b>Vote Required for Approval</b>	<b>Effect of Abstentions</b>	<b>Effect of Broker Non-Votes</b>
1	Stock Issuance Proposal	FOR votes from the holders of a majority of shares properly cast at a meeting at which a quorum is present	Against	None
2	Reverse Stock Split Proposal	FOR votes from the holders of a majority of outstanding shares	Against	Against
3	Equity Incentive Plan Proposal	FOR votes from the holders of a majority of shares properly cast at a meeting at which a quorum is present	Against	None

Except as stated below, no Edge Proposal is contingent upon any other Edge Proposal. Therefore, assuming all other closing conditions have been either satisfied or waived, the merger will be consummated even if the Reverse Stock Split Proposal is not approved by Edge's stockholders. However, if Edge's stockholders do not approve the Reverse Stock Split Proposal to effect the reverse stock split upon the closing of the merger, Edge has been advised that The Nasdaq Global Select Market will commence delisting proceedings immediately following the closing of the merger. If the Stock Issuance Proposal is not approved but the Reverse Stock Approval is approved, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on The Nasdaq Global Select Market. However, if the Merger is not consummated, the Equity Incentive Plan Proposal will be automatically withdrawn.

**PDS Solicitation of Written Consents**

The adoption of the Merger Agreement and the approval of the merger and related transactions by the PDS stockholders requires the affirmative votes of the holders of a majority of the shares of PDS common stock (voting as a single class).

Following the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC and pursuant to the conditions of the Merger Agreement, the PDS stockholders who are party to the support agreements have agreed to execute an action by written consent adopting the Merger Agreement, thereby approving the merger and related transactions. These stockholders own a sufficient number of shares of PDS common stock to adopt the Merger Agreement. No meeting of PDS stockholders to adopt the Merger Agreement and approve the merger and related transactions will be held; *however*, all PDS stockholders will have the opportunity to elect to adopt the Merger Agreement, thereby approving the merger and related transactions, by signing and returning to PDS a written consent.

In addition to the requirement of obtaining such stockholder approval and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

**Interests of Directors and Executive Officers of Edge and PDS***Interests of the Edge Directors and Executive Officers in the Merger*

In considering the recommendation of the Edge Board with respect to issuing shares of Edge common stock pursuant to the Merger Agreement and the other matters to be acted upon by Edge stockholders at the Edge special meeting, Edge stockholders should be aware that certain members of the Edge Board and executive officers of Edge have interests in the merger that may be different from, or in addition to, interests they have as Edge stockholders.

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Pursuant to the terms of their employment agreements, the Edge executive officers would be entitled to receive a total of approximately \$[•] million in cash severance benefits (collectively, not individually) in the event that their employment with Edge is terminated without cause or for good reason, in either case, within [ ] [before/after] the closing of the merger, based on data available as of the date of this proxy statement/prospectus/information statement. Additionally, all outstanding equity awards held by Edge's executive officers will accelerate fully and vest upon the closing of the merger. As of the date of this proxy statement/prospectus/information statement, Edge's executive officers hold Edge RSUs totaling 453,062 shares of Edge common stock and held stock options to purchase an aggregate of 4,032,228 shares of Edge common stock with a weighted average exercise price of \$7.10 per share (all of which are out of the money based on the closing price of Edge common stock as of [•], 2018) and Edge RSUs covering [•] shares of Edge common stock (which, based on the closing price of Edge common stock as of [•], 2018, had an aggregate value of [•]).

With respect to Edge's directors, Edge's non-employee directors hold Edge RSUs totaling 80,000 shares of Edge common stock and stock options to purchase an aggregate of 2,546,089 shares of Edge common stock with a weighted average exercise price of \$4.72 per share as part of Edge's non-employee director compensation program. These stock options will by their terms vest in full upon the closing of the merger, including Edge RSUs of 20,000 shares of Edge common stock and stock options for 220,607 and 64,286 shares of Edge common stock held by Robert J. Spiegel, M.D., Ph.D. and James Loughlin, respectively, each of whom is expected to remain on the combined company's board of directors. [In addition, Dr. Barer, as chairman of the transactions committee of the Edge Board, will receive a one-time cash payment of \$[•] for his service on such committee, and each of [•] and [•], the other members of the transactions committee, will receive \$[•] for their service on such committee.]

As of December 31, 2018, directors and executive officers of Edge owned approximately 5.8% of the outstanding shares of Edge common stock. All Edge executive officers and directors have entered into support agreements in connection with the merger. The support agreements are discussed in greater detail in the section titled *Agreements Related to the Merger-Support Agreements and Written Consent* in this proxy statement/prospectus/information statement.

***Interests of the PDS Directors and Executive Officers in the Merger***

In considering the recommendation of the PDS Board with respect to approving the merger and related transactions by written consent, PDS stockholders should be aware that certain members of the board of directors and executive officers of PDS have interests in the merger that may be different from, or in addition to, interests they have as PDS stockholders. For example, some 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., the current Chief Executive Officer of PDS, is expected to become the Chief Executive Officer of the combined company upon the closing of the merger. Additionally, Frank Bedu-Addo, Ph.D., Sir Richard Sykes, De Lyle W. Bloomquist and Gregory Freitag, J.D., CPA, who are current directors of PDS, will be designated to serve on the combined company's board of directors following the closing of the merger.

All PDS executive officers, directors and their affiliates have entered into support agreements in connection with the merger. The support agreements are discussed in greater detail in the section titled *Agreements Related to the Merger-Support Agreements and Written Consent* in this proxy statement/prospectus/information statement.

Certain PDS executive officers, directors and their affiliates currently hold shares of PDS common stock, stock options to purchase shares of common stock and unsecured promissory notes. In addition, in October 2018, the PDS Board agreed to grant each of Dr. Conn and Mr. King 137,559 stock options, and Dr. Bedu-Addo 550,235 stock options, immediately prior to the consummation of the merger.

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As of \_\_\_\_\_, 2018, all directors and executive officers of PDS, together with their affiliates, owned [•]% of the outstanding shares of PDS common stock (on an as-converted to common stock basis) and such persons held stock options to purchase an aggregate of [•] shares of common stock with a weighted average exercise price of \$[•] per share.

Based on an assumed conversion date of \_\_\_\_\_ 2018, affiliates of certain PDS directors and certain executive officers will also convert an aggregate of \$[•] million of unsecured subordinated convertible promissory notes, including accrued interest, into approximately [•] million shares of PDS common stock immediately prior to the closing of the merger pursuant to a note purchase agreement.



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The PDS Board was aware of these interests and considered them, among other matters, in its decision to approve the Merger Agreement. For more information, please see the sections titled *The Merger—Interests of the PDS Directors and Executive Officers in the Merger* and *Certain Relationships and Related-Party Transactions—PDS*.

### **Considerations with Respect to U.S. Federal Income Tax Consequences of the Merger**

Each of Edge and PDS intends that the merger qualify as a reorganization within the meaning of Section 368(a) of the Code. In general and subject to the qualifications and limitations set forth in the section titled *The Merger—Certain Material U.S. Federal Income Tax Consequences of the Merger*, the material tax consequences to U.S. Holders (as defined herein) of PDS common stock are expected to be as follows:

- a PDS stockholder should not recognize gain or loss upon the exchange of PDS common stock for Edge common stock pursuant to the merger, except to the extent of cash received in lieu of a fractional share of Edge common stock as described below;
- a PDS stockholder who receives cash in lieu of a fractional share of Edge common stock in the merger should recognize capital gain or loss in an amount equal to the difference between the amount of cash received instead of a fractional share and the stockholder's tax basis allocable to such fractional share;
- a PDS stockholder's aggregate tax basis for the shares of Edge common stock received in the merger (including any fractional share interest for which cash is received) should equal the stockholder's aggregate tax basis in the shares of PDS common stock surrendered upon the closing of the merger, decreased by the amount of any tax basis allocable to a fractional share for which cash is received; and
- the holding period of the shares of Edge common stock received by a PDS stockholder in the merger should include the holding period of the shares of PDS common stock surrendered in exchange therefor provided the surrendered PDS common stock is held as a capital asset (generally, property held for investment) at the time of the merger.

Tax matters are very complicated, and the tax consequences of the merger to a particular PDS stockholder will depend on such stockholder's circumstances. Accordingly, you should consult your tax advisor for a full understanding of the tax consequences of the merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For more information, please see the section titled *The Merger—Certain Material U.S. Federal Income Tax Consequences of the Merger*.

### **Risk Factors**

Both Edge and PDS are subject to various risks associated with their businesses and their industries. In addition, the merger, including the possibility that the merger may not be completed, poses a number of risks to each company and its respective stockholders, including the following risks:

- 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;
- 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;
- the merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes;
- the combined company may need to raise additional capital by issuing securities or debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations or proprietary rights;
- 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;

- the market price of the combined company's common stock may decline as a result of the merger;

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- 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;
- during the pendency 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;
- 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 lack of a public market for PDS shares makes it difficult to determine the fair market value of the PDS shares, and the stockholders of PDS 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; and
- if the conditions of the merger are not met, the merger will not occur.

These risks and other risks are discussed in greater detail under the section titled Risk Factors. Edge and PDS both encourage you to read and consider all of these risks carefully.

### **Regulatory Approvals**

In the United States, Edge must comply with applicable federal and state securities laws and the rules and regulations of The Nasdaq Stock Market LLC in connection with the issuance of shares of Edge common stock pursuant to the Merger Agreement and the filing of this proxy statement/prospectus/information statement with the SEC.

### **Nasdaq Stock Market Listing**

Edge intends to file an initial listing application for the combined company with The Nasdaq Capital Market pursuant to its reverse merger rules. However, if Edge's stockholders do not approve the Reverse Stock Split Proposal, Edge has been advised that The Nasdaq Stock Market LLC will commence delisting proceedings immediately following the closing of the merger. The combined company is obligated to use commercially reasonable efforts to take such steps as necessary to ensure the continued listing of its common stock on The Nasdaq Capital Market following the closing of the merger. It is expected that the combined company's common stock will trade under the symbol PDSB.

If the issuance of the shares of Edge common stock pursuant to the Merger Agreement is not approved but the reverse stock split proposal is, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on The Nasdaq Global Select Market.

### **Anticipated Accounting Treatment**

The merger will be treated by Edge as a reverse merger under the acquisition method of accounting in accordance with accounting principles generally accepted in the United States. For accounting purposes, PDS is considered to be acquiring Edge in the merger.

### **Appraisal Rights and Dissenters' Rights**

Holders of shares of Edge capital stock are not entitled to appraisal rights in connection with the merger. PDS stockholders are entitled to appraisal rights in connection with the merger under Delaware law. For more information about such rights, see the provisions of Section 262 of the Delaware General Corporation Law, or the DGCL, attached hereto as *Annex E*, and the section titled The Merger—Appraisal Rights and Dissenters' Rights.

### **Potential PDS Financing**

Although there is no current agreement in place with any potential financing source, nor any requirement to undertake a financing, under the Merger Agreement, after February 28, 2019 but prior to the Effective Time of the merger, PDS may issue, in a single transaction or a series of transactions, (a) shares of the common stock of

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PDS, (b) PDS warrants and/or (c) convertible promissory notes, which promissory notes shall convert into either shares of (i) common stock of PDS prior to the closing or (ii) common stock of Edge immediately after the closing. In no event shall the aggregate proceeds of the Permitted Bridge Financing exceed \$3,000,000 without the prior written consent of Edge, not to be unreasonably withheld, conditioned or delayed. To the extent any such potential financing is consummated consistent with the foregoing, the issuance of shares would be dilutive to both Edge and PDS stockholders, after giving effect to the Exchange Ratio, and shares issued in connection with this financing would not be used in the calculation of the Exchange Ratio.

**Comparison of Stockholder Rights**

Both Edge and PDS are incorporated under the laws of the State of Delaware and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the DGCL. If the merger is completed, PDS stockholders will become stockholders of Edge, and their rights will be governed by the DGCL, the bylaws of Edge and, the certificate of incorporation of Edge. The rights of Edge stockholders contained in the certificate of incorporation and bylaws of Edge differ from the rights of PDS stockholders under the certificate of incorporation and bylaws of PDS, as more fully described under the section titled Comparison of Rights of Holders of Edge Stock and PDS Stock.

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CONDENSED COMBINED FINANCIAL INFORMATION AND DATA**

*The following tables present summary historical financial data for Edge and PDS, summary unaudited pro forma condensed combined financial data for Edge and PDS, and comparative historical and unaudited pro forma per share data for Edge and PDS.*

**Selected Historical Condensed Financial Data of Edge**

The selected condensed statements of operations data for the fiscal years ended December 31, 2017 and 2016 and the selected condensed balance sheet data as of December 31, 2017 and 2016 are derived from Edge's audited condensed financial statements included elsewhere in this proxy statement/prospectus/information statement. The selected condensed statements of operations data for the nine months ended September 30, 2018 and 2017 and the selected condensed balance sheet data as of September 30, 2018 are derived from Edge's unaudited condensed financial statements included elsewhere in this proxy statement/prospectus/information statement.

The selected historical condensed financial data below should be read in conjunction with the section titled "Edge Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors—Risks Related to Edge" and Edge's condensed financial statements and related notes included elsewhere in this proxy statement/prospectus/information statement. Edge's historical results are not necessarily indicative of the results that may be expected in any future period.

	<b>Nine Months Ended September 30,</b>		<b>Years Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	<b>(unaudited)</b>			
<b>Selected Condensed Statements of Operations Data (in 000's, except per share amounts):</b>				
Total operating expenses	\$ 37,053.7	\$ 35,843.5	\$ 51,966.6	\$ 39,512.1
Net loss	\$ (37,782.9 )	\$ (36,956.2 )	\$ (50,859.8 )	\$ (38,821.0 )
Basic and diluted loss per common share	\$ (1.21 )	\$ (1.23 )	\$ (1.67 )	\$ (1.34 )
Shares used in calculation of net loss per share, basic and diluted	31,198,804	30,091,640	30,393,952	28,864,216
		<b>As of September 30, 2018</b>	<b>As of December 31, 2017</b>	<b>2016</b>
		<b>(unaudited)</b>		

**Selected Condensed Balance Sheet Data (in 000's):**

Cash, cash equivalents and investments	\$ 36,814.9	\$ 88,067.6	\$ 106,398.9
Total assets	\$ 37,673.1	\$ 92,621.1	\$ 110,914.4
Total liabilities	\$ 6,688.3	\$ 30,249.7	\$ 21,637.9
Total stockholders' equity	\$ 30,984.8	\$ 62,371.4	\$ 89,276.6

**Selected Historical Financial Data of PDS Biotechnology Corporation**

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The selected statements of operations data for the fiscal years ended December 31, 2017 and 2016 and the selected condensed balance sheet data as of December 31, 2017 and 2016 are derived from PDS's financial statements prepared using accounting principles generally accepted in the United States, which have been audited by an independent auditor, and are included in this proxy statement/prospectus/information statement. The statement of operations data for the nine months ended September 30, 2018 and 2017, as well as the balance sheet data as of September 30, 2018, are derived from PDS's unaudited condensed financial statements included elsewhere in this proxy statement/prospectus/information statement.

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The selected historical financial data should be read in conjunction with PDS's financial statements, related notes, other financial information, PDS Management's Discussion and Analysis of Financial Condition and Results of Operations and PDS's condensed financial statements and related notes appearing elsewhere in this proxy statement/prospectus/information statement. PDS's historical results are not necessarily indicative of results to be expected in any future period.

	<b>Nine Months Ended September 30,</b>		<b>Years Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	<b>(unaudited)</b>			
<b>Selected Condensed Statements of Operations Data (in 000's, except per share amounts):</b>				
Total operating expenses	\$ 2,013.3	\$ 2,940.6	\$ 3,420.3	\$ 4,217.8
Net loss	\$ (2,016.9 )	\$ (2,942.8 )	\$ (3,423.2 )	\$ (4,477.5 )
Basic and diluted loss per common share	\$ (0.20 )	\$ (0.32 )	\$ (0.37 )	\$ (0.54 )
Shares used in calculation of net loss per share, basic and diluted	9,972,670	9,300,214	9,329,526	8,363,131
		<b>As of September 30, 2018</b>	<b>As of December 31, 2017</b>	<b>As of December 31, 2016</b>
		<b>(unaudited)</b>		

**Selected Condensed Balance Sheet Data (in 000's):**

Cash, cash equivalents and investments	\$ 142.7	\$ 175.9	\$ 1,957.0
Total assets	\$ 251.8	\$ 340.8	\$ 2,244.5
Total liabilities	\$ 1,330.5	\$ 950.3	\$ 722.8
Total stockholders' equity (deficit)	\$ (1,078.8 )	\$ (609.5 )	\$ 1,521.7

**Selected Unaudited Pro Forma Condensed Combined Financial Data of Edge and PDS**

*The following information does not give effect to the proposed reverse stock split of Edge common stock described in the Reverse Stock Split Proposal.*

The following unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting under U.S. GAAP, and gives effect to the transaction between Edge and PDS to be accounted for as a reverse acquisition, with PDS being deemed the acquiring company for accounting purposes.

The unaudited pro forma condensed combined balance sheet as of September 30, 2018 assumes that the transaction took place on September 30, 2018 and combines the historical balance sheets of Edge and PDS as of such date. The unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2018 and the year ended December 31, 2017 assumes that the transaction took place as of January 1, 2017, and combines the historical results of Edge and PDS for each period. The historical financial statements of Edge and PDS have been adjusted to give pro forma effect to events that are (i) directly attributable to the transaction, (ii) factually supportable, and (iii) with respect to the unaudited pro forma condensed combined statements of operations, expected to have a continuing impact on the combined results.



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The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate Edge and PDS historical financial statements, and their respective management's discussion and analysis of financial condition and results of operations. PDS's historical audited financial statements for the years ended December 31, 2017 and 2016 and unaudited financial statements for the nine months ended September 30, 2018 and 2017 are included elsewhere in this proxy statement/prospectus/information statement. Edge's historical audited condensed financial statements for the years ended December 31, 2017 and December 31, 2016 and unaudited condensed financial statements for the nine months ended September 30, 2018 and 2017 are included elsewhere in this proxy statement/prospectus/information statement.

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	<b>Nine Months Ended September 30, 2018</b>	<b>Year Ended December 31, 2017</b>
<b>Unaudited Pro Forma Condensed Combined Statements of Operations (in 000's, except per share amounts):</b>		
Total operating expenses	\$ 35,599.5	\$ 55,386.9
Net loss	\$ (36,332.3 )	\$ (54,283.0 )
Basic and diluted net loss per common share	\$ (0.34 )	\$ (0.52 )
		<b>As of September 30, 2018</b>
<b>Unaudited Pro Forma Condensed Combined Balance Sheet (in 000's):</b>		
Cash, cash equivalents and investments		\$ 36,435.6
Total assets		\$ 38,402.9
Total liabilities		\$ 5,065.2
Stockholders' equity		\$ 33,337.7

**Comparative Historical and Unaudited Pro Forma per Share Data**

The information below reflects the historical net loss and book value per share of Edge common stock and the historical net loss and book value per share of PDS common stock in comparison with the unaudited pro forma net loss and book value per share after giving effect to the proposed merger of Edge with PDS on a pro forma basis. The unaudited pro forma net loss and book value per share does not give effect to the proposed reverse stock split of Edge common stock described in the Reverse Stock Split Proposal.

You should read the tables below in conjunction with the audited condensed financial statements of Edge for the years ended December 31, 2017 and December 31, 2016 and unaudited condensed financial statements the nine months ended September 30, 2018 and 2017 included in this proxy statement/prospectus/information statement and the audited financial statements of PDS for the years ended December 31, 2017 and 2016 and unaudited financial statements for the nine months ended September 30, 2018 and 2017 included in this proxy statement/prospectus/information statement and the related notes and the unaudited pro forma condensed combined financial information and notes related to such financial statements included elsewhere in this proxy statement/prospectus/information statement.

	<b>Nine Months Ended September 30, 2018</b>	<b>Year Ended December 31, 2017</b>
<b>Edge Historical Per Common Share Data:</b>		
Basic and diluted net loss per share	\$ (1.21 )	\$ (1.67 )
Book value per share	\$ 0.99	\$ 2.05
<b>PDS Historical Per Common Share Data:</b>		
Basic and diluted net loss per share	\$ (0.20 )	\$ (0.37 )
Book value per share	\$ (0.11 )	\$ (0.07 )
<b>Combined Company Per Common Share Data:</b>		
Basic and diluted net loss per share	\$ (0.34 )	\$ (0.52 )
Book value per share	\$ 0.31	\$ N/A



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Edge common stock is listed on the Nasdaq Global Select Market under the symbol EDGE. The following table presents, for the periods indicated, the range of high and low per share closing sales prices for Edge common stock as reported on the Nasdaq Global Select Market for each of the periods set forth below. PDS is a private company and its common stock is not publicly traded. These per share sales prices do not give effect to the proposed reverse stock split of Edge common stock to be implemented, if approved by the Edge stockholders, prior to the closing of the merger.

**Edge Common Stock**

	<b>High</b>	<b>Low</b>
<b>Year Ending December 31, 2018</b>		
First Quarter	\$ 17.77	\$ 1.12
Second Quarter	1.41	0.84
Third Quarter	1.12	0.70
Fourth Quarter	[•]	[•]
<b>Year Ended December 31, 2017</b>		
First quarter	\$ 12.99	\$ 7.62
Second quarter	10.72	8.81
Third quarter	11.51	9.20
Fourth quarter	11.16	9.07
<b>Year Ended December 31, 2016</b>		
First quarter	\$ 13.86	\$ 6.70
Second quarter	10.64	7.43
Third quarter	12.29	8.61
Fourth quarter	13.50	9.25
On _____, 2018, the last reported sale price of Edge common stock on the Nasdaq Global Select Market was \$ _____ per share.		

Because the market price of Edge common stock is subject to fluctuation, the market value of the shares of Edge common stock that PDS stockholders will be entitled to receive in the merger may increase or decrease.

Assuming the successful application for initial listing with the Nasdaq Capital Market, following the closing of the merger, Edge expects the combined company's common stock will be listed on the Nasdaq Capital Market and will trade under Edge's new name, PDS Biotechnology Corporation and trading symbol PDSB.

As of \_\_\_\_\_, 2018, there were approximately \_\_\_\_\_ stockholders of record and there were approximately \_\_\_\_\_ beneficial stockholders of Edge common stock.

**Dividend Policy**

Edge has never declared or paid any cash dividends on its common stock. Edge does not intend to pay cash dividends on its common stock for the foreseeable future. In addition, the terms of Edge's outstanding indebtedness restrict its

ability to pay dividends, and any future indebtedness that Edge may incur could preclude it from paying dividends. Any future determination related to dividend policy will be made at the discretion of the Edge Board and will depend on then-existing conditions, including Edge's financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors the Edge Board may deem relevant.

PDS has never paid or declared any cash dividends on its common stock or preferred stock. If the merger does not occur, PDS does not anticipate paying any cash dividends on its common stock in the foreseeable future, and PDS intends to retain all available funds and any future earnings to fund the development and expansion of its business. Any future determination to pay dividends will be at the discretion of the PDS Board and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the PDS Board deems relevant.

TABLE OF CONTENTS**RISK FACTORS**

*The combined company will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in this proxy statement/prospectus/information statement, you should carefully consider the material risks described below before deciding how to vote your shares of stock. In addition, you should read and consider the risks associated with the business of Edge because these risks may also affect PDS and the combined company. These risks can be found in Edge's Annual Report on Form 10-K, as updated by subsequent Quarterly Reports on Form 10-Q, all of which are filed with the SEC. You should also read and consider the other information in this proxy statement/prospectus/information statement and the other documents incorporated by reference into this proxy statement/prospectus/information statement. Please see the section titled "Where You Can Find More Information."*

**Risks Related to the Merger**

***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 as described in the section titled "The Merger-Merger Consideration." The pre-reverse stock split Exchange Ratio is [•], and the post-split 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. 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 \$[•] million, of which \$[•] 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 and described in the section titled The Merger Agreement-Conditions to the Closing of the Merger.

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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:

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



For example, Herbert J. Faleck, D.O., Edge's Chief Medical Officer, is expected to cease to serve as Chief Medical Officer on December 31, 2018, at which point Dr. Faleck's employment with Edge will end. Consistent with the terms of Dr. Faleck's existing employment agreement with Edge, upon the termination of Dr. Faleck's employment, assuming such termination occurs on December 31, 2018, and in accordance with Dr. Faleck's employment agreement, Dr. Faleck is expected to receive an aggregate of approximately \$[•] in cash severance benefits.

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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 20,000 shares of Edge common stock and stock options for 220,607 and 64,286 shares of Edge common stock held by Robert Spiegel, M.D., FACP, and James J. Loughlin, respectively, who are expected to remain on the combined company's board of directors)) 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 [•], 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, Brian Leuthner is expected to serve as President of the combined company and Andrew Saik is expected to serve as Chief Financial Officer of the combined company. Additionally, Brian Leuthner, James Loughlin and Robert Spiegel, each of whom are a current director of Edge, will be designated to serve on the combined company's board of directors following the closing of the merger.

For more information, please see the section titled "The Merger-Interests of the Edge Directors and Executive Officers in 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 DeLyle Bloomquist, Sir Richard Sykes and Gregory Freitag, each of whom is a current director of PDS, will be designated to serve on the combined company's board of directors following the closing of the merger.

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. For more information, please see the section titled "The Merger-Interests of the PDS Directors and Executive Officers in the Merger."

***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

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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 may Merger Agreement 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.

### **Risks Related to Edge**

*Investing in Edge common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this proxy statement/prospectus/information statement and in the other periodic and current reports and other documents it files with the SEC, before deciding to invest in its common stock. If any of the following risks materialize, Edge's business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of its common stock could decline and you could lose all or part of your investment.*

### **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.

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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. 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.

***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

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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.***



## Edgar Filing: Edge Therapeutics, Inc. - Form S-4

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.

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;

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- 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 until Edge receives approval of an NDA from the FDA or the requisite approval from

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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:

- 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

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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.

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

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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.

### **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 Edge's CROs and 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.

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### ***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.

### **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

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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.

***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.

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***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.

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

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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.

## **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, 2017 and December 31, 2016 and the nine months ended September 30, 2018, Edge reported a net loss of \$50.9 million, \$38.8 million and 37.8 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.

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***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 [40]% 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.

***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

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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. Additionally, 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.

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 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

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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 [•] shares, or [•]%, 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 [•] 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 [•]% 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.***

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;

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- 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.

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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.

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

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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 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 PDS****Risks Related to PDS's Business, Financial Position and Capital Requirements*****PDS has a limited operating history and has never generated any product revenue.***

PDS is a clinical-stage biopharmaceutical company with a limited operating history. PDS was founded in December 2005, and its operations to date have been limited to organizing its company and developing the Versamune® platform and related immunotherapy product candidates that incorporate the technology of its Versamune® platform. PDS has not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured Versamune® at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize its Versamune® products. Consequently, predictions about PDS's future success or viability may not be as accurate as they could be if it had a longer operating history or a history of successfully developing and commercializing immunotherapies.

PDS's ability to generate revenue and achieve and maintain profitability will depend upon its ability to successfully complete the development of its Versamune®-based products for the treatment of HPV-related cancers, or PDS0101, and/or complete the development of its PDS0102, PDS0103, or PDS0104 products, or, collectively with PDS0101, the Versamune® Products, for treatment of non-HPV-related cancers and other infectious diseases and to obtain the necessary regulatory approvals. PDS has never generated any product revenue, and has no immunotherapy candidate

in late-stage clinical development or approved for commercial sale.

Even if PDS receives regulatory approval for the sale of the Versamune® Products, it does not know when it will begin to generate revenue from PDS0101, if at all. PDS's ability to generate revenue depends on a number of factors, including its ability to:

- set an acceptable price for Versamune®-based immunotherapy candidates, including the Versamune® Products, and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems;

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- add operational, financial and management information systems and personnel, including personnel to support its clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of PDS0101 and other Versamune® Products at acceptable cost levels;
- achieve broad market acceptance of PDS0101 and other Versamune® Products in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of PDS0101 and other Versamune® Products, whether alone or in collaboration with others; and
- maintain, expand and protect PDS's intellectual property portfolio.

Because of the numerous risks and uncertainties associated with immunotherapy development and manufacturing, PDS is unable to predict the timing or amount of increased development expenses, or when it will be able to achieve or maintain profitability, if at all. PDS's expenses could increase beyond expectations if it is required by the U.S. Food and Drug Administration, or FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those it currently anticipates. Even if PDS0101 is approved for commercial sale, it anticipates incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for PDS0101 and other Versamune® Products. If PDS cannot successfully execute on any of the factors listed above, PDS's business may not succeed and your investment will be adversely affected.

***PDS has incurred significant losses since its inception and expects to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.***

PDS has never generated any product revenues and it expects to continue to incur substantial and increasing losses as it continues to develop PDS0101 and other Versamune® Products. PDS0101 has not been approved for marketing in the United States and may never receive such approval. As a result, PDS is uncertain when or if it will achieve profitability and, if so, whether it will be able to sustain it. PDS's ability to generate revenue and achieve profitability is dependent on its ability to complete development, obtain necessary regulatory approvals, and have PDS0101 manufactured and successfully marketed. PDS cannot assure you that it will be profitable even if it successfully commercializes PDS0101 or other Versamune® Products. If PDS does successfully obtain regulatory approval to market PDS0101, its revenues will be dependent, in part, upon, the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets for the approved indication, and the price at which PDS can offer PDS0101. If the indication approved by regulatory authorities is narrower than PDS expects, or the treatment population is narrowed by competition, physician choice or treatment guidelines, PDS may not generate significant revenue from sales of PDS0101, even if approved. Even if PDS does achieve profitability, PDS may not be able to sustain or increase profitability on a quarterly or annual basis. If PDS fails to become and remain profitable the market price of its common stock and PDS's ability to raise capital and continue operations will be adversely affected.

PDS expects research and development expenses to increase significantly for PDS0101 and other Versamune® Products. In addition, even if PDS obtains regulatory approval, significant sales and marketing expenses will be required to commercialize PDS0101. As a result, PDS expects to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on its financial position and working capital. As of September 30, 2018, PDS had an accumulated deficit of \$20.1 million.

***PDS is dependent on the success of PDS0101, which is still in early-stage clinical development, and if PDS0101 does not receive regulatory approval or is not successfully commercialized, its business may be harmed.***

PDS0101 is only in early clinical development, and as a consequence, it is too early to determine whether the Versamune® Products will ever be approved for commercial sale or marketable. PDS expects that a substantial portion of its efforts and expenditures over the next few years will be devoted to PDS0101 and other

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Versamune® Products. Accordingly, PDS's business currently depends heavily on the successful development, regulatory approval and commercialization of PDS0101. PDS0101 may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of PDS0101 is and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. PDS is not permitted to market PDS0101 in the United States until it receives approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until it receives the requisite approval from such countries. To date, PDS has only completed Phase 1/2A clinical trials for certain applications of PDS0101. As a result, PDS has not submitted a BLA to the FDA or comparable applications to other regulatory authorities and does not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of PDS0101 for many reasons, including:

- PDS may not be able to demonstrate that PDS0101 is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1/2A clinical trials of PDS0101 satisfy the FDA's requirements and may require PDS to conduct additional testing;
- the results of PDS's future clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of PDS's clinical trials;
- the contract research organizations, or CROs, that PDS retains to conduct clinical trials may take actions outside of PDS's control that materially and adversely impact its clinical trials;
- the FDA may not find the data from PDS's preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of PDS0101 outweigh the safety risks;
- the FDA may disagree with PDS's interpretation of data from PDS's preclinical studies and clinical trials;
- the FDA may not accept data generated at PDS's clinical trial sites;
- if PDS's BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of PDS's application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the FDA may identify deficiencies in PDS's manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

***PDS's independent auditor has expressed doubt about PDS's ability to continue as a going concern.***

Based on its cash balances, recurring losses since inception and existing capital resources to fund planned operations for the next twelve months, PDS's independent auditor has included an explanatory paragraph in its report on PDS's financial statements as of and for the year ending December 31, 2017 expressing substantial doubt about PDS's ability to continue as a going concern. If the merger is not consummated PDS will, during 2019, require significant additional funding to continue operations. If PDS is unable to continue as a going concern, it may be forced to liquidate its assets and the values it receives for its assets in liquidation or dissolution could be significantly lower than the values reflected in its financial statements.

***PDS will require additional capital to fund its operations, and if PDS fails to obtain necessary financing, it may not be able to complete the development and commercialization of PDS0101.***

PDS expects to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize PDS0101. Even with the expected cash reserves of the combined company, PDS will require

substantial additional capital to complete the development and potential commercialization of PDS0101 and the

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development of other Versamune® Products. If PDS is unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, if at all, it could be forced to delay, reduce or eliminate one or more of its development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of its management from day-to-day activities and harm its development efforts.

Based upon its current operating plan, PDS believes that the expected cash reserves of the combined company will enable it to fund its operating expenses and capital expenditure requirements into 2020. PDS's estimate as to what it will be able to accomplish is based on assumptions that may prove to be inaccurate, and it could exhaust its available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of PDS0101 is highly uncertain, PDS is unable to estimate the actual funds it will require for development and any approved marketing and commercialization activities. PDS's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of PDS's planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against PDS now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where PDS chooses to commercialize PDS0101 on PDS's own; and
- the initiation, progress, timing and results of the commercialization of PDS0101, if approved, for commercial sale.

Additional funding may not be available on acceptable terms, or at all. If PDS is unable to raise additional capital in sufficient amounts or on terms acceptable to it, PDS may have to significantly delay, scale back or discontinue the development or commercialization of PDS0101 or potentially discontinue operations.

***Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict PDS's operations or require it to relinquish proprietary rights.***

PDS expects that significant additional capital will be needed in the future to continue its planned operations. Until such time, if ever, as PDS can generate substantial product revenues, PDS expects to finance its cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. PDS does not currently have any committed external source of funds. To the extent that PDS raises additional capital by issuing equity securities, PDS's existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting PDS's ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming its stock or making investments.

If PDS raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, future revenue streams, research programs or Versamune® Products or grant licenses on terms that may not be favorable to us. If PDS is unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic



alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, it may be required to delay, limit, reduce or terminate its PDS0101 development or future commercialization efforts or grant rights to develop and market other Versamune® Products that it would otherwise develop and market.

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### ***PDS's future success depends on its ability to retain executive officers and attract, retain and motivate qualified personnel.***

PDS is highly dependent on its executive officers and the other principal members of the executive and scientific teams, particularly its President and Chief Executive Officer, Dr. Frank K. Bedu-Addo, its Chief Medical Officer, Dr. Lauren Wood, and its Chief Scientific Officer, Dr. Gregory L. Conn. The employment of PDS's executive officers are at-will and PDS's executive officers may terminate their employment at any time, subject to applicable notice requirements. The loss of the services of any of PDS's senior executive officers could impede the achievement of PDS's research, development and commercialization objectives. PDS does not maintain key person insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, and operational personnel is also critical to PDS's success. PDS may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. PDS also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. PDS's industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, PDS relies on consultants and advisors, including scientific and clinical advisors, to assist it in devising PDS's research and development and commercialization strategy. PDS's consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance PDS's strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to the company, PDS's business may be harmed.

### ***If PDS fails to obtain or maintain adequate coverage and reimbursement for PDS0101, its ability to generate revenue could be limited.***

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of PDS0101 that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of PDS0101 will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, PDS may not be able to successfully commercialize PDS0101. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow PDS to establish or maintain adequate pricing that will allow it to realize a sufficient return on PDS's investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and PDS believes the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause PDS to price PDS0101 on less favorable terms that it currently anticipates. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, PDS may be required to conduct a clinical trial that compares the cost-effectiveness of PDS0101 to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that it is able to charge for PDS0101. Accordingly, in markets outside the United States, the reimbursement for its products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for it PDS0101. PDS expects to experience pricing pressures in connection with the sale of PDS0101 due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

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***PDS will need to expand its organization, and may experience difficulties in managing this growth, which could disrupt operations.***

PDS's future financial performance and PDS's ability to commercialize PDS0101 and compete effectively will depend, in part, on PDS's ability to effectively manage any future growth. As of September 30, 2018, PDS had one employee and five consultants. PDS expects to hire additional employees for PDS's managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. PDS may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on its management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, PDS's management may need to divert a disproportionate amount of its attention away from PDS's day-to-day activities and devote a substantial amount of time to managing these growth activities. PDS may not be able to effectively manage the expansion of its operations, which may result in weaknesses in its infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. PDS's expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of PDS0101. If PDS is unable to effectively manage its growth, its expenses may increase more than expected, its ability to generate and/or grow revenues could be reduced, and PDS may not be able to implement its business strategy.

Many of the other pharmaceutical companies that PDS competes against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than PDS. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what it has to offer. If PDS is unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which it can select and develop PDS0101 and its business will be limited.

***PDS's employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on PDS's results of operations.***

PDS is exposed to the risk that its employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to PDS's reputation. It is not always possible to identify and deter third-party misconduct, and the precautions PDS takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it 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 PDS, and it is not successful in defending PDS or asserting its rights, those actions could have a significant impact on PDS's business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of its operations, any of which could adversely affect PDS's ability to operate its business and PDS's results of operations.

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

PDS's computer systems and those of its service providers, including its CROs, 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 PDS's or their operations, it could result in a material disruption of its development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in its regulatory approval efforts and

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significantly increase PDS's costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, PDS could incur liability and the further development of PDS0101 could be delayed.

***PDS expects to incur significant additional costs as a result of being a public company, which may adversely affect its operating results and financial condition.***

PDS expects to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or Dodd-Frank Act, the SEC, and Nasdaq. These rules and regulations are expected to increase PDS's accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, PDS will incur additional costs associated with its public company reporting requirements and PDS expects those costs to increase in the future. PDS also expects these rules and regulations to make it more expensive for it to maintain directors' and officers' liability insurance and PDS may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for PDS to attract and retain qualified persons to serve on its board of directors, its board committees, or as executive officers. Increases in costs incurred as a result of becoming a publicly traded company may adversely affect PDS's operating results and financial condition.

***The recently enacted tax reform bill could adversely affect PDS's business and financial condition.***

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or TCJA, which significantly amends the Internal Revenue Code of 1986. The TCJA, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted earnings, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as orphan drugs). PDS continues to examine the effect these changes may have on PDS's business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and PDS's business and financial condition could be adversely affected.

### **Risks Related to Clinical Development, Regulatory Approval and Commercialization**

***Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, PDS will be unable to commercialize PDS0101.***

PDS0101 is still in early-stage clinical development and will require extensive additional clinical testing before PDS is prepared to submit a BLA for regulatory approval for any indication or for any other treatment regime. PDS cannot predict with any certainty if or when it might submit a BLA for regulatory approval for PDS0101 or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with PDS's proposed endpoints for any clinical trial it proposes, which may delay the commencement of its clinical trials. The clinical trial process is also time-consuming. PDS estimates that the clinical trials it needs to conduct to be in a position to submit BLAs for PDS0101 will take several years to complete. Furthermore, failure can occur at any stage of the trials, and it could encounter problems that cause it to abandon or repeat clinical trials. In later stages of clinical trials, PDS0101 may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials of PDS0101 therefore may not be predictive of

the results of its planned Phase 1 and 2 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their immunotherapies performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and

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early clinical trials does not ensure that later clinical trials, which involve many more subjects and different cancers than PDS has studied in Phase 1/2A clinical trials to date, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

PDS may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize PDS0101, including that:

- regulators or institutional review boards may not authorize PDS or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- it may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of PDS0101 may produce negative or inconclusive results, and PDS may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of PDS0101 may be larger than PDS anticipates; enrollment in these clinical trials may be slower than PDS anticipates, or participants may drop out of these clinical trials at a higher rate than PDS anticipates;
- PDS third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all;
- regulators or institutional review boards may require that PDS or PDS's investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of PDS0101 may be greater than it anticipates; and
- the supply or quality of PDS0101 or other materials necessary to conduct clinical trials of PDS0101 may be insufficient or inadequate.

If PDS is required to conduct additional clinical trials or other testing of PDS0101 beyond those that it currently contemplates, if it is unable to successfully complete clinical trials of PDS0101 or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, PDS may:

- be delayed in obtaining marketing approval for PDS0101;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if PDS experiences delays in testing or in receiving marketing approvals. PDS does not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which PDS may have the exclusive right to commercialize PDS0101, could allow its competitors to bring products to market before it does, and could impair its ability to successfully commercialize PDS0101, any of which may harm its business and results of operations.

***Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside PDS's control.***

PDS may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of its clinical trials. Once enrolled, PDS may be unable to retain a sufficient number of participants to complete any of its trials. Late-stage clinical trials of PDS0101 may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including





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the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study.

Furthermore, any negative results PDS may report in clinical trials of PDS0101 may make it difficult or impossible to recruit and retain participants in other clinical trials of PDS0101. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on its ability to develop PDS0101, or could render further development impractical. In addition, PDS expects to rely on CROs and clinical trial sites to ensure proper and timely conduct of its future clinical trials and, while PDS intends to enter into agreements governing their services, it will be limited in its ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to its clinical development programs.

***PDS faces significant competition from other biotechnology and pharmaceutical companies, and its operating results will suffer if it fails to compete effectively.***

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, PDS0101 could become obsolete before PDS recoups any portion of its related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. PDS competes with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with PDS in recruiting and retaining highly qualified scientific personnel and consultants. PDS's ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

PDS is aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases PDS has targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with PDS0101 even though their approach to may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including companies like Advaxis, Transgene, ISA Pharmaceuticals, Genexine, and Inovio as well as Etubics, Vaccibody, Admedus, Cel-Sci, Neo-ImmuneTech, Kite Pharma, Immune Design, Dynavax, Bavarian Nordic, Seattle Genetics, and Selecta Bioscience, each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than PDS does (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). PDS also experiences competition in the development of its immunotherapies from universities and other research institutions and competes with others in acquiring technology from such universities and institutions.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. PDS's competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than PDS0101.

PDS will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other cancers and infectious diseases it is currently targeting. Therefore, its ability to compete successfully will depend largely on its ability to:

- develop and commercialize immunotherapies that are superior to other alternatives in the market;
- demonstrate through its clinical trials that PDS0101 is differentiated from existing and future therapies;
- attract qualified scientific, immunotherapy development and commercial personnel;

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- obtain additional patent or other proprietary protection for PDS0101;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new applications for PDS0101 or immunotherapies.

The availability of its competitors' immunotherapies and other treatments could limit the demand, and the price it is able to charge, for PDS0101. The inability to compete with existing or subsequently introduced immunotherapies and other treatments would have an adverse impact on its business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could PDS0101 less competitive. In addition, any new immunotherapy that competes with an approved treatment must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, PDS's competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before PDS does, which would have an adverse impact on its business and results of operations.

***PDS0101 may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.***

Adverse events caused by PDS0101 could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If clinical trials for PDS0101 report an unacceptable frequency or severity of adverse events, PDS's ability to obtain regulatory approval for PDS0101 may be negatively impacted.

Furthermore, if PDS0101 is approved and then causes serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of PDS0101 or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- PDS may be required to change the way PDS0101 is administered or to conduct additional clinical trials;
- PDS could be sued and held liable for injuries sustained by patients;
- PDS could elect to discontinue the sale of PDS0101; and
- PDS's reputation may suffer.

Any of these events could prevent PDS from achieving or maintaining market acceptance of PDS0101 and could substantially increase the costs of commercialization.

***If PDS is not able to obtain, or if there are delays in obtaining, required regulatory approvals, it will not be able to commercialize, or will be delayed in commercializing, PDS0101, and its ability to generate revenue will be impaired.***

PDS0101 and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for PDS0101 will prevent PDS from commercializing PDS0101. PDS has not received approval to market a PDS0101 from regulatory authorities in any jurisdiction. PDS has only limited experience in filing and supporting the applications necessary to gain marketing

approvals and expect to rely on CROs to assist it in this process.

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Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the safety and efficacy of PDS0101. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. PDS0101 may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude it obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors. PDS cannot assure you that it will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that PDS's data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of PDS0101. Additionally, any marketing approval PDS ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***Even if PDS obtains FDA approval in the United States, it may never obtain approval for or commercialize PDS0101 in any other jurisdiction, which would limit its ability to realize each product's full market potential.***

In order to market PDS0101 in a particular jurisdiction, PDS must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for PDS and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of PDS0101 in those countries. PDS0101 is not approved for sale in any jurisdiction, including in international markets, and PDS does not have experience in obtaining regulatory approval in international markets. If PDS fails to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, PDS's target market will be reduced.

***PDS's product candidates are in various stages of development.***

Favorable results in pre-clinical or early stage clinical trials may not be predictive of success in later clinical trials and may not lead to commercially viable products for any of several reasons. For example, PDS's product candidates may fail to be safe and effective in clinical trials or additional pre-clinical studies, or PDS may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. PDS's product candidates will require significant additional development, clinical trials, regulatory clearances and additional investment by PDS before they can be commercialized.

***Even if PDS obtains regulatory approval, it will still face extensive ongoing regulatory requirements and PDS0101 may face future development and regulatory difficulties.***

Marketing of PDS0101, if approved, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for PDS0101, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that PDS conducts post-approval. Even if marketing approval of PDS0101 is

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granted, the approval may be subject to limitations on the indicated uses for which PDS0101 may be marketed or to the conditions of approval. If PDS0101 receives marketing approval, an accompanying label may limit the approved use of PDS0101, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of PDS0101. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if PDS promotes or otherwise markets PDS0101 for indications other than its approved indications, PDS may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with PDS0101, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing PDS0101;
- restrictions on the labeling or marketing of PDS0101;
- restrictions on PDS0101 distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of PDS0101 from the market;
- refusal to approve pending applications or supplements to approved applications that PDS submits;
- recalls of PDS0101;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of PDS0101;
- seizures of PDS0101; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of PDS0101. If PDS is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if PDS is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained.

***Even if PDS0101 receive marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.***

If PDS0101 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If PDS0101 does not achieve an adequate level of acceptance, PDS may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- PDS's ability to offer PDS0101 for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;



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- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers PDS0101 in addition to or in the place of other immunotherapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of PDS0101 together with other medications.

Because PDS expects sales of PDS0101, if approved, to generate substantially all of its revenues for the foreseeable future, the failure of PDS0101 to achieve market acceptance would harm its business and could require it to seek additional financing sooner than it otherwise plans.

***PDS may expend its limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because PDS has limited financial and managerial resources, it is initially developing PDS's lead product candidate, PDS0101 and the other Versamune® Products. As a result, PDS may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. PDS's resource allocation decisions may cause PDS to fail to timely capitalize on viable commercial products or profitable market opportunities. PDS's spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If PDS does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for PDS to retain sole development and commercialization rights to such product candidate.

***If PDS fails to comply with state and federal healthcare regulatory laws, it could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of its operations, any of which could harm its business.***

Although PDS does not provide healthcare services or submit claims for third-party reimbursement, it is subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact its business. The laws that may affect its ability to operate include, but are not limited to:

- the Federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the FCA's civil provisions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the FCA's criminal provisions, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;



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- the federal beneficiary inducement statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively, the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while it does not submit claims and its customers make the ultimate decision on how to submit claims, from time to time, PDS may provide reimbursement guidance to its customers. If a government authority were to conclude that PDS provided improper advice to its customers or encouraged the submission of false claims for reimbursement, it could face action against it by government authorities. Any violations of these laws, or any action against PDS for violation of these laws, even if PDS successfully defends against it, could result in a material adverse effect on its reputation, business, results of operations and financial condition.

PDS has entered into consulting and employment arrangements with individuals, physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While PDS has worked to structure PDS's arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which it could be subject to other significant penalties. PDS could be adversely affected if regulatory agencies interpret PDS's financial relationships with providers who influence the ordering of and use PDS's products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase PDS's costs or otherwise have an adverse effect on its business.



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### ***Product liability lawsuits against PDS could cause it to incur substantial liabilities and could limit the commercialization of PDS0101.***

PDS faces an inherent risk of product liability exposure related to the testing of PDS0101 in human clinical trials and will face an even greater risk if it commercially sells any products that it may develop after approval. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for PDS0101 or other immunotherapies that PDS may develop;
- injury to PDS's reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products it may develop.

Although PDS maintains product liability insurance coverage in the amount of up to \$5 million per claim and in the aggregate, it may not be adequate to cover all liabilities that it may incur. PDS anticipates that it will need to increase its insurance coverage as it continues clinical trials and if it successfully commercializes any products. Insurance coverage is increasingly expensive. PDS may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

### ***If PDS is unable to establish sales, marketing and distribution capabilities either on its own or in collaboration with third parties, it may not be successful in commercializing PDS0101, if approved.***

PDS does not have any infrastructure for the sales, marketing or distribution of PDS0101, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market PDS0101, PDS must build its sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for PDS0101, PDS will need either its own, or a third party, sales and marketing organization. There are significant expenses and risks involved with creating teams for, or contracting for, sales, marketing and distribution capabilities. Any failure or delay in the development of its sales, marketing and distribution capabilities, either internally or in collaboration with third parties, could delay the launch of PDS0101, which would adversely affect commercialization.

PDS may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, it may be unable to compete successfully against these more established companies.

### ***If PDS obtains approval to commercialize PDS0101 outside of the United States, a variety of risks associated with international operations could harm its business.***

If PDS0101 is approved for commercialization, PDS may enter into agreements with third parties to market them in certain jurisdictions outside the United States. PDS expects that it will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;

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- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

PDS has no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which it will need to comply.

***Recently enacted and future legislation may increase the difficulty and cost for PDS to obtain marketing approval of and commercialize PDS0101 and affect the prices PDS may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of PDS0101, restrict or regulate post-approval activities and affect PDS's ability to profitably sell PDS0101.

For example, in March 2010, Affordable Care Act was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although the full effect of the Affordable Care Act may not yet be fully understood, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. PDS has not yet adopted the significant measures that will be required to comply with this law. PDS is not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on PDS's business, if any, may be.

PDS expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for immunotherapies, which could result in reduced demand for PDS0101 or additional pricing pressures.

### **Risks Related to PDS's Dependence on Third Parties**

***PDS has limited to no manufacturing, sales, marketing or distribution capability and it must rely upon third parties for such.***

PDS currently has agreements with various third-party manufacturing facilities for production of PDS0101 for research and development and testing purposes. PDS depends on third-party manufacturers to supply its preclinical and clinical materials and will be reliant on a third-party manufacturer to produce PDS0101 on a commercial scale, should that product receive regulatory approval. Third-party manufacturers must be able to meet PDS's deadlines and adhere to quality standards and specifications. PDS's predominant reliance on third parties for the manufacture of PDS0101 creates a dependency that could severely disrupt PDS's research and development, clinical testing, and sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. There is no assurance that any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or cGMP.

***PDS intends to rely on third parties to conduct, supervise and monitor PDS's clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm PDS's business.***

PDS intends to rely on CROs and clinical trial sites to ensure the proper and timely conduct of its clinical trials, and PDS expects to have limited influence over their actual performance.

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PDS intends to rely upon CROs to monitor and manage data for its clinical programs, as well as the execution of future nonclinical studies. PDS expects to control only certain aspects of its CROs' activities. Nevertheless, PDS will be responsible for ensuring that each of its studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and PDS's reliance on the CROs does not relieve PDS of its regulatory responsibilities.

PDS and its CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for PDS0101. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If PDS or its CROs fail to comply with GCPs, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require PDS to perform additional clinical trials before approving PDS's marketing applications. Accordingly, if PDS's CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, PDS may be required to repeat clinical trials, which would delay the regulatory approval process.

PDS's CROs will not be its employees, and PDS will not control whether or not they devote sufficient time and resources to its future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including PDS's competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm its competitive position. PDS faces the risk of potential unauthorized disclosure or misappropriation of its intellectual property by CROs, which may reduce PDS's trade secret protection and allow its potential competitors to access and exploit its proprietary technology. If its CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to PDS's clinical protocols or regulatory requirements or for any other reasons, its clinical trials may be extended, delayed or terminated, and it may not be able to obtain regulatory approval for, or successfully commercialize PDS0101. As a result, PDS's financial results and the commercial prospects for PDS0101 would be harmed, its costs could increase, and its ability to generate revenues could be delayed.

If PDS's relationship with these CROs terminate, it may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact PDS's ability to meet its desired clinical development timelines. Though PDS intends to carefully manage its relationships with PDS's CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on its business, financial condition and prospects.

***If PDS is unable to establish or manage strategic collaborations in the future, PDS's revenue and drug development may be limited.***

PDS's strategy may include potential reliance upon strategic collaborations for marketing and commercialization of PDS0101 and other Versamune® Products. PDS also relies on strategic collaborations for research, development, marketing and commercialization for PDS0101 and other Versamune® Products. PDS has also been heavily reliant upon third party outsourcing for its clinical trials execution and production of drug supplies for use in clinical trials.

Establishing strategic collaborations is difficult and time-consuming. PDS's discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. PDS faces significant competition in seeking appropriate collaborators. Whether PDS reaches a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the

proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for PDS0101 and other Versamune® Products, the costs and complexities of manufacturing and delivering PDS0101 and other Versamune® Products to patients, the potential of competing products, the existence of uncertainty with respect to PDS's ownership of technology, which can exist if there is a challenge to such ownership without regard to the

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merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative immunotherapies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with PDS for PDS0101 and other Versamune® Products.

PDS's current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of PDS0101 and other Versamune® Products or the generation of sales revenue. To the extent that PDS has entered or will enter into co-promotion or other collaborative arrangements, PDS0101 and other Versamune® Products revenues are likely to be lower than if PDS directly marketed and sold any products that it develops.

Management of PDS's relationships with its collaborators will require:

- significant time and effort from PDS's management team;
- financial funding to support said collaboration;
- coordination of PDS's research and development programs with the research and development priorities of its collaborators; and
- effective allocation of PDS's resources to multiple projects.

If PDS continues to enter into research and development collaborations, PDS's success will in part depend on the performance of its collaborators. PDS will not directly control the amount or timing of resources devoted by its collaborators to activities related to PDS0101 and other Versamune® Products. PDS's collaborators may not commit sufficient resources to PDS's research and development programs or the commercialization, marketing or distribution of PDS0101 and other Versamune® Products. If any collaborator fails to commit sufficient resources, PDS's preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, PDS's collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with PDS. If PDS fails to make required milestone or royalty payments to its collaborators or to observe other obligations in its agreements with them, PDS's collaborators may have the right to terminate those agreements. Additionally, PDS's collaborators may seek to renegotiate agreements it has entered into, or may disagree with PDS about the terms and implementation of these agreements. If collaborators disagree with PDS about the terms or implementation of its agreements, PDS may face legal claims that may involve considerable expense and could negatively affect PDS's financial results.

***PDS's relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of PDS0101 and other Versamune® Products, if approved for marketing. PDS's future arrangements with third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells and distributes PDS's medicines for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal

government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

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- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for
- executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a
- material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs,
- devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to
- comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring immunotherapy manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

**Risks Related to PDS’s Intellectual Property**

*If PDS is unable to obtain and maintain patent protection for its Versamune® platform, PDS0101, or other Versamune® Products or if the scope of the patent protection obtained is not sufficiently broad, it may not be able to compete effectively in its markets.*

PDS relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Versamune®. PDS’s success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries. PDS seeks to protect its proprietary position by filing patent applications in the United States and abroad related to PDS0101. The patent prosecution process is expensive and time-consuming, and PDS may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that PDS will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection. The patent applications that PDS owns or in-licenses may fail to result in issued patents with claims that cover PDS0101 or its applications in the United States or in other countries. There is no assurance that all potentially relevant prior art relating, which can invalidate a patent or prevent a patent from issuing from a pending patent application is known to PDS. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to PDS could deprive it of rights necessary for the successful commercialization of PDS0101 and other Versamune® Products that it may develop. Further, if PDS encounters delays in regulatory approvals, the period of time during which PDS could exclusively market PDS0101 and other Versamune® Products under patent protection could be reduced.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect PDS’s rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

Therefore, PDS cannot know with certainty whether it was the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of its patent rights are highly uncertain. PDS's pending and future patent applications may not result in patents being issued which protect PDS0101 or other Versamune® Products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and immunotherapies. Changes

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in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of PDS's patents or narrow the scope of its patent protection.

Recent patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of PDS's business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of PDS's patent applications and the enforcement or defense of PDS's issued patents, all of which could have an adverse effect on PDS's business and financial condition.

Moreover, PDS may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent Office, or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging its patent rights or the patent rights of others. In other countries, it may be subject to or become involved in opposition proceedings challenging its patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, its patent rights, allow third parties to commercialize PDS's technology or immunotherapies and compete directly with PDS, without payment to it, or result in its inability to manufacture or commercialize PDS0101 without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by its patents and patent applications is threatened, it could dissuade companies from collaborating with PDS to license, develop or commercialize PDS0101 and other Versamune® Products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and its owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit its ability to stop others from using or commercializing similar or identical technology and immunotherapies, or limit the duration of the patent protection of its technology and immunotherapies. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for PDS0101 and other Versamune® Products, PDS may be open to competition from generic versions of PDS0101 or other similar products using the PDS technology. Given the amount of time required for the development, testing and regulatory review of new immunotherapy candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, PDS's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing immunotherapies similar or identical to PDS's.

***PDS may be involved in lawsuits to protect or enforce its patents, the patents of its licensors or its other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate PDS's patents, the patents of its licensors or its other intellectual property rights. To counter infringement or unauthorized use, PDS may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of PDS's or its licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of PDS's patents at risk of being invalidated or interpreted narrowly and could put

PDS's patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against PDS such as claims asserting that its patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise



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similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. PDS cannot be certain that there is no invalidating prior art, of which it and the patent examiner were unaware during prosecution. For the patents and patent applications that PDS has licensed, it may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, PDS would lose at least part, and perhaps all, of any future patent protection on PDS0101 and other Versamune® Products. Such a loss of patent protection could harm its business.

PDS may also face claims that its products infringe patents that its competitors hold. Claims for alleged infringement and any resulting lawsuit, if successful, could subject PDS to significant liability for damages and invalidations of PDS's proprietary rights. Any such lawsuit, regardless of its success, would likely be time consuming and expensive to resolve and would divert management time and attention. Any potential intellectual property litigation could also force PDS to do one or more of the following: (a) stop selling PDS's products; (b) obtain a license(s), from the owner of any asserted intellectual property, to sell or use the relevant technology, which license may not be available on reasonable terms, or at all; or (c) redesign PDS's products to avoid using the relevant technology.

PDS may not be able to prevent, alone or with its licensors, misappropriation of its intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. PDS's business could be harmed if in litigation the prevailing party does not offer it a license on commercially reasonable terms. Any litigation or other proceedings to enforce its intellectual property rights may fail, and even if successful, may result in substantial costs and distract its management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of PDS's confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of its common stock.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing PDS's ability to protect the Versamune® platform, PDS0101 and other Versamune® Products.***

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to PDS's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken PDS's ability to obtain new patents or to enforce patents that it has licensed or that it might obtain in the future.

***PDS may not be able to protect its intellectual property rights throughout the world, which could impair its business.***

Filing, prosecuting and defending patents covering PDS0101 throughout the world would be prohibitively expensive. Competitors may use its technologies in jurisdictions where it has not obtained patent protection to develop their own immunotherapies and, further, may export otherwise infringing immunotherapies to territories where PDS may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These immunotherapies may compete with PDS0101 in jurisdictions where PDS does not have any issued or licensed patents and any future

patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

***PDS's reliance on third parties requires it to share its trade secrets, which increases the possibility that a competitor will discover them or that its trade secrets will be misappropriated or disclosed.***

PDS seeks to protect its proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with its advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary

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information. These agreements typically limit the rights of the third parties to use or disclose PDS's confidential information, including its trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by its competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that PDS's proprietary position is based, in part, on its know-how and trade secrets, a competitor's discovery of PDS's trade secrets or other unauthorized use or disclosure would impair its competitive position and may have an adverse effect on its business and results of operations.

In addition, these agreements typically restrict the ability of its advisors, employees, third-party contractors and consultants to publish data potentially relating to its trade secrets, although PDS's agreements may contain certain limited publication rights. Despite its efforts to protect its trade secrets, its competitors may discover its trade secrets, either through breach of PDS's agreements with third parties, independent development or publication of information by any of its third-party collaborators. A competitor's discovery of PDS's trade secrets would impair PDS's competitive position and have an adverse impact on PDS's business.

**Risks Related to the Combined Company**

*In determining whether you should approve the issuance of shares of Edge common stock and other matters related to the merger, as the case may be, you should carefully read the following risk factors in addition to the risks described above, which will also apply to the combined company.*

***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;
- 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;

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- 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 discussed in this proxy statement/prospectus/information statement lapse, the trading price of the common stock of the combined company could decline. Based on shares outstanding as of September 30, 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 [•] million shares of common stock (prior to giving effect to the proposed reverse stock split) immediately following the closing of the merger. Approximately [•] 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 [•] 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.

***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 [•]% 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

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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, 2017, Edge had federal and state net operating loss carryforwards, or NOLs, of \$101.5 million and \$31.9 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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### **CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS**

This proxy statement/prospectus/information statement and the documents incorporated by reference into this proxy statement/prospectus/information statement contain forward-looking statements. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as neither Edge nor PDS can assure you that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including anticipates, believes, continue, could, design, estimates, expects, intends, may, potentially, predict, pro forma seeks, should, will or the negative of these words and phrases or other variations of these words and phrases or comparable terminology.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include any statements of the plans, strategies and objectives of management for future operations, including the execution of integration and restructuring plans and the anticipated timing of filings; any statements concerning proposed new products or developments; any statements regarding future economic conditions or performance; statements of belief and any statement of assumptions underlying any of the foregoing. Forward-looking statements may also include any statements of the plans, strategies and objectives of management with respect to the approval and the closing of the merger, Edge's ability to solicit a sufficient number of proxies to approve the merger and other matters related to the closing of the merger.

For a discussion of the factors that may cause Edge, PDS or the combined company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risk associated with the ability of Edge and PDS to complete the merger and the effect of the merger on the business of Edge, PDS and the combined company, see the section titled Risk Factors.

These forward-looking statements include, but are not limited to, statements concerning the following:

- the expected benefits of and potential value created by the merger for the stockholders of Edge and PDS;
- 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;
- any statements of the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings;
- any statements of plans to develop and commercialize additional products;
- any statements concerning the attraction and retention of highly qualified personnel;
- any statements concerning the ability to protect and enhance the combined company's products and intellectual property;
- any statements concerning developments and projections relating to the combined company's competitors or industry;
- any statements concerning the combined company's financial performance;
- any statements regarding expectations concerning Edge's or PDS's relationships and actions with third parties; and
- future regulatory, judicial and legislative changes in Edge's or PDS's industry.

You should not rely upon forward-looking statements as predictions of future events. Neither Edge nor PDS can assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur.



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In addition, statements that Edge believes, PDS believes and similar statements reflect the beliefs and opinions on the relevant subject of Edge, PDS or the combined company, as applicable. These statements are based upon information available as of the date of this proxy statement/prospectus/information statement, and while Edge, PDS or the combined company, as applicable, believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and such statements should not be read to indicate that Edge, PDS or the combined company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Edge, PDS or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement/prospectus/information statement are current only as of the date on which the statements were made. Except as required by law, neither Edge nor PDS undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this proxy statement/prospectus/information statement or to conform these statements to actual results or to changes in expectations, even if new information becomes available in the future.

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### **THE SPECIAL MEETING OF EDGE STOCKHOLDERS**

#### **Date, Time and Place**

The special meeting of Edge stockholders will be held on \_\_\_\_\_, 2019, at commencing \_\_\_\_\_ at \_\_\_\_\_ local time. Edge is sending this proxy statement/prospectus/information statement to its stockholders in connection with the solicitation of proxies by the Edge Board for use at the Edge special meeting and any adjournments or postponements of the special meeting. This proxy statement/prospectus/information statement is first being furnished to stockholders of Edge on or about \_\_\_\_\_, 2019.

#### **Purposes of the Edge Special Meeting**

The purposes of the Edge special meeting are:

1. To consider and vote upon a proposal to approve the issuance of shares of Edge common stock pursuant to the Agreement and Plan of Merger and Reorganization, dated as of November 23, 2018, by and among Edge, Echos Merger Sub, Inc. and PDS, a copy of which is attached as *Annex A* to this proxy statement/prospectus/information statement, or the Merger Agreement, or the Stock Issuance Proposal;
2. To consider and vote upon the amendment to the certificate of incorporation of Edge to effect a reverse stock split of Edge common stock, at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved, solely by the Edge Board following the special meeting, the form of which is attached as *Annex B* to this proxy statement/prospectus/information statement, or the Reverse Stock Split Proposal; and
3. To consider and vote upon approving Amended and Restated Edge Therapeutics, Inc. 2014 Equity Incentive Plan, or the Restated Plan, the form of which is attached as *Annex C* to this proxy statement/prospectus/information statement, which, among other items, increases the number of shares Edge common stock available for grant under Edge's equity-based incentive compensation program, or the Equity Incentive Plan Proposal. If the Stock Issuance Proposal is not approved, the Equity Incentive Plan Proposal will be automatically withdrawn.

#### **Recommendation of the Edge Board**

- The Edge Board has determined and believes that the issuance of shares of Edge common stock pursuant to the Merger Agreement is in the best interests of Edge and its stockholders and has approved such items. The Edge Board unanimously recommends that Edge stockholders vote **FOR** the Stock Issuance Proposal as described in this proxy statement/prospectus/information statement.  
The Edge Board has determined and believes that it is advisable to, and in the best interests of, Edge and its stockholders to approve the amendment to the certificate of incorporation of Edge effecting a reverse stock split at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge stockholders, determined solely by the Edge Board following the special meeting as described in this proxy statement/prospectus/information statement. The Edge Board unanimously recommends that Edge stockholders vote **FOR** the Reverse Stock Split Proposal as described in this proxy statement/prospectus/information statement.
- The Edge Board has determined and believes that it is advisable to, and in the best interests of, Edge and its stockholders to approve the Restated Plan. The Edge Board unanimously recommends that Edge stockholders vote **FOR** the Equity Incentive Plan Proposal as described in this proxy statement/prospectus/information statement.

#### **Record Date and Voting Power**

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Only holders of record of Edge common stock at the close of business on the record date, , 2019, are entitled to notice of, and to vote at, the Edge special meeting. At the close of business on the record date, shares of Edge common stock were issued and outstanding. Each share of Edge common stock

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entitles the holder thereof to one vote on each matter submitted for stockholder approval. See the section titled Principal Stockholders of Edge for information regarding persons known to the management of Edge to be the beneficial owners of more than 5% of the outstanding shares of Edge common stock.

### **Voting and Revocation of Proxies**

The proxy accompanying this proxy statement/prospectus/information statement is solicited on behalf of the Edge Board for use at the Edge special meeting.

If you are a stockholder of record of Edge as of the record date referred to above, you may vote in person at the Edge special meeting or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the Edge special meeting, Edge urges you to vote by proxy to ensure your vote is counted. You may still attend the Edge special meeting and vote in person if you have already voted by proxy. As a stockholder of record you are entitled:

- to vote in person, come to the Edge special meeting and Edge will give you a ballot when you arrive.
- to vote using the proxy card, simply mark, sign and date your proxy card and return it promptly in the postage-paid envelope provided. If you return your signed proxy card to Edge before the Edge special meeting, Edge will vote your shares as you direct.
- to vote on the Internet, go to the website on the proxy card or voting instruction form to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by Eastern Time on , 2019 to be counted.

If your Edge shares are held by your broker as your nominee, that is, in street name, the enclosed voting instruction card is sent by the institution that holds your shares. Please follow the instructions included on that proxy card regarding how to instruct your broker to vote your Edge shares. If you do not give instructions to your broker, your broker can vote your Edge shares with respect to discretionary items but not with respect to non-discretionary items. Discretionary items are proposals considered routine under the rules of the Nasdaq Global Select Market on which your broker may vote shares held in street name in the absence of your voting instructions. On non-discretionary items for which you do not give your broker instructions, the Edge shares will be treated as broker non-votes. It is anticipated that the Stock Issuance Proposal and Equity Incentive Plan Proposal will be non-discretionary items and the Reverse Stock Split Proposal will be a discretionary item.

All properly executed proxies that are not revoked will be voted at the Edge special meeting and at any adjournments or postponements of the Edge special meeting in accordance with the instructions contained in the proxy. If a holder of Edge common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted

- FOR the Stock Issuance Approval to approve the issuance of shares of Edge common stock pursuant to the Merger Agreement;
- FOR the Reverse Stock Split Proposal to approve the amendment to the certificate of incorporation of Edge effecting a reverse stock split at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge stockholders, determined solely by the Edge Board following the special meeting; and
- FOR the Equity Incentive Plan Proposal to approve the Restated Plan.

Edge stockholders of record, other than those Edge stockholders who have executed support agreements, may change their vote at any time before their proxy is voted at the Edge special meeting in one of three ways. First, a stockholder of record of Edge can send a written notice to the Secretary of Edge stating that the stockholder would like to revoke its proxy. Second, a stockholder of record of Edge can submit new proxy instructions either on a new proxy card or via the Internet. Third, a stockholder of record of Edge can attend the Edge special meeting and vote in person. Attendance alone will not revoke a proxy. If an Edge stockholder of record or a stockholder who owns Edge shares in

street name has instructed a broker to vote its shares of Edge common stock, the stockholder must follow directions received from its broker to change those instructions.

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The presence, in person or represented by proxy, at the Edge special meeting of the holders of a majority of the shares of Edge common stock outstanding and entitled to vote at the Edge special meeting is necessary to constitute a quorum at the meeting. Abstentions and broker non-votes will be counted towards a quorum.

<b>Proposal Number</b>	<b>Proposal Description</b>	<b>Vote Required for Approval</b>	<b>Effect of Abstentions</b>	<b>Effect of Broker Non-Votes</b>
1	Stock Issuance Proposal	<b>FOR</b> votes from the holders of a majority of shares properly cast at a meeting at which a quorum is present	Against	None
2	Reverse Stock Split Proposal	<b>FOR</b> votes from the holders of a majority of outstanding shares	Against	Against
3	Equity Incentive Plan Proposal	<b>FOR</b> votes from the holders of a majority of shares properly cast at a meeting at which a quorum is present	Against	None

Except as stated below, no Edge Proposal is contingent upon any other Edge Proposal. Therefore, assuming all other closing conditions have been either satisfied or waived, the merger will be consummated even if the Reverse Stock Split Proposal is not approved by Edge's stockholders. However, if Edge's stockholders do not approve the Reverse Stock Split Proposal to effect the reverse stock split upon the closing of the merger, Edge has been advised that The Nasdaq Stock Market LLC will commence delisting proceedings immediately following the closing of the merger. In such event, then pursuant to the Merger Agreement, the combined company's board of directors will immediately call for a second special meeting following the closing of the merger and request the stockholders of the combined company to approve a reverse stock split that will allow the combined company to remain in compliance with the listing requirements of The Nasdaq Stock Market LLC. The combined company is obligated to use commercially reasonable efforts to take such steps as necessary to ensure the continued listing of the combined company's common stock on the Nasdaq Capital Market following the closing of the merger. If the Stock Issuance Proposal is not approved but the Reverse Stock Approval is approved, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on the Nasdaq Global Select Market. However, if the Merger is not consummated, the Equity Incentive Plan Proposal will be automatically withdrawn.

As of \_\_\_\_\_, 2019, the directors and executive officers of Edge owned approximately [•]% of the outstanding shares of Edge common stock entitled to vote at the Edge special meeting. The directors and executive officers of Edge owning these shares are subject to support agreement to vote all shares of Edge common stock owned by them as of the record date in favor of the issuance of shares of Edge common stock in the merger pursuant to the Merger Agreement and the reverse stock split. As of \_\_\_\_\_, 2019, Edge is not aware of any affiliate of PDS owning any shares of Edge common stock entitled to vote at the Edge special meeting.

**Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of Edge may solicit proxies from Edge stockholders by personal interview, telephone, telegram, email or otherwise. Edge and PDS will share equally the costs of printing and filing this proxy statement/prospectus/information statement and proxy card. Arrangements will



also be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of Edge common stock for the forwarding of solicitation materials to the beneficial owners of Edge common stock. Edge and PDS will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. Edge has engaged D.F. King & Co, Inc. to assist in the solicitation of proxies and provide related advice and informational support, for a service fee, plus customary disbursements, which are not expected to exceed \$15,000 in total, which amount shall be borne equally by Edge and PDS.

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**Other Matters**

As of the date of this proxy statement/prospectus/information statement, the Edge Board does not know of any business to be presented at the Edge special meeting other than as set forth in the notice accompanying this proxy statement/prospectus/information statement. If any other matters should properly come before the Edge special meeting, it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the persons voting the proxies.

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### **THE MERGER**

*This section and the section titled "The Merger Agreement" in this proxy statement/prospectus/information statement describe the material aspects of the merger, including the Merger Agreement. While Edge and PDS believe that this description covers the material terms of the merger and the Merger Agreement, it may not contain all of the information that is important to you. You should read carefully this entire proxy statement/prospectus/information statement for a more complete understanding of the merger and the Merger Agreement, including the Merger Agreement attached as Annex A, the opinion of Piper Jaffray & Co., attached as Annex D, and the other documents to which you are referred herein. See the section titled "Where You Can Find More Information" in this proxy statement/prospectus/information statement.*

#### **Background of the Merger**

Edge is a clinical-stage biotechnology company that seeks to discover, develop and commercialize novel, hospital-based therapies capable of transforming treatment paradigms for the management of acute, life-threatening conditions.

The Edge Board, and management, regularly review Edge's operating and strategic plans in an effort to enhance stockholder value. This review involves, among other things, discussions of opportunities and risks associated with Edge's product candidates, development programs, financial condition and market, as well as consideration of strategic alternatives and options available to Edge.

The terms of the Merger Agreement are the result of extensive arm's-length negotiations among members of the Transactions Committee, Edge's management team, and the management team of PDS with the assistance of their respective advisors and under the guidance of each company's board of directors, after an extensive strategic review process. From the beginning, Edge followed a careful process assisted by experienced outside financial, medical, scientific and legal advisors to rigorously examine potential transactions and transaction candidates in a broad and inclusive manner. The following is a summary of the background of the process undertaken by Edge, and the identification and evaluation of strategic alternatives and the negotiation of the Merger Agreement, including the circumstances surrounding Edge's decision to review strategic alternatives available to it. The following chronology does not purport to catalogue every conversation among representatives of Edge, PDS and other parties. Unless otherwise noted, all meetings described below were held telephonically.

On March 27, 2018, Edge learned that the pre-specified interim analysis performed on data from the Day 90 visit of the first 210 subjects randomized and treated in the Phase 3 NEWTON 2 study of EG-1962 in adults with aneurysmal subarachnoid hemorrhage, or aSAH, 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 DMC, for NEWTON 2 recommended that the study be stopped based on its conclusion that the study had a low probability of meeting its primary endpoint. Favorable outcome was defined as a score of 6 to 8 on the extended Glasgow Outcome Scale, or GOSE, at Day 90. 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.

On March 27, 2018, the Edge Board held a telephonic meeting. Also participating in the meeting were members of Edge management and representatives of outside corporate counsel, Dechert LLP, or Dechert. The participants discussed the results of the NEWTON 2 interim analysis, as conducted by the DMC, and related matters, including the decision to terminate the NEWTON 2 trial. The decision to terminate the NEWTON 2 trial was publicly announced before the market opened on March 28, 2018.

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On April 2, 2018, an Edge employee (who was not an executive officer of Edge) received an email, which the employee then forwarded to Edge management, from a third-party individual with experience in the biopharmaceutical industry and an investor in PDS, who suggested several companies that Edge might want to consider as potential strategic partners, including PDS. After considering the list and identifying PDS as a potentially attractive target, introductions were made and, on April 6, 2018, Frank K. Bedu-Addo, Ph.D., President and Chief Executive Officer of PDS and Brian Leuthner, President and Chief Executive Officer of Edge, exchanged emails indicating a mutual desire to speak.

On April 12, 2018, certain members of the Edge management team and the PDS management team had an introductory telephone call, during which PDS provided an overview of PDS's business.

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On April 17, 2018, the Edge Board held a regularly scheduled meeting. At the meeting:

- The Edge Board made a determination that it was in the best interest of Edge that it undertake a review of strategic alternatives, including 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, each such option, a Strategic Alternative.

- The Edge Board delegated to a committee, or the Transactions Committee, as a committee of convenience, the authority to oversee Edge's assessment of Strategic Alternatives, which included the authority, working as appropriate with management of Edge, to (i) select, seek and obtain advice from investment bankers, financial advisors, legal counsel and such other consultants, advisors and agents, or Advisors, as the Transactions Committee deemed necessary to evaluate Strategic Alternatives, with all of the fees and expenses of such Advisors to be paid by Edge; (ii) solicit transaction proposals with regard to any Strategic Alternatives that it deemed necessary, appropriate or desirable to pursue, (iii) review and evaluate, and, if it determined appropriate, with the assistance from its Advisors, negotiate the terms and conditions of any transaction proposal received by Edge, (iv) determine, with assistance from its Advisors, whether any transaction proposal that may be received by Edge was advisable and in the best interests of Edge and, if appropriate, as determined by the Transactions Committee and its Advisors based upon the nature of the transaction, was fair to and in the best interests of Edge's stockholders, (v) endeavor to keep the Edge Board generally apprised on the activities of the Transactions Committee, except to the extent that the fiduciary duties of the Transactions Committee dictated otherwise, (vi) recommend to the full board of directors whether or not Edge should proceed with any specific transaction proposal or other Strategic Alternative and (vii) if the Transactions Committee deemed appropriate, request from the Edge Board the authority to take such other action related to or arising in connection with any such transaction proposal or Strategic Alternative as the Transactions Committee deemed necessary, appropriate or advisable, including, without limitation, the solicitation of alternative transactions and the evaluation of other Strategic Alternatives to any transaction proposal.

- The Edge Board appointed Dr. Sol Barer, chairman of the Edge Board, Rosemary Crane and Dr. Robert Spiegel as members of the Transactions Committee, with Dr. Barer serving as chairman of the Transactions Committee. Each of the members of the Transactions Committee is an independent director as defined in the rules and regulations promulgated by the Securities and Exchange Commission and the Nasdaq Stock Market.

- The Edge Board determined that it was advisable to engage an investment banker to the Edge Board and the Transactions Committee to assist in the evaluation of Strategic Alternatives and any other transaction proposal which may be received by Edge. The Transactions Committee identified certain investment bankers and asked Edge management to identify additional bankers and provide an assessment of their capabilities for presentation to, and consideration by, the Transactions Committee.

During the course of the Edge Board's discussion, Dechert advised the Edge Board of its fiduciary duties applicable to a strategic review process. The foregoing process to identify and evaluate Strategic Alternatives available to Edge ultimately resulted in the execution of the Merger Agreement with PDS.

On April 20, 2018, the Transactions Committee held its first meeting. At the meeting, management discussed its review of potential investment banks for consideration by the Transactions Committee to serve as the Edge Board's and the Transactions Committee's financial advisor in connection with Edge's review of strategic alternatives. The Transactions Committee selected Piper Jaffray to advise the Edge Board and the Transactions Committee. In selecting Piper Jaffray, the Transactions Committee gave weight to, among other things, Piper Jaffray's deep experience in the industry and relevant transactions, and the experience that members of the Edge Board had previously had with Piper Jaffray in other circumstances, none of which were deemed to give rise to any potential conflicts of interest except as more fully set forth in The Merger—Opinion of the Financial Advisor to the Edge Board.

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On April 20, 2018 and May 5, 2018, Mr. Andrew Saik, Chief Financial Officer of Edge, and Mr. Michael King, Chief Financial Officer of PDS, engaged in telephonic conversations about potential interest in exploring a transaction between the two companies.

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On April 23, 2018, Dr. Bedu-Addo and Mr. King made a presentation about PDS to Edge management at Edge's offices. Members of Edge management who participated in this and/or subsequent due diligence meetings with PDS included: Brian Leuthner, President and Chief Executive Officer; Andrew Saik, Chief Financial Officer; Brad Middlekauff, Senior Vice President, General Counsel and Secretary; Bert Marchio, Chief Accounting and Administrative Officer; Herb Faleck, Chief Medical Officer; Alyssa Wyant, Senior Vice President, Regulatory Affairs; Ming Leung, Director, Program Management; and Paul D'Angio, Head, Technical Operations and Precisa Development.

On April 27, 2018, representatives of each of Piper Jaffray and Dechert and certain representatives of Edge management had a meeting to organize the search for Strategic Alternatives, consistent with the direction of the Edge Board and the Transactions Committee.

On April 30, 2018, Edge publicly announced that:

- its board of directors was conducting a comprehensive review of Strategic Alternatives focused on maximizing Edge stockholder value;
- in conjunction with the exploration of Strategic Alternatives, Edge intended to streamline its operations in order to preserve its cash resources;
- Edge had retained Piper Jaffray to act as its financial advisor to assist with the review process;
- potential Strategic Alternatives that might be explored or evaluated as part of this review included, but were not limited to, an acquisition, merger, business combination or other transaction involving Edge; and
- there was no defined timeline for completion of the review process.

Beginning on April 30, 2018, the Transactions Committee and members of Edge's management, with assistance from representatives of Piper Jaffray, identified and evaluated 131 potential candidates for a transaction. Members of Edge management, with the assistance of representatives of Piper Jaffray, narrowed that list to 76 companies that best matched Edge's selected screening criteria. The screening criteria included an evaluation of each party's financing risk at closing; each party's product pipeline; upcoming milestones with respect to each party's product candidates likely to occur after a closing that may create greater value for stockholders; the experience and expertise of each party's management and scientific teams; each party's investor base; each party's ability to maintain Edge's Nasdaq listing and operate a public company after closing; the relative potential valuations of Edge and each party; and the party's ability to effectively fund operations after a closing. Between May 4 and June 26, 2018, at the direction of the Transactions Committee with the assistance of Edge management, representatives of Piper Jaffray contacted those 76 parties regarding their respective interest in a potential transaction with Edge. Of those parties contacted, 39 declined further discussions, and 37 were sent and executed confidential disclosure agreements, or CDAs. PDS received its copy of the form of CDA on May 9, 2018.

In connection with its review of Strategic Alternatives, the Transactions Committee also authorized representatives of Piper Jaffray to contact potential strategic partners regarding a possible transaction in respect of EG-1962. Such contacts continued throughout the spring and summer of 2018. On July 2, 2018, representatives of Piper Jaffray contacted 14 companies regarding a potential transaction with EG-1962, including a sale or out-licensing of the asset. Of the parties that were contacted, two signed CDAs and held discussions with Edge management and representatives of Piper Jaffray regarding EG-1962, including discussing the potential clinical development plan going forward and market opportunity among other topics. Neither party elected to pursue a potential transaction with respect to EG-1962.

On May 9, 2018, the Transactions Committee met with Edge management, and representatives of each of Piper Jaffray and Dechert. During the course of the meeting:

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Representatives of Piper Jaffray outlined the primary Strategic Alternatives that the Transactions Committee and the Edge Board might consider, including a reverse merger, a merger with a public company, acquisition/licensing and liquidation.

- Representatives of Piper Jaffray led a discussion of a possible process and timeline for completing a review of Strategic Alternatives and consummating a transaction.



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- Representatives of Piper Jaffray led a discussion of the screening criteria to be used in further evaluating potential transaction partners.  
Representatives of Piper Jaffray led a discussion of a possible engagement protocols between Piper Jaffray,
- Edge management, the Transactions Committee and the Edge Board in connection with the process for completing a review of Strategic Alternatives and consummating a transaction.  
Representatives of Piper Jaffray reviewed the actions that had been taken to date with respect to potential
- candidates for a transaction and potential strategic partners regarding a possible transaction in respect of EG-1962.

Between May 14 and July 24, 2018, Edge management and representatives of Piper Jaffray held 35 individual due diligence calls with parties that executed a CDA.

Beginning on May 18, 2018, representatives of Piper Jaffray provided a first-stage process letter to the parties that had executed a CDA (23 as of such date, and 37 overall throughout the process), requesting that such parties return preliminary indications of interest on or before June 8, 2018.

On June 8, 2018 PDS presented a non-binding merger proposal to Edge that reflected a 22.2% Edge / 77.8% PDS equity split.

On June 11, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. During the course of the meeting, representatives of Piper Jaffray led a high-level discussion and analysis of each company that had submitted an indication of interest (a total of 24 companies as of the meeting, including PDS's indication of interest received on June 8) based on criteria that had been previously approved by the Transactions Committee.

On June 13, 2018, the Transactions Committee met with Edge management and representatives of each of Piper Jaffray and Dechert. Representatives of Piper Jaffray led a high-level discussion and analysis of an additional company that had submitted an indication of interest. The Transactions Committee settled on a list of eight companies, including PDS, which would be invited to move to the next phase of the strategic review process.

On June 19, 2018, the Edge Board held a regularly scheduled meeting. At the meeting, representatives of Piper Jaffray and the members of the Transactions Committee led a discussion of the progress on the strategic review process. The Edge Board discussed each of the companies that the Transactions Committee had recommended advancing to the next stage of the strategic review process. During the course of the discussion, certain members of the Edge Board noted that, because of their relationships with certain of the counterparties, they might have a conflict of interest should a transaction be pursued with any such counterparty. None of the counterparties with which certain of the directors had a relationship ended up participating further in later stages of the strategic review process.

On June 27, 2018, representatives of Piper Jaffray sent process letters to the eight companies that the Transactions Committee authorized to be invited to continue the process.

On June 29, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. Representatives of Piper Jaffray and members of Edge management updated the Transactions Committee on its activities. This included noting that the eight companies had been notified of their invitation to continue in the process, recent additional inbound contacts from other potential targets, including Target C, which was also sent a first-stage process letter prior to the meeting. It was also noted that one of the potential targets completed a reverse merger with another party and another filed for an IPO, and as a result, neither would continue in the process with Edge. Following this meeting on June 29, Edge management began conducting additional due diligence with the companies remaining in the process, which included Targets A, B, C, D, E and F, along with PDS.

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On July 11, 2018, Dr. Spiegel (a member of the Transactions Committee), a consultant to Edge, members of Edge management and representatives of Piper Jaffray participated in a due diligence session with PDS management.

On July 13, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. A member of the Transactions Committee led a detailed discussion of the results of diligence calls with Target D, Target F and PDS, which members of the Transactions Committee and management had

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met with in depth over the preceding days. Members of the Transactions Committee, representatives of Piper Jaffray and members of Edge management offered their views on the three companies, as well as areas for further review relating to the companies. Following this meeting, Edge management continued to conduct additional due diligence with the other companies still in the process.

On July 23, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. Members of the Transactions Committee led a detailed discussion of three of the companies that were invited to remain in the process, including Target C, which members of the Transactions Committee and management had met with in depth for the first time over the preceding days. Other than Target D, Target F and PDS, the remaining two invited parties were not discussed as in-depth meetings had not yet been conducted. Members of the Transactions Committee, representatives of Piper Jaffray and members of management offered their views of the pros and cons of the three companies, as well as areas for further review relating to the companies. The Transactions Committee discussed how it would evaluate and how it ranked each of the companies that had made it to this point in the strategic review process, and the status of due diligence with the other two remaining companies in the process was not discussed in detail at this meeting.

On August 1, 2018, Dr. Bedu-Addo provided an email update to Mr. Leuthner regarding various matters relating to PDS and a potential transaction between the parties.

On August 1, 2018, the Transactions Committee met with Edge management and representatives of each of Piper Jaffray and Dechert. A member of the Transactions Committee led a detailed discussion of certain due diligence that had been conducted on Target A at a meeting conducted earlier on that day, with Dr. Spiegel and members of Edge management participating in that due diligence meeting. Representatives of Piper Jaffray led a discussion of a possible reverse merger with Target B. Members of the Transactions Committee, representatives of Piper Jaffray and members of Edge management offered their assessments of the companies in the strategic review process, as well as areas for further review relating to certain of such companies.

On August 14, 2018, the Transactions Committee met with Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee instructed Edge management to prioritize Targets A, B, C and D. The Transactions Committee held a detailed discussion of certain diligence matters relating to Targets A, C and D, as the Transactions Committee learned that Target B decided to pursue an alternate financing transaction. These included regulatory, clinical, compliance, legal, commercialization and manufacturing due diligence matters. Members of the Transactions Committee, representatives of Piper Jaffray and members of Edge management offered their views on the three companies discussed during the meeting, as well as areas for further review relating to such companies.

On August 27, 2018, the Transactions Committee met with Edge management and representatives of each of Piper Jaffray and Dechert. Following a review of activities to date, the Transactions Committee discussed its ranking of each of Targets A, C and D targets relative to the others remaining in the process. The Transactions Committee discussed next steps with members of Edge management and Edge's outside advisors. These steps included sending out a process letter, along with a draft merger agreement, to Targets C and D, as discussions between representatives of each of Piper Jaffray and Target A suggested that pending further diligence, Target A's timelines for development activities would not be favorable for a potential transaction.

On September 17, 2018, Target C submitted its bid proposal and mark-up of the draft merger agreement. In addition, on or about such date, the Transactions Committee learned that Target D had decided to pursue an alternative financing transaction and, as a result, would not submit a proposal.

On September 20, 2018, the Transactions Committee met with members of Edge management, and representatives of each of Piper Jaffray and Dechert. The Transactions Committee had a detailed discussion of the bid received from

Target C. During the course of the discussion, representatives from Piper Jaffray engaged with the Transaction Committee on the methodology, analysis and results of the preliminary financial analyses with respect to Target C that representatives of Piper Jaffray had undertaken. The Transactions Committee also discussed with members of Edge management certain execution risks associated with Target C and discussed certain issues arising from the Target C mark-up of the draft merger agreement with Dechert. The Transactions Committee engaged in a discussion with representatives of Piper Jaffray and management about alternatives to a transaction with Target C. Finally, the Transactions Committee provided guidance to the representatives of Piper Jaffray regarding the messages to deliver to Target C with respect to certain aspects of their bid and mark-up of the proposed merger agreement.

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On September 23, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee had a detailed discussion of how to respond to the updated timelines and additional information received from Target C concerning its bid, including potential mechanisms, and the associated timelines, for consummating a transaction with Target C. The Transactions Committee provided direction to representatives of Piper Jaffray to engage with Target C on such deal terms. The Transactions Committee also engaged in a discussion with representatives of Piper Jaffray and management about alternatives to doing a transaction with Target C, including whether to re-engage with Target A, Target E, Target F and/or PDS. The Transactions Committee considered the merits of doing transactions with each of these potential targets. During the course of the discussion, the Transactions Committee (i) directed representatives of Piper Jaffray to more fully engage in conversations with PDS about a transaction with Edge, (ii) provided guidance to representatives of Piper Jaffray that it was not interested in pursuing a transaction with Target A, and (iii) directed representatives of Piper Jaffray to spend limited or no resources on pursuit of a transaction with Targets E and F.

On September 28, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee had a detailed discussion of (i) a counterproposal received from Target C in response to certain issues that had been raised by the Transactions Committee; (ii) how the Transactions Committee should respond to Target C's counterproposal; and (iii) the potential timeline for closing a transaction with Target C. In addition, the Transactions Committee engaged in a discussion with representatives of Piper Jaffray and members of Edge management about pursuing a transaction with PDS, including additional diligence on PDS and a renewed focus on the due diligence that had previously been undertaken with respect to PDS.

On October 2, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee had a detailed discussion of how the Transactions Committee should respond to the subsequent discussions between representatives of Piper Jaffray and Target C concerning Target C's bid. In addition, the Transactions Committee engaged in further discussion with representatives of Piper Jaffray and Edge management about plans for in-depth due diligence with PDS and the process for moving forward with PDS.

On October 3, 2018, representatives of Piper Jaffray, at the instruction of the Transactions Committee, sent PDS a process letter and draft merger agreement. In addition, representatives of each of Piper Jaffray and Target C discussed Target C's bid and the timelines for consummating a transaction.

On October 4, 2018, the Transactions Committee met with Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee held a detailed discussion of how the Transactions Committee should respond to Target C and the additional information provided by Target C to representatives of Piper Jaffray on October 3. In addition, the Transactions Committee received an update regarding discussions concerning a transaction with PDS.

On October 4, 2018 and October 8, 2018, Dr. Faleck, Mr. Middlekauff and representatives of each of Jones Day (Edge's outside patent counsel) and Piper Jaffray met with Dr. Bedu-Addo and PDS's outside patent counsel regarding PDS's patent portfolio.

On October 9, 2018, Dr. Spiegel, members of Edge management and representatives of Piper Jaffray held three separate meetings with three key opinion leaders regarding PDS's platform and products and the medical and market opportunities for such products.

On October 10, 2018, Dr. Spiegel, members Edge management and representatives of Piper Jaffray had an in-person meeting at Edge with PDS management, a member of the PDS Board and a member of the PDS scientific advisory board to discuss PDS, its platform and its product opportunities.

On October 11, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee had a detailed discussion of where matters stood with respect to Target C. After extensive deliberation, the Transactions Committee concluded that it was not prepared to continue discussions with Target C on the terms proposed by Target C, and asked that representatives of Piper Jaffray convey this conclusion to Target C. The Transactions Committee then engaged in a discussion with representatives of each of Piper Jaffray and Dechert and Edge management about pursuing a transaction with PDS, with a focus on the status of the due diligence investigation with respect to PDS and the

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process for moving forward with PDS. The Transactions Committee also discussed the interest of PDS in retaining certain members of Edge management should a transaction be completed. The Transactions Committee, with input from representatives of Dechert, concluded that any discussion regarding the retention of Edge employees by PDS should be deferred until deal terms were agreed by Edge and PDS.

On October 15, 2018, PDS, in response to a process letter sent to PDS on October 3, 2018, submitted what it termed a final offer, which contained a proposed ownership split in the combined company of approximately 21.6% for Edge stockholders and 78.4% for PDS stockholders. It also proposed a combined company board consisting of four designees of PDS and three designees of Edge and the desire to retain certain members of Edge management. It also proposed that Edge enter into an agreement providing for a period of exclusive negotiations with Edge. PDS also provided a mark-up of the merger agreement.

On October 16, 2018, the Edge Board held a regularly scheduled meeting. The members of the Transactions Committee, with input from representatives of Piper Jaffray and Dechert, and members of Edge management led a discussion of the status of the strategic review process with a focus on (i) whether there might be a path forward for Target C, on a basis different from that proposed by Target C in its prior communications and (ii) a potential path forward with PDS. Members of the Edge Board offered their comments on the targets under consideration and the potential transactions with such companies. During the course of the discussion, the Edge Board engaged in extensive dialogue with management and the Edge Board's advisors and, in the course of such discussions, provided guidance to Piper Jaffray about next steps with respect to Target C and PDS. In particular, with respect to Target C, the Edge Board discussed the implications of moving forward with Target C in light of the timing of upcoming regulatory reviews of Target C and issues related thereto, the timing of Edge's stockholder meeting to seek approval of a merger with Target C, as well as the parameters pursuant to which the Edge Board could terminate any merger agreement with Target C prior to closing. With respect to PDS, the Edge Board noted the inclusion in the PDS proposal of a proposed combined company board split of four PDS designees and three Edge designees and the desire to retain certain Edge management. Dr. Barer noted that, while he would not be able to continue on the combined company board if asked to do so, he would be willing to serve in a role as a combined company board advisor. The Edge Board discussed that there should be no discussion about compensation on any retained individual until at least the principal terms of a transaction was agreed with PDS. The Edge Board provided specific guidance on the relative valuations for each of PDS and Edge that it would seek to attain and additional diligence that would enable the Edge Board to more fully assess the opportunity provided by a potential merger with PDS.

On October 19, 2018, representatives Piper Jaffray had a discussion with members of PDS management regarding the Transactions Committee's response to PDS's proposal.

On October 22, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee engaged in a discussion with representatives of Piper Jaffray and Dechert and Edge management about subsequent information concerning PDS's revised bid that PDS provided to Piper Jaffray since the Edge Board's previous meeting, a potential response from Edge to PDS, and the path to signing a definitive agreement with PDS. During the course of the discussion, the Transactions Committee provided guidance to representatives of Piper Jaffray about next steps to take with PDS. In addition, the Transactions Committee had a discussion regarding the process going forward with respect to a potential transaction with Target C, notwithstanding the issues discussed at the Edge Board's previous meeting.

On October 22, 2018, representatives of Piper Jaffray had a discussion with PDS management regarding the Transactions Committee's response to PDS's latest proposal.

During the period from October 22, 2018 through November 15, 2018, mutual legal, regulatory and intellectual property diligence was conducted by Edge and PDS and their respective counsel. In addition, counsel to each of Edge

and PDS negotiated the merger agreement, exchanging drafts periodically during the period through November 21, reflecting revised proposals.

On October 26, 2018, Dr. Faleck, Mr. Middlekauff and representatives of each of Jones Day and Piper Jaffray had a conference call with Dr. Bedu-Addo and PDS's outside patent counsel regarding PDS's patent portfolio.



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On October 28, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee engaged in a discussion with representatives of Piper Jaffray and management about the PDS's response on October 26 to Edge's latest proposal with respect to a potential transaction, Piper Jaffray's preliminary exchange ratio analysis relating thereto and the methodologies of such analysis and a potential response from Edge to PDS's latest proposal to, among other things, make the exchange ratio more favorable to Edge's stockholders. During the course of the discussion, the Transactions Committee provided guidance to Piper Jaffray about next steps with PDS. In addition, at the request of the Transactions Committee, representatives of Piper Jaffray provided an update on the status of discussions regarding a potential transaction with Target C in light of the structure and timelines set out in Target C's materials provided to date.

On October 29, 2018, representatives of Piper Jaffray met with members of PDS management and presented a counterproposal to PDS on key deal terms.

On October 31, 2018, Mr. Leuthner and Dr. Bedu-Addo had a discussion regarding PDS's expected funding strategy.

On November 1, and November 2, 2018, representatives of Piper Jaffray had discussions with members of PDS management regarding key deal terms of a potential merger agreement. On November 2, PDS confirmed its revised proposal reflecting an ownership split in the combined company of approximately 30% for Edge stockholders and 70% for PDS stockholders.

On November 2, 2018, the Transactions Committee met with members of Edge management and representatives of each of Piper Jaffray and Dechert. The Transactions Committee engaged in a discussion with representatives of Piper Jaffray, Dechert and Edge management about further conversations that representatives of Piper Jaffray had held with PDS with respect to a potential transaction, including PDS's reaction to an exchange ratio more favorable to Edge's stockholders than its last proposal, and the path to signing a definitive agreement with PDS. During the course of the discussion, the Transactions Committee provided guidance to representatives of Piper Jaffray about next steps with PDS. With respect to Target C, representatives of Piper Jaffray indicated that Target C had not yet responded to Edge's latest counter-proposal.

On November 5, 2018, Dr. Bedu-Addo and Dr. Barer met to discuss certain key terms of a proposed Edge-PDS merger agreement. The discussion included the interest of PDS in retaining certain members of Edge management for the combined company. The potential three representatives from the Edge Board who would serve on the combined company's board were also discussed. During the course of that discussion, Dr. Barer indicated that he was not able to serve on the combined company board, but would be willing to consider a role as advisor to the combined company's board. No compensation arrangements for anyone were discussed.

On November 5, 2018, members of Edge management and representatives of each of Piper Jaffray and Dechert, members of PDS management and representatives of DLA Piper LLP, or DLA, PDS's outside counsel, met to discuss the process for ongoing negotiations of the merger agreement.

On November 6, 2018, Mr. Leuthner and Dr. Bedu-Addo spoke to discuss Dr. Bedu-Addo's meeting with Dr. Barer on November 5, 2018. They also discussed a potential press release to announce a merger between Edge and PDS.

On November 9, 2018, members of Edge and PDS management, as well as representatives of each of Piper Jaffray Dechert and DLA continued to discuss the status of the merger agreement.

On November 7, 2018, members of Edge management met with members of PDS management and representatives of each of DLA and Dechert to discuss certain due diligence and transaction-related matters.

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On November 12, 2018, Mr. Leuthner and Dr. Bedu-Addo spoke regarding reactions of their respective boards of directors to the proposed merger and outstanding issues with respect to the merger agreement.

On November 13 and November 14, Dr. Bedu-Addo visited Edge's offices to (i) meet with various Edge employees, (ii) discuss the press release and investor slide deck to be presented upon public announcement of the merger, and (iii) meet with Mr. Leuthner to discuss various non-executive employees. Also on November 14, 2018, members of Edge and PDS management, along with representatives of each of Piper Jaffray, Dechert and DLA continued to discuss the status of the merger agreement and next steps.

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On November 15, 2018, Mr. Leuthner and Dr. Bedu-Addo spoke regarding the investor slide deck and miscellaneous matters relating to the business of PDS.

On November 15, 2018, Edge and PDS management, and representatives of Piper Jaffray, held a call to discuss the status of the merger agreement and certain open issues.

From November 17, 2018 through November 21, 2018, representatives of Piper Jaffray had multiple discussions with PDS management regarding certain deal terms of a potential merger agreement.

On November 18, 2018, members of Edge management and representatives of each of Piper Jaffray and Dechert met with Dr. Barer to update him on the ongoing negotiations with PDS.

Between November 19 and November 21, 2018, Dr. Bedu-Addo and Mr. Leuthner spoke several times regarding the planned press release, investor slide deck and conference call script for the announcement of the potential merger.

On November 19, 2018, members of Edge management and representatives of each of Piper Jaffray and Dechert met with Ms. Crane about the status of the proposed merger with PDS. Ms. Crane requested the call because she would be unable to join the joint meeting of the Transactions Committee and the Edge Board scheduled for later in the day.

On November 19, 2018, there was a joint meeting of the Transactions Committee and the Edge Board. In advance of the meeting, the Transactions Committee and Edge Board received written materials, including the actions the Transactions Committee and Edge Board were going to be asked to consider, the draft financial analysis materials prepared by representatives of Piper Jaffray, and a summary of the merger agreement prepared by representatives of Dechert. Representatives of each of Piper Jaffray and Dechert reviewed the terms of the potential merger. Representatives of Piper Jaffray also reviewed their preliminary financial analysis of the potential merger. A representative of Dechert reviewed the terms of the merger agreement, and further reviewed the potential interest of various members of the Edge Board and management. He noted the interest of PDS in retaining certain members of Edge management to serve in similar capacities in the combined company, including the retention of Mr. Leuthner as president and Mr. Saik as Chief Financial Officer, that three current Edge directors, Mr. Leuthner, Mr. Loughlin and Dr. Spiegel, would serve as Edge's designees on the combined company board, and that Dr. Barer would possibly serve in a capacity as an adviser to the combined company board. It was noted that to date there had been no discussion with PDS as to the compensation arrangements for any Edge board or management member in the combined company. The Edge Board engaged in discussion throughout the meeting.

On November 20, 2018, members of Edge and PDS management, along with representatives of each of Piper Jaffray, Dechert and DLA, had calls to discuss the merger agreement.

Discussions between representatives of Dechert and DLA continued through November 21, 2018 as to certain provisions of the merger agreement.

On November 23, 2018, there was a joint meeting of the Transactions Committee and the Edge Board. In advance of the meeting, the Transactions Committee and Edge Board had received written materials, including the actions the Transactions Committee and Edge Board were going to be asked to consider, the draft financial analysis materials prepared by Piper Jaffray, and a summary of the merger agreement prepared by Dechert. A representative of Dechert first reviewed the proposed changes to the merger agreement from that which was presented to the Edge Board and Transactions Committee at its previous meeting, and further noted that the potential interests of various board and management members had previously been identified to the Edge Board, as more fully described in the section, *The Merger-Interests of the Edge Directors and Executive Officers in the Merger*. Representatives of Piper Jaffray reviewed the results of Piper Jaffray's financial analysis with respect to the Exchange Ratio and presented and

delivered to the Edge Board and Transactions Committee Piper Jaffray's oral opinion, which opinion was confirmed in writing on the same date, that, as of such date, and based upon and subject to the various assumptions and limitations set forth in its written opinion, the Exchange Ratio was fair to Edge, from a financial point of view, as more fully described in the section titled "The Merger – Opinion of the Financial Advisor to the Edge Board." Several questions by Edge board members related to deal terms were asked and answered by representatives of Piper Jaffray, Edge management and Dechert. Representatives of Piper Jaffray then left the meeting, and representatives of Dechert reviewed again the fiduciary duties of the Edge Board under Delaware law. After the presentations and discussions, the Edge Transactions Committee,

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recommended to the Edge Board, and the Edge Board unanimously, with Mr. Leuthner abstaining, (a) determined that the transaction, the issuance of shares of Edge common stock pursuant to the transaction and the other transactions contemplated by the Merger Agreement were fair to, advisable and in the best interests of Edge and its stockholders, (b) approved the issuance of shares of Edge common stock pursuant to the transaction, the Merger Agreement and the other transactions contemplated thereby, (c) approved and declared advisable the Merger Agreement and the transactions contemplated thereby, and (d) resolved to recommend that the Edge stockholders vote to approve the issuance of shares of Edge common stock in the transaction pursuant to the terms of the Merger Agreement.

Following the close of trading on November 23, 2018, each of Edge, PDS and Merger Sub executed and delivered the merger agreement. Before the opening of the Nasdaq Stock Market on November 26, 2018, (1) Edge and PDS issued a joint press release announcing the execution of the Merger Agreement and the plans of Edge and PDS to consummate the merger and (2) Edge and PDS held a conference call to discuss the planned merger.

### **Edge Reasons for the Merger**

As noted above, the Edge Board and executive management team have regularly reviewed and discussed Edge's operating and strategic plans, both near-term and long-term, as well as potential partnerships and strategic transactions, in an effort to enhance stockholder value. These reviews and discussions have focused, among other things, on the opportunities and risks associated with Edge's business and financial condition and strategic relationships and other strategic options. In particular, recent setbacks in the clinical development of Edge's product candidate, EG-1962, have prompted the Edge Board to focus on alternative means for providing returns to stockholders.

In the course of its evaluation of the merger and the Merger Agreement, the Edge Board held numerous meetings, consulted with Edge's executive management, legal counsel and financial advisors, and reviewed and assessed a significant amount of information and, in reaching its decision to approve the merger, the issuance of shares of Edge common stock pursuant to the Merger Agreement and the other transactions contemplated by the Merger Agreement, the Edge Board considered a number of factors, including, among others, the following:

- The Edge Board considered the historical and current information concerning Edge's business, financial performance, financial condition, including Edge's cash position, operations, management and competitive position, the prospects of Edge and its product candidate, the nature of the biotechnology industry generally, including financial projections of Edge under various scenarios and its short- and long-term strategic objectives and the related risks and the belief that the combination of Edge's and PDS's businesses would create more value for Edge stockholders in the long-term than Edge could create as an independent, stand-alone company.
- The Edge Board's belief, based in part on the judgment, advice and analysis of Edge management with respect to the potential strategic, financial and operational benefits of the merger (which judgment, advice and analysis was informed in part by the business, technical, financial, accounting, intellectual property and legal due diligence investigation performed by Edge with respect to PDS), that PDS's proprietary platform, as well as its immunotherapies pipeline, which includes clinical stage candidates that hold the potential to address sizeable market opportunities, and may provide new medical benefits for patients and returns for investors.
- The Edge Board also reviewed with the management of Edge the current development plans of PDS to confirm the likelihood that the combined company would possess sufficient resources, or have access to sufficient resources, to allow the management team to focus on its plans for the continued development of PDS's product pipeline. The Edge Board also considered the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of the Edge public company structure with the PDS business to raise additional funds in the future.

- The Edge Board also considered the valuation and business prospects of all the potential strategic transaction candidates. In particular, their collective view was that PDS was the most attractive candidate because of the promising results of its previous clinical trials and the potential large market opportunities that PDS's product candidates address. After considering the comprehensive diligence review that Edge management had completed of other prospective transaction partners, the board of
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directors concluded that the merger with PDS would create a publicly traded company focused on advancing its proprietary platform, with its applicability in several cancer markets, as well as its product pipeline, which includes clinical stage candidates that hold the potential to address potential sizeable market opportunities.

- The Edge Board concluded that the merger would provide existing Edge stockholders a significant opportunity to participate in the potential growth of the combined company following the merger. The Edge Board also considered that the combined company is expected to be led by an experienced senior management team and a board of directors with representation from each of the current boards of directors of Edge and PDS.
- The Edge Board considered the opinion of Piper Jaffray, delivered to the Edge Board on November 23, 2018, to the effect that, as of such date and based on and subject to the assumptions made, procedures followed, matters considered and limitations on the scope of the review undertaken by Piper Jaffray, as described in its written opinion, the Exchange Ratio was fair, from a financial point of view, to Edge, as more fully described below under The Merger - Opinion of the Financial Advisor to the Edge Board beginning on page 85.

The Edge Board also reviewed the recent results of operations and financial condition of Edge, including:

- the Phase 3, NEWTON 2 study of EG-1962 demonstrating a low probability of achieving a statistically-significant difference compared to the standard of care in the study’s primary endpoint and the resulting discontinuation of the NEWTON 2 study;
- the loss of certain operational capabilities of Edge, and the risks associated with continuing to operate Edge on a stand-alone basis, including the resources needed to continue to develop EG-1962 and its remaining pipeline of product candidates;
- the costs and time to conduct another Phase 3 trial of EG-1962 in a subgroup population based on the post-hoc analysis of the NEWTON 2 study;
- the results of substantial efforts made over a significant period of time by Edge’s senior management and financial advisor to solicit strategic alternatives for Edge to the merger, including the discussions that Edge management, Edge’s representatives and the Edge Board had in 2018 with other potential strategic transaction candidates; and
- current financial market conditions and historical market prices, volatility and trading information with respect to Edge common stock.

The Edge Board also reviewed the terms of the Merger Agreement and associated transactions, including:

- the relative percentage ownership of Edge securityholders and PDS securityholders immediately following the closing of the merger;
- the number and nature of the conditions to PDS’s obligation to consummate the merger and the limited risk of non-satisfaction of such conditions as well as the likelihood that the merger will be consummated on a timely basis;
- the rights of, and limitations on, Edge under the Merger Agreement to consider certain unsolicited acquisition proposals under certain circumstances, should Edge receive a superior offer (as defined below);
- the reasonableness of the potential termination fee of up to \$1.75 million, which could become payable by Edge if the Merger Agreement is terminated in certain circumstances and certain events occur;
- the agreement by the stockholders of PDS holding the requisite number of shares of PDS common stock to vote such shares in favor of approving the transactions contemplated by the Merger Agreement and against actions that could adversely affect the closing of the merger; and
- the belief that the terms of the Merger Agreement, including the parties’ representations, warranties and covenants, and the conditions to their respective obligations, are reasonable under the circumstances.

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In the course of its deliberations, the Edge Board also considered a variety of risks and other countervailing factors related to the merger, including:

- the up to \$1.75 million termination fee payable by Edge upon the occurrence of certain events and the potential effect of such termination fee in deterring other potential acquirors from proposing an alternative transaction that may be more advantageous to Edge stockholders;
- the substantial expenses to be incurred in connection with the merger;
- the possible volatility, at least in the short term, of the trading price of Edge common stock resulting from the announcement of the merger;
- the risk that the merger might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the merger or on the delay or failure to complete the merger on the reputation of Edge;
- the risk to the business of Edge, operations and financial results in the event that the merger is not consummated;
- the strategic direction of the continuing entity following the closing of the merger, which is expected to be determined by a combination of individuals from Edge's and PDS's respective present management teams and a board of directors initially comprised of a combination of Edge's and PDS's respective boards of directors; and
- various other risks associated with the combined company and the merger, including those described in the sections titled Risk Factors and Cautionary Statement Concerning Forward-Looking Statements.

The foregoing information and factors considered by the Edge Board are not intended to be exhaustive but are believed to include all of the material factors considered by the Edge Board. In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, the Edge Board did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the Edge Board may have given different weight to different factors. The Edge Board conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, the Edge management team and the legal and financial advisors of Edge, and considered the factors overall to be favorable to, and to support, its determination.

### **PDS Reasons for the Merger**

In the course of reaching its decision to approve the merger, the PDS Board consulted with its senior management and legal counsel, reviewed a significant amount of information and considered a number of factors, including, among others:

- the potential increased access to sources of capital at a lower cost and a broader range of investors to support PDS's commercialization efforts than it could otherwise obtain if it continued to operate as a privately-held company;
- the ability to access institutional investors who may otherwise be unable to invest in a privately-held company;
- the potential to provide its current stockholders with greater liquidity by owning stock in a public company;
- the PDS Board's belief that no alternatives to the merger were reasonably likely to create greater value for the PDS stockholders after reviewing the various strategic options to enhance stockholder value that were considered by the PDS Board;
- the cash resources of the combined company expected to be available at the closing of the merger, including Edge's cash balance of \$[ ] million as of [ ], 2018;
- the availability of appraisal rights under the DGCL to holders of PDS common stock who comply with the required procedures under the DGCL, which allow such holders to seek appraisal of the fair value of their shares of PDS common stock as determined by the Delaware Court of Chancery;





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- the expectation that the merger with Edge would be a more time- and cost-effective means to access capital than other options considered;
- the terms and conditions of the Merger Agreement, including, without limitation, the following:
  - the determination that the expected relative percentage ownership of Edge stockholders and PDS stockholders in the combined company was appropriate based, in the judgment of the PDS Board, on the board of directors' assessment of the approximate valuations of Edge and PDS and the comparative costs and risks associated with alternatives to the merger;
  - the expectation that the merger will be treated as a reorganization for U.S. federal income tax purposes, with the result that the PDS stockholders will generally not recognize taxable gain or loss for U.S. federal income tax purposes upon the exchange of PDS common stock for Edge common stock pursuant to the merger;
  - the limited number and nature of the conditions of the obligation of Edge to consummate the merger; and
  - the conclusion of the PDS Board that the potential termination fee of \$1.75 million payable by Edge to PDS and the circumstances when such fee may be payable, were reasonable;
- the fact that shares of Edge common stock to be issued to PDS stockholders will be registered on a Form S-4 registration statement by Edge and will become freely tradable;
- the belief that increased visibility as a public company would provide access to additional strategic partnering transactions; and
- the likelihood that the merger will be consummated on a timely basis.

The PDS Board also considered a number of uncertainties and risks in its deliberations concerning the merger and the other transactions contemplated by the Merger Agreement, including the following:

- the possibility that the merger might not be completed and the potential adverse effect of the public announcement of the merger on the reputation of PDS and the ability of PDS to obtain financing in the future in the event the merger is not completed;
- the risk that the merger might not be consummated in a timely manner or at all;
- the expenses to be incurred in connection with the merger and related administrative challenges associated with combining the companies;
- the additional public company expenses and obligations that PDS's business will be subject to following the merger that it has not previously been subject to; and
- various other risks associated with the combined company and the merger, including the risks described in the section titled *Risk Factors* in this proxy statement/prospectus/information statement.

**Opinion of the Financial Advisor to the Edge Board**

On November 23, 2018, Piper Jaffray rendered its oral opinion to the Edge Board (which was subsequently confirmed in writing by delivery of Piper Jaffray's written opinion dated November 23, 2018) to the effect that, as of November 23, 2018, and based upon and subject to the various assumptions and limitations set forth therein, the Exchange Ratio was fair, from a financial point of view, to Edge.

**The full text of the Piper Jaffray written opinion dated November 23, 2018, which sets forth, among other things, the assumptions made, procedures followed, matters considered and limitations on the scope of the review undertaken by Piper Jaffray in rendering its opinion, is attached as *Annex D* to this proxy statement/prospectus. The Piper Jaffray opinion addresses only the fairness, from a financial point of view and as of the date of the opinion, of the Exchange Ratio. Piper Jaffray's opinion was directed to the Edge Board in connection with its consideration of the merger and was not intended to be, and does not constitute, a recommendation to any Edge stockholder as to how such stockholder should act or vote with respect to the merger or any other matter. Piper Jaffray's opinion was approved for issuance by the Piper Jaffray opinion committee.**



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In connection with rendering the opinion described above and performing its related financial analyses, Piper Jaffray, among other things:

- reviewed and analyzed the financial terms of the draft of the Merger Agreement dated November 23, 2018;
- reviewed and analyzed certain financial and other data with respect to Edge and PDS that was publicly available;
- reviewed and analyzed certain information, including financial forecasts, relating to the estimated cash usage of each of Edge and PDS, on stand-alone bases, that were furnished to Piper Jaffray by Edge and PDS; conducted discussions with members of senior management and representatives of each of Edge and PDS
- concerning the matters described in the second and third bullets above, as well as the business and prospects of Edge before and after giving effect to the merger;
- reviewed the current and historical reported prices and trading activity of Edge;
- compared the business profile of PDS with that of certain publicly traded companies that Piper Jaffray deemed relevant; and
- reviewed the valuations of certain companies implied by the pricing of such companies' initial public offerings that Piper Jaffray deemed relevant.

In addition, Piper Jaffray conducted such other analyses, examinations and inquiries and considered such other financial, economic and market criteria as Piper Jaffray deemed necessary in arriving at its opinion.

The following is a summary of the material financial analyses performed by Piper Jaffray in connection with the preparation of its fairness opinion and reviewed with the Edge Board at a meeting held on November 23, 2018.

This summary includes information presented in tabular format, which tables must be read together with the text of each analysis summary and considered as a whole in order to fully understand the financial analyses presented by Piper Jaffray. The tables alone do not constitute a complete summary of the financial analyses. The order in which these analyses are presented below, and the results of those analyses, should not be taken as any indication of the relative importance or weight given to these analyses by Piper Jaffray or the Edge Board. Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before November 21, 2018, and is not necessarily indicative of current market conditions.

### **Review of Solicitation Process**

Piper Jaffray reviewed with the Edge Board the solicitation that Piper Jaffray undertook to assist Edge in exploring third party interest in a transaction involving Edge, including the potential sale of EG-1962 and all associated intellectual property, after the release of interim results of the Newton 2 trial in April 2018. Piper Jaffray highlighted that:

- A total of 131 parties (including PDS) were evaluated for a potential acquisition, licensing or reverse merger transaction:
  - 37 parties (including PDS) executed confidentiality agreements and received invitations to submit indications of interest;
  - 27 parties (including PDS) submitted initial indications of interest for a reverse merger;
  - Nine parties (including PDS) were invited to conduct further mutual diligence; Three parties (including PDS) were invited to submit final indications of interest, of which one withdrew
  - from the process to pursue other financing alternatives and one was unable to negotiate terms due to extraneous circumstances specific to it;
- Discussions with 14 additional potential strategic partners were held with respect to a potential acquisition of EG-1962 and all associated intellectual property, which discussions yielded no interest.



TABLE OF CONTENTS**Financial Analyses of Edge***Edge Current Valuation and Capitalization; Projected Cash Balances*

Piper Jaffray reviewed, among other things, the current implied equity and enterprise valuations, capitalization and cash balances, and projected closing capitalization and cash balances of Edge. The analysis indicated, among other things, that Edge had diluted shares outstanding as of the date of the Merger Agreement of 32,001,038, using the treasury stock method, cash and cash equivalents on hand of \$34,660,351, a current implied enterprise value of (\$12,579,635), and estimated cash and cash equivalents at closing of the merger of \$24,885,685.

**Financial Analyses of PDS***Selected IPO Analysis**Comparable Biotech Company IPO Business Profile*

Piper Jaffray also reviewed certain market data for certain US-listed biotech companies that completed an initial public offering, referred to as an IPO, of common stock since January 1, 2017. Specifically, Piper Jaffray (a) selected IPOs of immuno-oncology companies targeting solid tumors (i) with lead product candidates in Phase 2 or earlier stage clinical trials (excluding companies whose lead product candidates are in pre-clinical development) and (ii) with biologic or injectable drug type products, and (b) excluded companies with discovery-based antibody/antibody-associated platforms.

Set forth below are the six selected IPOs, as well as their respective targeted lead treatment indications, stages of development and IPO pricing dates:

<b>Company</b>	<b>Indication</b>	<b>Phase</b>	<b>Pricing Date</b>
Replimune Group, Inc.	Mixed Advanced Solid Tumors	Phase 1	July 19, 2018
Neon Therapeutics, Inc.	Metastatic Melanoma, NSCLC	Phase 1B	June 26, 2018
Aileron Therapeutics, Inc.	PTCL	Phase 2A	June 28, 2017
G1 Therapeutics, Inc.	SCLC	Phase 1B/2A	May 16, 2017
Tocagen Inc.	Recurrent HGG	Phase 2	April 12, 2017
Jounce Therapeutics, Inc.	Solid Tumors	Phase 1/2	February 1, 2017

For the selected biotech IPO companies, Piper Jaffray reviewed each of their (i) implied equity value, based on the offering price of each such company's shares in the IPO and the number of each such company's shares outstanding prior to the IPO, excluding any shares being issued in the offering, using the treasury stock method, referred to as the pre-money equity value, together with (ii) pre-money equity value, plus net debt (calculated as debt, less cash and cash equivalents at the time of the IPO), referred to as the pre-money enterprise value. The analysis indicated the following maximum, 75<sup>th</sup> percentile, mean, median, 25<sup>th</sup> percentile and minimum pre-money equity values and pre-money enterprise values for the selected companies:

	<b>Pre-Money Equity Value</b>	<b>Pre-Money Enterprise Value</b>
Maximum	\$ 449	\$ 348
75 <sup>th</sup> Percentile	\$ 393	\$ 316

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Mean	\$	309	\$	234
Median	\$	364	\$	244
25 <sup>th</sup> Percentile	\$	222	\$	166
Minimum	\$	100	\$	87

For the selected biotech IPO companies analysis, Piper Jaffray derived a range of implied enterprise values for PDS based on the implied enterprise value ranges for the selected companies and then adjusted for net cash, to calculate an implied PDS equity value. Piper Jaffray then derived an implied number of shares of Edge common stock to be issued in the merger, assuming an Edge intrinsic valuation of \$24.9 million, which was equal to the closing cash balance and which implied an Edge share price of \$0.78 per share based on diluted shares, using the treasury stock method. Piper Jaffray then calculated an implied pro forma equity value for the combined company by adjusting the implied enterprise value for PDS for pro forma net cash at the closing of the

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merger of approximately \$24.9 million for Edge and approximately (\$2.9) million for PDS, excluding any bridge financing cash PDS raised between the announcement and the closing of the merger and any cash adjustments at the closing of the merger.

The analysis indicated the following implied ownership percentage range for Edge stockholders in the combined company, pro forma for the merger:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Edge Shareholder Ownership	22 %	13 %	9 %	7 %	7 %

In addition, the analysis indicated the following implied pro forma valuation range of the aggregate equity interest in the combined company to be retained by Edge stockholders:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Value to Edge Shareholders at 30% Ownership (in millions)	\$ 111	\$ 101	\$ 80	\$ 56	\$ 33

***Selected Comparable Public Companies Analysis****Similar Stage Cancer-Vaccine Business Profile*

Piper Jaffray reviewed certain market data for five selected cancer-vaccine companies that have publicly traded equity securities and that Piper Jaffray deemed relevant. Piper Jaffray selected US-listed public companies that it considered to be cancer-vaccine companies similar to PDS: (i) that are biopharmaceutical companies developing drugs for oncology using vaccine modality and (ii) whose lead product candidate is in Phase 2 or earlier stage clinical trials (excluding companies whose lead product candidates are in pre-clinical development).

Set forth below are the five selected cancer-vaccine companies, as well as their respective targeted lead treatment indications and stages of development:

<b>Company</b>	<b>Indication</b>	<b>Phase</b>
Gritstone Oncology, Inc.	Solid Tumors	Phase 1
Replimune Group, Inc.	Mixed Advanced Solid Tumors	Phase 1/2
Agenus Inc.	Glioblastoma	Phase 2
Neon Therapeutics, Inc.	Solid Tumors	Phase 1
Genocea Biosciences, Inc.	Solid Tumors	Phase 1/2A

For the selected cancer-vaccine companies, Piper Jaffray reviewed each of their current (i) implied equity values, calculated as the aggregate value of each company's outstanding equity securities, based on such company's applicable closing common stock price as of November 21, 2018, using the treasury stock method, and (ii) implied enterprise values. Enterprise values were calculated as implied equity values, as described in the immediately preceding sentence, plus debt outstanding, less cash and cash equivalents (referred to herein as net cash), in each case, as of their most recent respective reported quarter-ends. The analysis indicated the following maximum, 75<sup>th</sup> percentile, mean, median, 25<sup>th</sup> percentile and minimum equity values and enterprise values for the selected companies:

<b>Equity Value</b>	<b>Enterprise Value</b>
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Maximum	\$	652	\$	482
75 <sup>th</sup> Percentile	\$	472	\$	223
Mean	\$	325	\$	197
Median	\$	264	\$	187
25 <sup>th</sup> Percentile	\$	185	\$	63
Minimum	\$	50	\$	30

For the selected cancer-vaccine companies analysis, Piper Jaffray derived a range of implied enterprise values for PDS based on the implied enterprise value ranges for the selected companies and then adjusted for net cash, to calculate an implied range of PDS equity values. Piper Jaffray then derived an implied number of shares

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of Edge common stock to be issued in the merger, assuming an Edge intrinsic valuation of \$24.9 million, which was equal to the estimated closing cash balance and which implied an Edge share price of \$0.78 per share based on diluted shares using the treasury stock method. Piper Jaffray then calculated an implied pro forma equity value for the combined company by adjusting the implied enterprise value for PDS for pro forma net cash at the closing of the merger of approximately \$24.9 million for Edge and approximately (\$2.9) million for PDS. This analysis assumed no bridge financing by PDS between the announcement and the closing of the merger and no additional cash adjustments at the closing of the merger.

The analysis indicated the following implied ownership percentage range for Edge stockholders in the combined company, pro forma for the merger:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Edge Shareholder Ownership	46 %	30 %	13 %	10 %	5 %

In addition, the analysis indicated the following implied pro forma valuation range of the aggregate equity interest in the combined company to be retained by Edge stockholders:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Value to Edge Shareholders at 30% Ownership (in millions)	\$ 151	\$ 73	\$ 63	\$ 26	\$ 16

*Similar Stage Immuno-Oncology Business Profile*

Piper Jaffray reviewed certain market data for five selected immuno-oncology companies that have publicly traded equity securities and that Piper Jaffray deemed relevant. Piper Jaffray selected US-listed public companies that it considered to be immuno-oncology companies similar to PDS: (i) that are biopharmaceutical immuno-oncology companies targeting solid tumors, (ii) whose lead product candidate is in Phase 2 or earlier stage clinical trials (excluding companies whose lead product candidates are in pre-clinical development) and (iii) other than companies with discovery-based immuno-oncology platform technologies, gene/vaccine therapies and antibody/antibody-associated platform technologies.

Set forth below are the five selected immuno-oncology companies, as well as their respective targeted lead treatment indications and stages of development:

<b>Company</b>	<b>Indication</b>	<b>Phase</b>
Ziopharm Oncology, Inc.	rGBM	Phase 2
Arcus Biosciences, Inc.	Multiple Tumor Types	Phase 1/1B
Five Prime Therapeutics, Inc.	Pancreatic Cancer	Phase 2
Corvus Pharmaceuticals, Inc.	Solid Tumors	Phase 1/1B
Calithera Biosciences, Inc.	Renal Cell Carcinoma	Phase 2

For the selected immuno-oncology companies, Piper Jaffray reviewed each of their current implied equity values and implied enterprise values, in each case, calculated as described above under *Similar Stage Cancer-Vaccine Business Profile*. The analysis indicated the following maximum, 75<sup>th</sup> percentile, mean, median, 25<sup>th</sup> percentile and minimum equity values and enterprise values for the selected companies:

	<b>Equity Value</b>	<b>Enterprise Value</b>
Maximum	\$ 544	\$ 464
75 <sup>th</sup> Percentile	\$ 531	\$ 260
Mean	\$ 377	\$ 190
Median	\$ 436	\$ 114
25 <sup>th</sup> Percentile	\$ 190	\$ 67
Minimum	\$ 186	\$ 45

For the selected immuno-oncology companies analysis, Piper Jaffray derived a range of implied enterprise values for PDS based on the implied enterprise value ranges for the selected companies and then adjusted for net

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cash, to calculate an implied PDS equity value. Piper Jaffray then derived an implied number of shares of Edge common stock to be issued in the merger, assuming an Edge intrinsic valuation of \$24.9 million, which was equal to the closing cash balance and which implied an Edge share price of \$0.78 per share based on diluted shares, using the treasury stock method. Piper Jaffray then calculated an implied pro forma equity value for the combined company by adjusting the implied enterprise value for PDS for pro forma net cash at the closing of the merger of approximately \$24.9 million for Edge and approximately (\$2.9) million for PDS, excluding any bridge financing cash PDS raised between the announcement and the closing of the merger and any cash adjustments at the closing of the merger.

The analysis indicated the following implied ownership percentage range for Edge stockholders in the combined company, pro forma for the merger:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Edge Shareholder Ownership	35 %	26 %	21 %	9 %	6 %

In addition, the analysis indicated the following implied pro forma valuation range of the aggregate equity interest in the combined company to be retained by Edge stockholders:

	<b>Maximum</b>	<b>75<sup>th</sup> Percentile</b>	<b>Median</b>	<b>25<sup>th</sup> Percentile</b>	<b>Minimum</b>
Implied Value to Edge Shareholders at 30% Ownership (in millions)	\$ 146	\$ 85	\$ 41	\$ 27	\$ 20

**Other Information**

Piper Jaffray also noted for the Edge Board the following analysis that was not considered part of Piper Jaffray's financial analyses with respect to its opinion but was referenced for informational purposes:

*Pro Forma Cash Sensitivity Analysis*

Piper Jaffray reviewed, for illustrative purposes, the pro forma equity ownership for Edge stockholders in the combined company, under certain sensitivity cases tied to ranges of projected net cash amounts to be held at closing by each of Edge and PDS. Projected net cash for Edge was sensitized at a range of \$24.6 million to \$25.4 million at closing. Projected net cash for PDS was sensitized at a range of \$0.1 million to (\$2.9) million. Applying these sensitivity ranges to the Exchange Ratio mechanic set forth in the Merger Agreement resulted in a range of pro forma equity ownership for Edge stockholders in the combined company of 29.54% to 30.46%.

**Miscellaneous**

The summary set forth above does not contain a complete description of the analyses performed by Piper Jaffray and reviewed with the Edge Board, but summarizes the material analyses performed by Piper Jaffray in rendering its opinion. The preparation of a fairness opinion is not necessarily susceptible to partial analysis or summary description. Piper Jaffray believes that its analyses and the summary set forth above must be considered as a whole and that selecting portions of its analyses or of the summary, without considering the analyses as a whole or all of the factors included in its analyses, would create an incomplete view of the processes underlying the analyses set forth in the Piper Jaffray opinion. In arriving at its opinion, Piper Jaffray considered the results of all of its analyses and did not attribute any particular weight to any factor or analysis. Instead, Piper Jaffray made its determination as to fairness on the basis of its experience and financial judgment after considering the results of all of its analyses. In addition, the ranges of valuations resulting from any particular analysis described above should not be taken to be Piper Jaffray's view of the actual value of Edge common stock.

None of the selected companies or transactions used in the analyses above for purposes of comparison is identical to PDS. Accordingly, an analysis of the results of the comparisons is not mathematical; rather, it involves considerations and judgments about differences in the companies and transactions to which PDS was compared and other factors that could affect the public trading value or transaction value of the companies involved.

Piper Jaffray performed its analyses for purposes of providing its opinion to the Edge Board. In performing its analyses, Piper Jaffray made numerous assumptions with respect to industry performance, general business

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and economic conditions and other matters. Certain of the analyses performed by Piper Jaffray are based upon financial projections of future cash usages furnished to Piper Jaffray by Edge management, which are not necessarily indicative of actual future results and may be significantly more or less favorable than actual future results. These financial projections are inherently subject to uncertainty because, among other things, they are based upon numerous factors or events beyond the control of the parties or their respective advisors. Piper Jaffray does not assume responsibility if future results are materially different from projected financial results.

Piper Jaffray's opinion was one of many factors taken into consideration by the Edge Board in making the determination to approve the Merger Agreement. While Piper Jaffray provided advice to the Edge Board during Edge's negotiations with PDS, Piper Jaffray did not recommend any specific Exchange Ratio.

Piper Jaffray relied upon and assumed, without assuming liability or responsibility for independent verification, the accuracy and completeness of all information that was publicly available or was furnished, or otherwise made available, to Piper Jaffray or discussed with or reviewed by Piper Jaffray. Piper Jaffray further relied upon the assurances of Edge management that the financial information provided to Piper Jaffray by Edge management was prepared on a reasonable basis in accordance with industry practice, and that Edge management was not aware of any information or facts that would make any information provided to Piper Jaffray incomplete or misleading. Without limiting the generality of the foregoing, for the purpose of its opinion, Piper Jaffray assumed that with respect to financial forecasts reviewed by Piper Jaffray, that such forecasts were reasonably prepared based on assumptions reflecting the best currently available estimates and judgments of Edge management and PDS management as to the expected future cash usages of each of Edge and PDS. Piper Jaffray expressed no opinion as to any such financial forecasts, estimates or forward-looking information or the assumptions on which they were based. In particular, Piper Jaffray's opinion and the underlying analyses relating thereto were based upon the estimated respective amounts of Parent Net Cash and Company Net Cash (in each case, as defined in the Merger Agreement) as of the consummation of the merger, as provided to Piper Jaffray by the respective managements of Edge and PDS. Piper Jaffray relied, with consent of the Edge Board, on advice of the outside counsel and the independent accountants to Edge, and on the assumptions of Edge management, as to all accounting, legal, tax and financial reporting matters with respect to each of Edge, PDS and the Merger Agreement.

In arriving at its opinion, Piper Jaffray assumed that the executed Merger Agreement would be in all material respects identical to the last draft reviewed by Piper Jaffray. Piper Jaffray relied upon and assumed, without independent verification, that (i) the representations and warranties of all parties to the Merger Agreement and all other related documents and instruments that are referred to therein are true and correct, consistent with any standards set forth therein, (ii) each party to such agreements will fully and timely perform all of the covenants and agreements required to be performed by such party, (iii) the merger will be consummated pursuant to the terms of the Merger Agreement without amendments thereto, and (iv) all conditions to the consummation of the merger will be satisfied without waiver by any party of any conditions or obligations thereunder. Additionally, Piper Jaffray assumed that all the necessary regulatory approvals and consents required for the merger will be obtained in a manner that will not adversely affect Edge, PDS or the contemplated benefits of the merger.

In arriving at its opinion, Piper Jaffray did not perform any appraisals or valuations of any specific assets or liabilities (fixed, contingent or other) of Edge or PDS, and Piper Jaffray was not furnished or provided with any such appraisals or valuations, nor did Piper Jaffray evaluate the solvency of Edge or PDS under any state or federal law relating to bankruptcy, insolvency or similar matters. The analyses performed by Piper Jaffray in connection with its opinion were going concern analyses. Piper Jaffray expressed no opinion regarding the liquidation value of any of Edge, PDS or any other entity. Without limiting the generality of the foregoing, Piper Jaffray undertook no independent analysis of any pending or threatened litigation, regulatory action, possible unasserted claims or other contingent liabilities, to which any of Edge, PDS or any of its affiliates is a party or may be subject, and at Edge's direction and with its consent, Piper Jaffray's opinion made no assumption concerning, and therefore did not consider, the possible assertion

of claims, outcomes or damages arising out of any such matters. Piper Jaffray also assumed that neither Edge or PDS is party to (or contemplates becoming party to) any material pending transaction, including without limitation, any financing, recapitalization, acquisition or merger, divestiture or spin-off, other than (i) the merger; (ii) the reverse stock split of Edge common stock contemplated by the Merger Agreement; and (iii) a possible permitted financing contemplated by the Agreement.

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Piper Jaffray's opinion was necessarily based upon the information available to it and facts and circumstances as they existed and were subject to evaluation on the date of its opinion. Events occurring after the date of its opinion could materially affect the assumptions used in preparing its opinion. Piper Jaffray did not express any opinion as to the price at which shares of Edge common stock may trade following announcement of the merger or at any future time. Piper Jaffray did not undertake to reaffirm or revise its opinion or otherwise comment upon any events occurring after the date of its opinion and does not have any obligation to update, revise or reaffirm its opinion.

Piper Jaffray's opinion addressed solely the fairness, from a financial point of view, to Edge of the proposed Exchange Ratio and did not address any other terms or agreement relating to the merger or any other terms of the Merger Agreement. Piper Jaffray was not requested to opine as to, and its opinion does not address, (i) the basic business decision to proceed with or effect the merger, (ii) the merits of the merger relative to any alternative transaction or business strategy that may be available to Edge, (iii) any other terms contemplated by the Merger Agreement, or (iv) the solvency or financial viability of Edge or PDS at the date of Piper Jaffray's opinion, upon consummation of the merger, or at any future time. Furthermore, Piper Jaffray expressed no opinion with respect to the amount or nature of compensation to be paid in the merger to any officer, director or employee of any party to the merger, or any class of such persons, relative to the Exchange Ratio or with respect to the fairness of any such compensation.

In selecting Piper Jaffray, the Transactions Committee gave weight to, among other things, Piper Jaffray's deep experience in the industry and relevant transactions, and the experience that members of the Edge Board had previously had with Piper Jaffray in other circumstances, none of which were deemed to give rise to any potential conflicts of interest except as more fully set forth below.

Piper Jaffray acted as a financial advisor to Edge in connection with the merger and will receive a fee of \$2,250,000 from Edge, which is contingent upon the consummation of the merger, except for \$500,000 of such fee which has been earned by Piper Jaffray for rendering its fairness opinion and is creditable against the total fee. The opinion fee was not contingent upon the consummation of the merger or the conclusions reached in Piper Jaffray's opinion. Edge has also agreed to indemnify Piper Jaffray against certain liabilities and reimburse Piper Jaffray for certain expenses in connection with its services. Piper Jaffray has, in the past, acted as one of several underwriters of equity offerings completed by portfolio companies of New Leaf Venture Partners, a significant stockholder of Edge and an entity in which a member of the Edge Board is a partner, for which Piper Jaffray received fees. In addition, in the ordinary course of its business, Piper Jaffray and its affiliates may actively trade securities of Edge for their own account or the account of their customers and, accordingly, may at any time hold a long or short position in such securities. Piper Jaffray may also, in the future, provide investment banking and financial advisory services to Edge, PDS or entities that are affiliated with Edge or PDS, for which Piper Jaffray would expect to receive compensation.

### **Interests of the Edge Directors and Executive Officers in the Merger**

In considering the recommendation of the Edge Board with respect to issuing shares of Edge common stock as contemplated by the Merger Agreement and the other matters to be acted upon by the Edge stockholders at the Edge special meeting, the Edge stockholders should be aware that certain members of the board of directors and executive officers of Edge have interests in the merger that may be different from, or in addition to, the interests of the Edge stockholders. These interests relate to or arise from the matters described below. The board of directors of each of Edge and PDS was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement and the transactions contemplated thereby, and to recommend, as applicable, that the Edge stockholders approve the Edge proposals to be presented to the Edge stockholders for consideration at the Edge special meeting as contemplated by this proxy statement/prospectus/information statement, and that the PDS stockholders sign and return the written consent as contemplated by this proxy statement/prospectus/information statement.



**Severance Payments**

Brian Leuthner, Edge's Chief Executive Officer, is party to an employment agreement with Edge that provides that in the event Mr. Leuthner's employment is terminated by Mr. Leuthner for good reason (as defined in his employment agreement) or by Edge for any reason other than cause, death or disability, in either case, within sixty days prior to or one year after the consummation of a change in control, Edge will pay

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Mr. Leuthner, subject to his execution, delivery, and nonrevocation of a release, the following payments and benefits: (i) continued payment of his base salary for the eighteen month period following termination of employment, (ii) reimbursement for his (and his eligible dependents ) health care continuation premiums for the eighteen month period following termination and (iii) 1.5 times the amount of his annual bonus opportunity. Although it is expected that Mr. Leuthner will continue with Edge as its President following the merger, if Mr. Leuthner's employment was terminated by Edge without cause upon the closing of the merger, Mr. Leuthner would be entitled to receive approximately \$[•] in cash severance benefits.

Herbert J. Faleck, D.O., Edge's Chief Medical Officer, is expected to cease to be Chief Medical Officer and an employee of Edge on December 31, 2018. Under the terms of Dr. Faleck's existing employment agreement with Edge, in the event Dr. Faleck's employment is terminated by Dr. Faleck for good reason (as defined in Dr. Faleck's employment agreement) or by Edge for any reason other than cause, death or disability, in either case, within sixty days prior to or one year after the consummation of a change in control, Edge will pay Dr. Faleck, subject to Dr. Faleck's execution, delivery, and nonrevocation of a release, the following payments and benefits: (i) continued payment of his base salary for the twelve month period following termination of employment and (ii) reimbursement for his (and his eligible dependents ) health care continuation premiums for the twelve month period following termination. Assuming that Dr. Faleck's employment with Edge is terminated without cause on December 31, 2018, Dr. Faleck is expected to receive an aggregate of approximately \$[•] in cash severance benefits.

Brad Middlekauff, Edge's Senior Vice President, General Counsel and Secretary, is party to an employment agreement with Edge that provides that in the event Mr. Middlekauff's employment is terminated by Mr. Middlekauff for good reason (as defined in his employment agreement) or by Edge for any reason other than cause, death or disability, in either case, within sixty days prior to, or one year after, the consummation of a change in control Edge will pay Mr. Middlekauff, subject to his execution, delivery, and nonrevocation of a release, the following payments and benefits: (i) continued payment of his base salary for the twelve month period following termination of employment and (ii) reimbursement for his (and his eligible dependents ) health care continuation premiums for the twelve month period following termination. If Mr. Middlekauff's employment is terminated by Edge without cause upon the closing of the merger, Mr. Middlekauff would be entitled to receive approximately \$[•] in cash severance benefits.

Edge and Alyssa Wyant, Edge's former Senior Vice President, Regulatory Affairs, are parties to a separation agreement pursuant to which (i) Ms. Wyant will receive a cash payment in the amount of \$125,400 on the first payroll date after February 1, 2019 and (ii) all of Ms. Wyant's stock options and Edge RSUs, in each case, granted on August 21, 2018 (99,534 stock options and 49,766 Edge RSUs) became fully vested upon the effectiveness of the release of claims in her separation agreement. All such stock options will remain exercisable for a period of three years following her termination date (which was December 14, 2018).

The merger will constitute a change in control for each of the Edge employment agreements described above.

Andrew Saik, Edge's Chief Financial Officer, is party to an employment agreement with Edge that provides that in the event Mr. Saik's employment is terminated by Mr. Saik for good reason (as defined in his employment agreement) or by Edge for any reason other than cause, death or disability, Edge will pay Mr. Saik, subject to his execution, delivery, and nonrevocation of a release, the following payments and benefits: (i) continued payment of his base salary for the twelve month period following termination of employment and (ii) reimbursement for his (and his eligible dependents ) health care continuation premiums for the twelve month period following termination. Although it is expected that Mr. Saik will continue with Edge following the merger, if Mr. Saik's employment is terminated by Edge without cause upon the closing of the merger, Mr. Saik would be entitled to receive approximately \$[•] in cash severance benefits.

## **Equity Awards and Edge Common Stock**

All outstanding stock options and restricted stock units held by Edge executive officers and directors will be accelerated and fully vest upon the closing of the merger. All such restricted stock units will be settled in shares of Edge common stock within [\_\_] days following the closing of the merger.

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As of December 31, 2018, the directors and officers of Edge held the following options, restricted stock units and shares of Edge common stock (inclusive of shares of Edge common stock held through Edge's 401(k) plan):

<b>Name</b>	<b>Number of Vested Options</b>	<b>Value of Vested Options<sup>(1)</sup></b>	<b>Number of Unvested Options</b>	<b>Value of Unvested Options<sup>(1)</sup></b>	<b>Number of Restricted Stock Units</b>	<b>Value of Restricted Stock Units<sup>(2)</sup></b>	<b>Number of Shares of Edge Common Stock</b>	<b>Value of Edge Common Stock<sup>(2)</sup></b>
Brian A. Leuthner								
Andrew Saik								
W. Bradford Middlekauff								
Sol Barer, Ph.D.								
Isaac Blech								
Rosemary A. Crane								
James J. Loughlin								
R. Loch Macdonald, M.D., Ph.D.								
Liam Ratcliffe, M.D., Ph.D.								
Robert Spiegel, M.D., FACP								

(1) This represents, with respect to each option, the difference between the closing price of one share of Edge common stock on [\_\_] and the per share exercise price of such option.

(2) This represents the number of restricted stock units, multiplied by the closing price of one share of Edge common stock on [\_\_].

**Continued Service**

Additionally, certain of Edge's existing directors are expected to remain directors of the combined company. Brian A. Leuthner, Robert Spiegel, M.D. and James Loughlin are expected to continue as directors of the combined company. [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.]

**Stock Ownership and Support Agreements**

As of December 31, 2018, Edge directors and executive officers held [•] shares of Edge common stock in the aggregate. Edge directors and executive officers have entered into support agreements in connection with the merger. For a more detailed discussion of the support agreements see the section titled "Agreements Related to the Merger—Support Agreements and Written Consent."

**Indemnification and Insurance**

As described in this proxy statement/prospectus/information statement, including in "The Merger—Limitations of Liability and Indemnification," certain of Edge's directors and officers will be entitled to certain ongoing rights of indemnification and coverage under directors' and officers' liability insurance policies.

The Edge Board was aware of these interests and considered them, among other matters, in its decision to approve the Merger Agreement. For more information, please see the section titled "The Merger—Interests of the Edge Directors and Executive Officers in the Merger."

**Interests of the PDS Directors and Executive Officers in the Merger**

PDS stockholders should be aware that certain members of the board of directors and executive officers of PDS have interests in the merger that may be different from, or in addition to, interests they may have as PDS stockholders. The PDS Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching their respective decisions to approve the Merger Agreement, the merger and related transactions, and to recommend that the PDS stockholders sign and return the written consent as contemplated by this proxy statement/prospectus/information statement.

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***Indemnification and Insurance***

Under the Merger Agreement, from and after the closing of the merger, Edge must fulfill and honor in all respects the obligations of PDS and Edge existing prior to the date of the Merger Agreement to indemnify PDS's and Edge's present and former directors and officers and their heirs, executors and assigns.

In accordance with the Merger Agreement, the certificate of incorporation and bylaws of PDS, as the surviving corporation in the merger, shall contain provisions at least as favorable with respect to indemnification.

***Combined Company Management***

Upon the closing of the merger, the executive management team of the combined company is expected to be composed of the following members of the PDS executive management team:

<b>Name</b>	<b>Title</b>
Frank Bedu-Addo, PhD	Chief Executive Officer and Director
Gregory Conn, PhD	Chief Scientific Officer
Lauren Wood, MD	Chief Medical Officer

***Stock Ownership and Support Agreements***

As of December 31, 2018, PDS directors and executive officers held [•] shares of PDS common stock in the aggregate. In addition, in October 2018, the PDS Board agreed to grant each of Dr. Conn and Mr. King 137,559 stock options, and Dr. Bedu-Addo 550,235 stock options, immediately prior to the consummation of the merger. PDS directors and executive officers and certain stockholders of PDS have entered into support agreements in connection with the merger. For a more detailed discussion of the support agreements see the section titled "Agreements Related to the Merger—Support Agreements and Written Consent."

***Transition Services Agreement***

Edge and PDS expect that they may enter into a transition services agreement, pursuant to which Edge may provide PDS with certain clinical and manufacturing consulting services prior to the expected closing of the merger. Edge and PDS expect that any such transition services agreement, if entered into, would contain customary terms as to the scope of services, the period of the services, termination of the transition services agreement, fees, cooperation, intellectual property, confidentiality and other customary arm's-length terms. Entry into such agreement is subject to mutual agreement of the parties on each of the foregoing terms.

***Indemnification and Insurance***

As described in this proxy statement/prospectus/information statement, including in "The Merger—Limitations of Liability and Indemnification," certain of PDS's directors and officers will be entitled to certain ongoing rights of indemnification and coverage under directors' and officers' liability insurance policies.

**Limitations of Liability and Indemnification**

In addition to the indemnification required by Edge's certificate of incorporation and bylaws, Edge has entered into indemnification agreements with each of its directors and officers. These agreements provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were officers, directors or agents of Edge, or by reason of

anything done or not done in their capacities as such. Edge believes that the indemnification provisions in its certificate of incorporation and bylaws and its indemnification agreements are necessary to attract and retain qualified persons as directors and officers of Edge.

Additionally, under the Merger Agreement, from the Effective Time through the sixth anniversary thereof, Edge and PDS, as the surviving corporation in the merger, shall indemnify and hold harmless each person who is now, has been at any time prior to November 23, 2018, or who becomes prior to the Effective Time, a director, officer, fiduciary or agent of Edge or PDS, respectively, against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that such person is or was a director, officer, fiduciary or agent of Edge or

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PDS, whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent permitted under applicable law. In addition, each such person is entitled to advancement of expenses incurred in the defense of any such claim, action, suit, proceeding or investigation from each of Edge and PDS, as the surviving corporation in the merger, jointly and severally, upon receipt by either entity of a request therefor.

Under the Merger Agreement, the provisions of Edge's certificate of incorporation and bylaws with respect to indemnification, advancement of expenses and exculpation of present and former directors and officers of Edge shall not be amended, modified or repealed for a period of six years from the Effective Time in a manner that would adversely affect the rights thereunder of individuals who, at or prior to the Effective Time, were officers or directors of Edge. The certificate of incorporation and bylaws of PDS, as the surviving corporation in the merger, shall contain provisions no less favorable with respect to indemnification, advancement of expenses and exculpation of former and present directors and officers that are presently set forth in Edge's certificate of incorporation and bylaws.

The Merger Agreement also provides that Edge shall maintain directors' and officers' liability insurance policies commencing on the closing time of the merger, on commercially available terms and conditions with coverage limits customary for U.S. public companies similarly situated to Edge. In addition, each of Edge and PDS shall purchase, prior to the Effective Time, a six-year prepaid tail policy for the non-cancellable extension of the directors' and officers' liability coverage of Edge's and PDS's respective existing directors' and officers' insurance policies for a claims reporting or discovery period of at least six years from and after the Effective Time with respect to any claim related to any period of time at or prior to the Effective Time.

### **Form of the Merger**

The Merger Agreement provides that at the Effective Time, Merger Sub will be merged with and into PDS. Upon the closing of the merger, PDS will continue as the surviving corporation and will be a wholly-owned subsidiary of the combined company.

After the closing of the merger, Edge will be renamed PDS Biotechnology Corporation and, subject to satisfying the Nasdaq's initial trading standards, expects to trade on the Nasdaq Capital Market under the symbol PDSB.

### **Merger Consideration**

Immediately after the merger, based on the Exchange Ratio, PDS securityholders will own approximately 70% of the outstanding capital stock of the combined company, and Edge securityholders will own approximately 30% of the outstanding capital stock of the combined company. Adjustments to the Exchange Ratio are described in more detail in the Merger Agreement and in this proxy statement/prospectus/information statement. The Merger Agreement does not include a price-based termination right.

No fractional shares of Edge common stock will be issuable pursuant to the Merger Agreement to PDS stockholders. Instead, each PDS stockholder who would otherwise be entitled to receive a fraction of a share of Edge common stock, after aggregating all fractional shares of Edge common stock issuable to such stockholder, will be entitled to receive in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by the volume weighted average trading price of a share of Edge common stock as quoted on Nasdaq for the five trading days ending the trading day immediately prior to the date upon which the merger becomes effective.

The Merger Agreement provides that, at the Effective Time, Edge will deposit with an exchange agent acceptable to Edge and PDS evidence of book-entry shares representing the shares of Edge common stock issuable to PDS stockholders and a sufficient amount of cash to make payments in lieu of fractional shares.



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The Merger Agreement provides that, promptly after the Effective Time, the exchange agent will mail to each record holder of PDS common stock immediately prior to the Effective Time a letter of transmittal and instructions for surrendering and exchanging the record holder's PDS stock certificates for shares of Edge common stock. Upon surrender of a PDS stock certificate for exchange to the exchange agent, together with a duly signed letter of transmittal and such other documents as the exchange agent or Edge may reasonably require, the PDS stock certificate surrendered will be cancelled and the holder of the PDS stock certificate will be entitled to receive the following:

- the book-entry shares representing the number of whole shares of Edge common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and

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- cash in lieu of any fractional share of Edge common stock.

From and after the Effective Time, until surrendered, all holders of certificates representing shares of PDS common stock that were outstanding immediately prior to the Effective Time will be deemed to represent only the right to receive book-entry shares of Edge common stock, and cash in lieu of fractional shares of Edge common stock.

If any PDS stock certificate has been lost, stolen or destroyed, Edge may, in its discretion and as a condition to the delivery of any shares of Edge common stock, require the owner of such lost, stolen or destroyed certificate to deliver an affidavit claiming such certificate has been lost, stolen or destroyed.

Edge will not pay dividends or other distributions on any shares of Edge common stock to be issued in exchange for any unsurrendered PDS stock certificate until the PDS stock certificate is surrendered as provided in the Merger Agreement.

### **Effective Time of the Merger**

The Merger Agreement requires the parties to consummate the merger as promptly as practicable (and in any event within two business days) after all of the conditions to the closing of the merger contained in the Merger Agreement are satisfied or waived, including the adoption of the Merger Agreement by the PDS stockholders and the approval by the Edge stockholders of the Stock Issuance Proposal. The merger will become effective upon the filing of a certificate of merger with the Secretary of State of the State of Delaware or at such later time as is agreed by Edge and PDS and specified in the certificate of merger. Neither Edge nor PDS can predict the exact timing of the closing of the merger.

### **Regulatory Approvals**

In the United States, Edge must comply with applicable federal and state securities laws and the rules and regulations of the Nasdaq Global Select Market in connection with the issuance of shares of Edge common stock and the filing of this proxy statement/prospectus/information statement with the SEC.

### **Tax Treatment of the Merger**

Edge and PDS intend the merger to qualify as a reorganization within the meaning of Section 368(a) of the Code. The parties shall treat and shall not take any tax reporting position inconsistent with the treatment of the merger as a reorganization within the meaning of Section 368(a) of the Code for U.S. federal, state and other relevant tax purposes, unless otherwise required pursuant to a determination within the meaning of Section 1313(a) of the Code. For a description of certain of the considerations regarding U.S. federal tax consequences of the merger, see the section titled *The Merger – Certain Material U.S. Federal Income Tax Consequences of the Merger* below.

### **Certain Material U.S. Federal Income Tax Consequences of the Merger**

The following is a discussion of certain material U.S. federal income tax consequences of the Merger applicable to U.S. Holders (as defined below) who exchange their PDS common stock for Edge common stock in the merger, but does not purport to be a complete analysis of all potential tax effects.

This discussion and the discussion of tax consequences elsewhere in this proxy statement/prospectus/information statement are limited to U.S. Holders who hold their PDS common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not address all aspects of U.S. federal income taxation that may be relevant to U.S. Holders in light of their particular circumstances or to U.S. Holders who may be subject to special tax treatment under the Code, including, without limitation, dealers in

securities, commodities or foreign currency; banks, thrifts, insurance companies, and other financial institutions; traders that mark-to-market their securities; tax-exempt organizations or governmental organizations; small business investment companies; regulated investment companies; real estate investment trusts; tax-deferred or other retirement accounts; persons whose functional currency is not the U.S. dollar; persons who hold PDS common stock as part of a straddle, hedge, conversion transaction or other risk reduction transaction; persons who hold or receive PDS common stock pursuant to the exercise of compensatory stock options, the vesting of previously restricted shares of stock or

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otherwise as compensation; persons holding PDS common stock who exercise dissenters' rights; any entity or arrangement that is a partnership for U.S. federal income tax purposes; companies subject to the stapled stock rules; expatriated entities; certain former citizens or long-term residents of the United States.

This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service, or the IRS, in effect as of the date of the merger, all of which are subject to change, possibly with retroactive effect, or differing interpretations. Neither PDS nor Edge have sought any ruling from the IRS with respect to the statements made and the conclusions reached in this discussion, and there can be no assurance that the IRS will agree with these statements and conclusions. The effects of other U.S. federal tax laws, such as estate and gift tax laws, the alternative minimum tax and the 3.8% tax on net investment income, and any applicable state, local, or foreign tax laws or the tax consequences occurring prior to, concurrently with or after the merger (whether or not such transactions are in connection with the merger) are not discussed.

Each U.S. Holder is urged to consult its own tax advisor with regard to the merger and the application of U.S. federal income tax laws, as well as the laws of any state, local or foreign taxing jurisdictions, to its particular situation.

For purposes of this discussion, a U.S. Holder is a beneficial owner of PDS common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or a trust if either a court within the United States is able to exercise primary supervision over the administration of such trust and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of such trust, or the trust has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds PDS common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding PDS common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE MERGER ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

Subject to the qualifications and assumptions described in this proxy statement/prospectus/information statement, the merger is intended to be treated for U.S. federal income tax purposes as a reorganization within the meaning of Section 368(a) of the Code. Accordingly, it is expected that the U.S. federal income tax consequences to U.S. Holders of PDS common stock will be as follows:

- a U.S. Holder will not recognize gain or loss upon the exchange of PDS common stock for Edge common stock pursuant to the merger, except to the extent of cash received in lieu of a fractional share of Edge common stock as described below;

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- a U.S. Holder who receives cash in lieu of a fractional share of Edge capital stock in the merger will generally recognize capital gain or loss in an amount equal to the difference between the amount of cash received instead of a fractional share and the U.S. Holder's tax basis allocable to such fractional share;

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- a U.S. Holder's aggregate tax basis for the shares of Edge common stock received in the merger (including any fractional share interest for which cash is received) will equal the U.S. Holder's aggregate tax basis in the shares of PDS common stock surrendered upon the closing of the merger, decreased by the amount of any tax basis allocable to a fractional share for which cash is received; and
- the holding period of the shares of Edge common stock received by a U.S. Holder in the merger will include the holding period of the U.S. Holder's shares of PDS common stock surrendered in exchange therefor.

Capital gains or losses recognized in the merger as described above, if any, generally will constitute long-term capital gain or loss if the U.S. Holder's holding period in the PDS common stock surrendered in the merger is more than one year as of the effective date of the merger. The deductibility of capital losses is subject to limitations. In addition, for purposes of the above discussion of the bases and holding periods for shares of PDS common stock and Edge common stock, U.S. Holders who acquired different blocks of PDS common stock at different times for different prices must calculate their gains and losses and holding periods separately for each identifiable block of such stock exchanged in the merger.

U.S. Holders who owned at least one percent (by vote or value) of the total outstanding stock of PDS and U.S. Holders with a basis in their PDS common stock of \$1,000,000 or more are required to attach a statement to their tax returns for the year in which the merger is consummated that contains the information listed in Treasury Regulation Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in the U.S. Holder's PDS common stock and the fair market value of such stock.

### **Tax Consequences if the Merger Failed to Qualify as a Reorganization**

If the merger fails to qualify as a reorganization within the meaning of Section 368(a) of the Code, then a U.S. Holder would recognize gain or loss upon the exchange of PDS common stock for Edge common stock equal to the difference between the fair market value, at the time of the merger, of the Edge common stock received in the merger (including any cash received in lieu of a fractional share) and such U.S. Holder's tax basis in the PDS common stock surrendered in the merger. Such gain or loss would be long-term capital gain or loss if the PDS common stock was held for more than one year at the time of the merger. In such event, the tax basis of Edge common stock received in the merger would equal its fair market value at the time of the merger and the holding period of such Edge common stock would commence the day after the merger.

### **Information Reporting and Backup Withholding**

A U.S. Holder of shares of PDS common stock may be subject to information reporting and backup withholding on cash paid in lieu of fractional shares, unless the U.S. Holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. Holder fails to furnish a correct taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Each U.S. Holder of shares of PDS common stock should properly complete and sign, and deliver, an IRS Form W-9 in order to provide the information and certification necessary to avoid backup withholding, or otherwise establish an applicable exemption in a manner acceptable to the paying agent. U.S. Holders of shares of PDS common stock should consult their own tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption. Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

### **Nasdaq Stock Market Listing**

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Edge common stock currently is listed on the Nasdaq Global Select Market under the symbol EDGE. Edge has agreed to use commercially reasonable efforts to obtain approval, to the extent required by the rules and regulations of The Nasdaq Stock Market LLC, for listing on The Nasdaq Stock Market LLC of the shares of Edge common stock that PDS stockholders will be entitled to receive pursuant to the merger.

Edge and PDS intend to file an initial listing application for the combined company with The Nasdaq Stock Market LLC pursuant to its reverse merger rules. If such application is accepted, Edge anticipates that the combined company's common stock will be listed on the Nasdaq Capital Market or another Nasdaq market following the closing of the merger under the trading symbol PDSB.

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### **Anticipated Accounting Treatment**

The merger will be treated by Edge as a reverse merger under the acquisition method of accounting in accordance with accounting principles generally accepted in the United States. For accounting purposes, PDS is considered to be acquiring Edge in this transaction. Management of Edge and PDS have made a preliminary estimate of the purchase price calculated as described in Note 2 to the unaudited pro forma condensed combined financial statements and of the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed as of September 30, 2018. The net tangible and intangible assets acquired and liabilities assumed in connection with the transaction will be recorded at their estimated acquisition date fair values. The acquisition method of accounting is dependent upon certain valuations and other studies that have yet to commence or progress to a stage where there is sufficient information for a definitive measurement. A final determination of these estimated fair values, which cannot be made prior to the completion of the transaction, will be based on the actual net tangible and intangible assets of Edge that exist as of the date of completion of the transaction. Any excess of the fair value of the identifiable net assets acquired over the fair value of the consideration transferred will be recognized as a bargain purchase gain. Adjustments to these preliminary estimates are expected to occur and these adjustments could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

### **Appraisal Rights and Dissenters' Rights**

If the merger is completed, PDS stockholders who do not deliver a written consent approving the merger are entitled to appraisal rights under Section 262 of the DGCL, or Section 262, provided that they comply with the conditions established by Section 262. Holders of Edge common stock are not entitled to appraisal rights under Delaware law in connection with the merger.

The discussion below is not a complete summary regarding a PDS stockholder's appraisal rights under Delaware law and is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this proxy statement/prospectus/information statement as *Annex E*. Stockholders intending to exercise appraisal rights should carefully review *Annex E*. Failure to follow precisely any of the statutory procedures set forth in *Annex E* may result in a termination or waiver of these rights. This summary does not constitute legal or other advice, nor does it constitute a recommendation that PDS stockholders exercise their appraisal rights under Delaware law.

Under Section 262, where a merger is adopted by stockholders by written consent in lieu of a meeting of stockholders pursuant to Section 228 of the DGCL, either the constituent corporation before the effective date of the merger or the surviving corporation, within 10 days after the effective date of the merger, must notify each stockholder of the constituent corporation entitled to appraisal rights of the approval of the merger, the effective date of the merger and that appraisal rights are available.

If the merger is completed, within 10 days after the effective date of the merger PDS will notify its stockholders that the merger has been approved, the effective date of the merger and that appraisal rights are available to any stockholder who has not approved the merger. Holders of shares of PDS common stock who desire to exercise their appraisal rights must deliver a written demand for appraisal to PDS within 20 days after the date of mailing of that notice, and that stockholder must not have delivered a written consent approving the merger. A demand for appraisal must reasonably inform PDS of the identity of the stockholder and that such stockholder intends thereby to demand appraisal of the shares of PDS common stock held by such stockholder. Failure to deliver a written consent approving the merger will not in and of itself constitute a written demand for appraisal satisfying the requirements of Section 262. All demands for appraisal should be addressed to PDS Biotechnology Corporation, 303B College Road East, Princeton, NJ 08540, Attention: Secretary, and should be executed by, or on behalf of, the record holder of shares of PDS common stock. ALL DEMANDS MUST BE RECEIVED BY PDS WITHIN 20 DAYS AFTER THE DATE PDS MAILS A NOTICE TO ITS STOCKHOLDERS NOTIFYING THEM THAT THE MERGER HAS BEEN



APPROVED, THE EFFECTIVE DATE OF THE MERGER AND THAT APPRAISAL RIGHTS ARE AVAILABLE TO ANY STOCKHOLDER WHO HAS NOT APPROVED THE MERGER.

If you fail to deliver a written demand for appraisal within the time period specified above, you will be entitled to receive the merger consideration for your shares of PDS common stock as provided for in the Merger Agreement, but you will have no appraisal rights with respect to your shares of PDS common stock.

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To be effective, a demand for appraisal by a holder of shares of PDS common stock must be made by, or in the name of, the registered stockholder, fully and correctly, as the stockholder's name appears on the stockholder's stock certificate(s). Beneficial owners who do not also hold the shares of record may not directly make appraisal demands to PDS. The beneficial owner must, in these cases, have the registered owner, such as a broker, bank or other custodian, submit the required demand in respect of those shares. If shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, execution of a demand for appraisal should be made by or for the fiduciary; and if the shares are owned of record by more than one person, as in a joint tenancy or tenancy in common, the demand should be executed by or for all joint owners. An authorized agent, including an authorized agent for two or more joint owners, may execute the demand for appraisal for a stockholder of record; however, the agent must identify the record owner or owners and expressly disclose the fact that, in executing the demand, he or she is acting as agent for the record owner. A record owner, such as a broker, who holds shares as a custodian for others, may exercise the record owner's right of appraisal with respect to the shares held for one or more beneficial owners, while not exercising this right for other beneficial owners. In that case, the written demand should state the number of shares as to which appraisal is sought. Where no number of shares is expressly mentioned, the demand will be presumed to cover all shares held in the name of the record owner. In addition, the stockholder must continuously hold the shares of record from the date of making the demand through the Effective Time.

If you hold your shares of PDS common stock in a brokerage account or in other custodian form and you wish to exercise appraisal rights, you should consult with your bank, broker or other custodian to determine the appropriate procedures for the making of a demand for appraisal by the custodian.

At any time within 60 days after the Effective Time, any stockholder who has demanded an appraisal, but has neither commenced an appraisal proceeding or joined an appraisal proceeding as a named party, has the right to withdraw such stockholder's demand and accept the terms of the merger by delivering a written withdrawal to PDS. If, following a demand for appraisal, you have withdrawn your demand for appraisal in accordance with Section 262, you will have the right to receive the merger consideration for your shares of PDS common stock.

Within 120 days after the effective date of the merger, any stockholder who has delivered a demand for appraisal in accordance with Section 262 will, upon written request to the surviving corporation, be entitled to receive a written statement setting forth the aggregate number of shares not voted in favor of the Merger Agreement and with respect to which demands for appraisal rights have been received and the aggregate number of holders of these shares. This written statement will be mailed to the requesting stockholder within 10 days after the stockholder's written request is received by the surviving corporation or within ten days after expiration of the period for delivery of demands for appraisal, whichever is later. Within 120 days after the effective date of the merger, either the surviving corporation or any stockholder who has delivered a demand for appraisal in accordance with Section 262 may file a petition in the Delaware Court of Chancery demanding a determination of the fair value of the shares held by all such stockholders. Upon the filing of the petition by a stockholder, service of a copy of the petition must be made upon the surviving corporation. The surviving corporation has no obligation to file a petition in the Delaware Court of Chancery in the event there are dissenting stockholders, and PDS, which is expected to be the surviving corporation, has no present intent to file a petition in the Delaware Court of Chancery. Accordingly, the failure of a stockholder to file a petition within the period specified could nullify the stockholder's previously written demand for appraisal.

If a petition for appraisal is duly filed by a stockholder and a copy of the petition is delivered to the surviving corporation, the surviving corporation will then be obligated, within 20 days after receiving service of a copy of the petition, to provide the Delaware Court of Chancery with a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached by the surviving corporation. After notice to dissenting stockholders who demanded appraisal of their shares, the Delaware Court of Chancery is empowered to conduct a hearing upon the petition, and to determine those stockholders who have complied with Section 262 and who have become entitled to the appraisal

rights provided thereby. The Delaware Court of Chancery may require the stockholders who have demanded appraisal for their shares to submit their stock certificates to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with that direction, the Delaware Court of Chancery may dismiss the proceedings as to that stockholder.

After determination of the stockholders entitled to appraisal of their shares, the Delaware Court of Chancery will appraise the fair value of the shares owned by those stockholders. This value will be exclusive of any

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element of value arising from the accomplishment or expectation of the merger, but may include a fair rate of interest, if any, upon the amount determined to be the fair value. When the value is determined, the Delaware Court of Chancery will direct the payment of the value, with interest thereon accrued during the pendency of the proceeding, if the Delaware Court of Chancery so determines, to the stockholders entitled to receive the same, upon surrender by the holders of the certificates representing those shares.

In determining fair value, and, if applicable, a fair rate of interest, the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court should be considered, and that fair price obviously requires consideration of all relevant factors involving the value of a company.

Section 262 provides that fair value is to be exclusive of any element of value arising from the accomplishment or expectation of the merger. In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that this exclusion is a narrow exclusion [that] does not encompass known elements of value, but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court construed Section 262 to mean that elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered.

You should be aware that the fair value of your shares as determined under Section 262 could be more than, the same as, or less than the value that you are entitled to receive under the terms of the Merger Agreement.

Costs of the appraisal proceeding may be imposed upon the surviving corporation and the stockholders participating in the appraisal proceeding by the Delaware Court of Chancery as the Court deems equitable in the circumstances. Upon the application of a stockholder, the Delaware Court of Chancery may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorneys' fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal. In the absence of such a determination of assessment, each party bears its own expenses. Any stockholder who had demanded appraisal rights will not, after the Effective Time, be entitled to vote shares subject to that demand for any purpose or to receive payments of dividends or any other distribution with respect to those shares, other than with respect to payment as of a record date prior to the Effective Time; however, if no petition for appraisal is filed within 120 days after the Effective Time, or if the stockholder delivers a written withdrawal of his or her demand for appraisal and an acceptance of the terms of the merger within 60 days after the Effective Time, then the right of that stockholder to appraisal will cease and that stockholder will be entitled to receive the merger consideration for shares of his or her PDS common stock pursuant to the Merger Agreement. Any withdrawal of a demand for appraisal made more than 60 days after the Effective Time may only be made with the written approval of the surviving corporation. No appraisal proceeding in the Delaware Court of Chancery will be dismissed as to any stockholder without the approval of the court.

Failure to follow the steps required by Section 262 for perfecting appraisal rights may result in the loss of appraisal rights. In view of the complexity of Section 262, stockholders who may wish to dissent from the merger and pursue appraisal rights should consult their legal advisors.

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### **THE MERGER AGREEMENT**

*The following is a summary of the material terms of the Merger Agreement. A copy of the Merger Agreement is attached as Annex A to this proxy statement/prospectus/information statement and is incorporated by reference into this proxy statement/prospectus/information statement. The Merger Agreement has been attached to this proxy statement/prospectus/information statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Edge, PDS, or Merger Sub. The following description does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement. You should refer to the full text of the Merger Agreement for details of the merger and the terms and conditions of the Merger Agreement.*

*The Merger Agreement contains representations and warranties that Edge and Merger Sub, on the one hand, and PDS, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Merger Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Merger Agreement. While Edge and PDS do not believe that these disclosure schedules contain information required to be publicly disclosed under the applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of factual information about Edge or PDS, because they were made as of specific dates, may be intended merely as a risk allocation mechanism between Edge and PDS, and are modified by the disclosure schedules.*

#### **General**

Under the Merger Agreement, Echos Merger Sub, Inc., a Delaware corporation, or Merger Sub, a wholly-owned subsidiary of Edge, will merge with and into PDS, with PDS surviving as a wholly-owned subsidiary of the combined company.

#### **Merger Consideration**

At the closing of the merger:

- each outstanding share of common stock of PDS will be converted into the right to receive approximately [•] shares of Edge common stock, subject to adjustment as provided below under Exchange Ratio and for any reverse stock split (such final exchange ratio referred to herein as the Exchange Ratio);
- each PDS stock option that is outstanding immediately prior to the Effective Time shall be fully vested and converted into and become an option to purchase that number shares of Edge common stock equal to the Exchange Ratio multiplied by the number of shares of PDS common stock issuable pursuant to such option, and the exercise price of such option shall be adjusted accordingly; and
- each warrant to purchase PDS common stock that is outstanding immediately prior to the Effective Time shall be converted into and become a warrant to purchase that number shares of Edge common stock equal to the Exchange Ratio multiplied by the number of shares of PDS common stock issuable pursuant to such warrant, and the exercise price of such warrant shall be adjusted accordingly.

#### **Exchange Ratio**

The Exchange Ratio will be determined using a formula intended to allocate to the existing PDS stockholders a percentage of the combined company based on the relative valuations of PDS and Edge.

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The Exchange Ratio formula is the quotient obtained by dividing the PDS merger shares (as defined below) by the PDS outstanding shares (as defined below), where:

- PDS merger shares means (a) the product determined by multiplying (i) the post-closing Edge shares (as defined below) by (ii) the PDS allocation percentage (as defined below), minus (b) the number of shares of Edge common stock issuable upon the conversion of any convertible notes issued by PDS under a Permitted Bridge Financing (as defined below).

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- Post-closing Edge shares means the quotient determined by dividing (i) the Edge outstanding shares (as defined below) by (ii) the Edge allocation percentage (as defined below).
- Edge allocation percentage means the quotient determined by dividing (i) the Edge valuation by (ii) the aggregate valuation (as defined below).  
Edge outstanding shares means the total number of shares of Edge common stock outstanding immediately prior to the Effective Time expressed on a fully-diluted basis and assuming, without limitation or duplication, (i) the cashless exercise of all Edge options and warrants outstanding as of immediately prior to the Effective Time with an exercise price less than the Edge closing price (as defined below) and (ii) the settlement of each Edge RSU that is outstanding immediately prior to the Effective Time for an equivalent number of shares of Edge common stock. No out-of-the-money Edge options or warrants will be included as Edge outstanding shares.
- Edge closing price means the volume weighted average closing trading price of a share of Edge common stock on Nasdaq for the five consecutive trading days ending five trading days prior to the Effective Date.
- Edge valuation means \$30 million, subject to any adjustments provided in the Merger Agreement with respect to the amount of cash held by Edge as compared to Edge’s outstanding current liabilities, transaction expenses and indebtedness, in each case as of the anticipated closing date.
- PDS allocation percentage means the quotient determined by dividing (i) the Edge valuation by (ii) the aggregate valuation.  
PDS outstanding shares means the total number of shares of PDS common stock outstanding immediately prior to the Effective Time expressed on a fully-diluted and as-converted to PDS common stock basis and assuming, without limitation or duplication, (i) the cashless exercise of all PDS options and warrants outstanding as of immediately prior to the Effective Time with an exercise price less than the Edge closing price (on a converted to PDS common stock basis) and (ii) the conversion of any notes convertible into shares of PDS common stock. No out-of-the-money PDS options or warrants will be included as PDS outstanding shares.  
PDS valuation means \$70 million, subject to any adjustments provided in the Merger Agreement with respect to the amount of cash held by PDS as compared to PDS’s outstanding current liabilities, transaction expenses and indebtedness, in each case as of (i) the anticipated closing date or (ii) February 28, 2019, if the closing has not occurred by such date, PDS has received stockholder approval of the merger and certain other conditions to closing have been met (as provided in the Merger Agreement).
- Aggregate valuation means the sum of (a) the PDS valuation, plus (b) the Edge valuation.  
Permitted Bridge Financing means PDS’s issuance of (a) shares of PDS common stock, in which event such shares shall be included in the calculation of PDS’s outstanding shares, (b) PDS warrants, in which event such shares shall be included in the calculation of PDS’s outstanding shares to the extent provided in the definition thereof, and/or (c) convertible promissory notes, which promissory notes shall convert into either shares of (i) PDS common stock immediately prior to the closing of the merger, in which event such shares shall be included in the calculation of PDS’s outstanding shares, or (ii) Edge common stock immediately after the closing of the merger, in which event such shares shall be deducted from the calculation of PDS merger shares.

The Merger Agreement does not include a price-based termination right, so there will be no adjustment to the total number of shares of Edge common stock that PDS stockholders will be entitled to receive for changes in the market price of Edge common stock. Accordingly, the market value of the shares of Edge common stock issued pursuant to the merger will depend on the market value of the shares of Edge common stock at the time the merger closes, and could vary significantly from the market value on the date of this proxy statement/prospectus/information statement.

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No fractional shares of Edge common stock will be issued in connection with the merger. Instead, each PDS stockholder who would otherwise be entitled to receive a fraction of a share of Edge common stock, after aggregating all fractional shares of Edge common stock issuable to such stockholder, will be entitled to receive in cash the dollar amount, rounded to the nearest whole cent, without interest, determined by multiplying such fraction by the Edge closing price.

The Merger Agreement provides that, at the Effective Time, Edge will deposit with an exchange agent acceptable to Edge and PDS, stock certificates representing the shares of Edge common stock issuable to the PDS stockholders and a sufficient amount of cash to make payments in lieu of fractional shares.

The Merger Agreement provides that, promptly after the Effective Time, the exchange agent will mail to each record holder of PDS common stock immediately prior to the Effective Time a letter of transmittal and instructions for surrendering and exchanging the record holder's PDS stock certificates for shares of Edge common stock. Upon surrender of a PDS stock certificate for exchange to the exchange agent, together with a duly signed letter of transmittal and such other documents as the exchange agent or Edge may reasonably require, the PDS stock certificate surrendered will be cancelled and the holder of the PDS stock certificate will be entitled to receive the following:

- the book-entry shares representing the number of whole shares of Edge common stock that such holder has the right to receive pursuant to the provisions of the Merger Agreement; and
- cash in lieu of any fractional share of Edge common stock.

At the Effective Time, all holders of certificates representing shares of PDS common stock that were outstanding immediately prior to the Effective Time will cease to have any rights as stockholders of PDS. In addition, no transfer of PDS common stock after the Effective Time will be registered on the stock transfer books of PDS.

If any PDS stock certificate has been lost, stolen or destroyed, Edge may, in its discretion, and as a condition precedent to the delivery of any shares of Edge common stock, require the owner of such lost, stolen or destroyed certificate to deliver an affidavit claiming such certificate has been lost, stolen or destroyed and agree to indemnify Edge against any claim suffered by Edge related to the lost, stolen or destroyed certificate or any Edge common stock issued in exchange for such certificate as Edge may reasonably request.

From and after the Effective Time, until it is surrendered, each certificate that previously evidenced PDS common stock will be deemed to represent only the right to receive shares of Edge common stock and cash in lieu of any fractional share of Edge common stock. Edge will not pay dividends or other distributions on any shares of Edge common stock to be issued in exchange for any unsurrendered PDS stock certificate until the PDS stock certificate is surrendered or the holder delivers an affidavit of loss or destruction, in each case as provided in the Merger Agreement.

### **Treatment of Edge Stock Options and Edge RSUs**

Immediately prior to the Effective Time, each outstanding and unexercised Edge stock option, whether vested or unvested, and each outstanding and unvested Edge RSU, shall be accelerated in full with each (i) unexercised Edge Stock option remaining immediately after the Effective Time in accordance with its terms and (ii) Edge RSUs to be settled within five days after the Effective Time (with settlement to be one share of Edge common stock for each share of Edge common stock underlying such Edge RSU).



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**Directors and Executive Officers of the Combined Company Following the Merger**

Pursuant to the Merger Agreement, the directors of PDS and Edge who will not serve as directors following the closing of the merger will resign at or prior to the closing of the merger. Effective as of the closing of the merger, the combined company's board of directors will be fixed at seven members, four of whom will be directors designated by PDS and three of whom will be directors designated by the Edge. It is anticipated that the Edge designees will be Brian A. Leuthner, James Loughlin and Robert Spiegel, M.D. and the PDS designees will be Frank Bedu-Addo, Sir Richard Sykes, DeLyle W. Bloomquist and Gregory Freitag, J.D., CPA. Upon the closing of the merger, the combined company's board of directors will appoint each of the following as officers of the combined company:

<b>Name</b>	<b>Title</b>
Frank Bedu-Addo	Chief Executive Officer
Brian A. Leuthner	President
Gregory Conn, PhD.	Chief Scientific Officer
Andrew Saik	Chief Financial Officer
Lauren Wood, M.D.	Chief Medical Officer

**Conditions to the Closing of the Merger**

Each party's obligation to complete the merger is subject to the satisfaction or waiver by each of the parties, at or prior to the closing of the merger, of various conditions, which include, in addition to other customary closing conditions, the following:

- the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, shall have been declared effective by the SEC in accordance with the Securities Act and shall not be subject to any stop order or proceeding, or any proceeding threatened by the SEC, seeking a stop order; there shall not have been issued any temporary restraining order, preliminary or permanent injunction or other order preventing the closing of the merger by any court of competent jurisdiction or other governmental entity of competent jurisdiction, and no law, statute, resolution, ordinance, code, rule, regulation, requirement, ruling or decree shall be in effect which has the effect of making the closing of the merger illegal;
- the holders of a majority of the outstanding shares of PDS common stock shall have adopted and approved the Merger Agreement, the merger and the transactions contemplated by the Merger Agreement, and the holders of a majority of the outstanding shares of Edge common stock shall have adopted and approved
- the Merger Agreement, the merger and the transactions contemplated by the Merger Agreement, and the reverse stock split;

In addition, the obligation of Edge and Merger Sub to complete the merger is further subject to the satisfaction or waiver of the following conditions:

- certain fundamental representations and warranties of PDS shall have been true and correct in all material respects on the date of the Merger Agreement and shall be true and correct in all material respects on the closing date of the merger with the same force and effect as if made on and as of the date on which the merger is to be completed or, if such representations and warranties address matters as of a particular date, then such fundamental representations and warranties shall be so true and correct as of that particular date;
- certain representations and warranties regarding the capitalization of PDS in the Merger Agreement shall have been true and correct in all respects as of the date of the Merger Agreement and shall be true and correct on the closing date of the merger with the same force and effect as if made on the date on which the merger is to be completed, except, in each case, (x) for such inaccuracies representing less than 0.50% of PDS

outstanding shares (as defined above) in the aggregate or (y) for those representations and warranties which address matters only as of a particular date (which representations and warranties shall have been true and correct, subject to the qualifications as set forth in the preceding clause (x), as of such particular date);

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all other representations and warranties of PDS in the Merger Agreement shall have been true and correct as of the date of the Merger Agreement and shall be true and correct on the closing date of the merger with the same force and effect as if made on the date on which the merger is to be completed or, if such

- representations and warranties address matters as of a particular date, then such representations and warranties shall be true and correct as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have a material adverse effect on PDS;
- PDS shall have performed or complied with in all material respects all of its covenants and agreements in the Merger Agreement required to be performed or complied with by it on or before the closing of the merger;
- PDS shall have delivered certain certificates and other documents required under the Merger Agreement for the closing of the merger;
- all stockholders agreements, voting agreement, registration rights agreement, co-sale agreement or any other similar contract between PDS and any holders of PDS's stock, including any contract granting any person investor rights, rights of first refusal, rights of first offer, registration rights, director designation rights or similar rights, shall have been terminated;
- Edge shall have received a copy of the lock-up agreement from certain identified stockholders of PDS and each executive officer and director of PDS who is elected or appointed as an executive officer and director of Edge as of immediately following the closing of the merger; and
- since the date of the Merger Agreement, there shall have been no effect, change, event, circumstance, or development that has had or would reasonably be expected to have had a material adverse effect on the business, condition (financial or otherwise), assets, liabilities, or results of operations of PDS. The Merger Agreement provides that certain effects, changes, events, circumstances, or developments arising or resulting from the following shall not be considered a material adverse effect on PDS:
  - general economic or business conditions affecting the industry in which PDS operates;
  - acts of war, armed hostilities or terrorism;
  - changes in financial, banking or securities markets;
  - the taking of any action required to be taken under the Merger Agreement;
  - any change in or any compliance with or action taken for the purpose of complying with any law or U.S. GAAP; or
  - the announcement of the Merger Agreement or pendency of the merger.

In addition, the obligation of PDS to complete the merger is further subject to the satisfaction or waiver of the following conditions:

certain fundamental representations and warranties of Edge shall have been true and correct in all material respects on the date of the Merger Agreement and shall be true and correct in all material respects on the

- closing date of the merger with the same force and effect as if made on and as of the date on which the merger is to be completed or, if such representations and warranties address matters as of a particular date, then such fundamental representations and warranties shall be so true and correct as of that particular date;
- certain representations and warranties regarding the capitalization of Edge in the Merger Agreement shall have been true and correct in all respects as of the date of the Merger Agreement and shall be true and correct on the closing date of the merger with the same force and effect as if made on the date on which the merger is to be completed, except, in each case, (x) for such inaccuracies representing less than 0.50% of Edge outstanding shares (as defined above) in the aggregate or (y) for those representations and warranties which address matters only as of a particular date (which representations and warranties shall have been true and correct, subject to the qualifications as set forth in the preceding clause (x), as of such particular date);

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all other representations and warranties of Edge in the Merger Agreement shall have been true and correct as of the date of the Merger Agreement and shall be true and correct on the closing date of the merger with the same force and effect as if made on the date on which the merger is to be completed or, if such

- representations and warranties address matters as of a particular date, then such representations and warranties shall be true and correct as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have a material adverse effect on Edge;
- Edge and Merger Sub shall have performed or complied with in all material respects all of their covenants and agreements in the Merger Agreement required to be performed or complied with by it on or before the Effective Time;
- Edge shall have delivered certain certificates and other documents required under the Merger Agreement for the closing of the merger;
- Edge shall have delivered to PDS written resignations of the officers and directors of Edge who are not to continue as officers or directors of Edge pursuant to the terms of the Merger Agreement, in a form reasonably satisfactory to PDS; and
- since the date of the Merger Agreement, there shall have been no effect, change, event, circumstance, or development that that has had or would reasonably be expected to have had a material adverse effect on the business, condition (financial or otherwise), assets, liabilities, or results of operations of Edge. The Merger Agreement provides that certain effects, changes, events, circumstances, or developments arising or resulting from the following shall not be considered a material adverse effect on Edge, including without limitation:
  - general business or economic conditions affecting the industry in which Edge operates;
  - acts of war, armed hostilities or terrorism;
  - changes in financial, banking or securities markets;
  - the taking of any action required to be taken under the Merger Agreement;
  - any change in the stock price or trading volume of Edge stock;
  - any clinical trial programs or studies, including any adverse data, event or outcome arising out of related to any such programs or studies; or
  - the announcement of the Merger Agreement or pendency of the merger.

**Representations and Warranties**

The Merger Agreement contains customary representations and warranties of Edge, Merger Sub, and PDS for a transaction of this type relating to, among other things:

- corporate organization, organizational and governing documents, and power, and similar corporate matters;
- subsidiaries;
- capitalization;
- financial statements;
- absence of certain changes or events;
- title to assets;
- real property and leaseholds;
- intellectual property;
- the validity of material contracts to which the parties or their subsidiaries are a party and any violation, default or breach under such contracts;
- non-contravention and required consents;

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- absence of undisclosed liabilities;
- regulatory compliance, permits and restrictions;
- tax matters;
- employee and labor matters and benefit plans;
- environmental matters;
- insurance;
- legal proceedings and orders;
- authority to enter into the Merger Agreement and the related agreements;
- with respect to PDS, compliance with anti-bribery laws;
- full disclosure;
- governmental authorization;
- transactions with affiliates;
- votes required for the closing of the merger and approval of the proposals that will come before the Edge special meeting and that will be the subject of PDS stockholder approval;
- any brokerage or finder's fee or other fee or commission in connection with the merger;
- information technology and data privacy
- with respect to Edge, opinion of its financial advisor;
- with respect to Edge, the valid issuance in the merger of the Edge common stock;
- with respect to Edge, contract termination fees and severance payments; and
- with respect to PDS, accuracy of the information supplied by PDS for inclusion in this registration statement on Form S-4.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of some of the conditions to the obligations of PDS and Edge to complete the merger.

**Non-Solicitation**

Each of PDS and Edge agreed that, subject to certain exceptions, Edge, PDS, and any of their respective subsidiaries will not, and each party will not authorize its officers, directors, employees, investment bankers, attorneys, accountants, representatives, consultants or other agents retained by to, directly or indirectly:

- solicit, initiate, knowingly encourage, induce or knowingly facilitate the communication, making, submission or announcement of, any acquisition proposal (as defined below) or acquisition inquiry (as defined below), or take any action that could reasonably be expected to lead to an acquisition proposal or an acquisition inquiry;
- furnish any non-public information with respect to it to any person in connection with or in response to an acquisition proposal or an acquisition inquiry;
- engage in discussions or negotiations with any person with respect to any acquisition proposal or acquisition inquiry;
- subject to certain exceptions for Edge, approve, endorse or recommend an acquisition proposal;
- execute or enter into any letter of intent or similar document or any contract contemplating or otherwise relating to an acquisition transaction; or
- publicly propose to do any of the foregoing.

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An acquisition inquiry means an inquiry, indication of interest or request for information (other than an inquiry, indication of interest or request for information made or submitted by PDS, on the one hand, or Edge, on the other hand, to the other party) that would reasonably be expected to lead to an acquisition proposal.

An acquisition proposal means any offer or proposal, whether written or oral (other than an inquiry, indication of interest or request for information made or submitted by PDS, on the one hand, or Edge, on the other hand, to the other party) contemplating or otherwise relating to any acquisition transaction, as defined below.

An acquisition transaction means the following:

any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction: (i) in which Edge or PDS is a constituent entity; (ii) in which a person or group (as defined in the Exchange Act and the rules promulgated thereunder) of persons directly or indirectly acquires beneficial or record ownership of securities representing more than 20% of the outstanding securities of any class of voting securities of Edge or PDS or any of their subsidiaries; or (iii) in which Edge or PDS or any of its subsidiaries issues securities representing more than 20% of the outstanding securities of any class of voting securities of Edge or PDS or any of its subsidiaries; provided that in the case of PDS, a Permitted Bridge Financing or permitted post-measurement date financing (as defined below) shall not be an acquisition transaction ; and

- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or assets that constitute 20% or more of the consolidated book value or the fair market value of the assets of a party and its subsidiaries, taken as a whole.

A permitted post-measurement date financing means PDS's issuance in a single transaction or series of transactions, in each case after the anticipated closing date of the merger of (a) shares of PDS common stock, (b) PDS warrants, and/or (c) convertible promissory notes, which promissory notes shall convert into either shares of (i) PDS common stock prior to the closing of the merger, or (ii) Edge common stock immediately after the closing of the merger. No securities issued in a permitted post-measurement date financing shall be included in the calculation of PDS outstanding shares or deducted from the calculation of PDS merger shares such that, for the avoidance of doubt, any permitted post-measurement date financing shall dilute the equity holders of Edge and PDS pro rata based on the Edge allocation percentage and PDS allocation percentage, respectively.

Before obtaining the applicable Edge stockholder approvals required to consummate the merger, Edge may furnish nonpublic information regarding Edge and its subsidiaries to, and may enter into discussions or negotiations with, any person in response to a bona fide written acquisition proposal made or received after the date of the Merger Agreement, which the Edge Board determines in good faith, after consultation with Edge's outside financial advisors and outside legal counsel, constitutes or is reasonably likely to result in a superior offer, as defined below, and is not withdrawn, if:

- neither Edge nor any of Edge's representatives has breached the non-solicitation provisions of the Merger Agreement described above;
- the Edge Board concludes in good faith, based on the advice of outside legal counsel, that the failure to take such action is reasonably likely to be inconsistent with the fiduciary duties of such board of directors under applicable law;
- Edge receives from the third-party an executed confidentiality agreement containing provisions at least as favorable to Edge as those contained in the confidentiality agreement between Edge and PDS; and
- substantially contemporaneously with furnishing of any such nonpublic information to a person, Edge furnishes the same non-public information to PDS.

A superior offer means an unsolicited bona fide written acquisition proposal (with all references to 20% in the definition of acquisition transaction being treated as references to greater than 50% for these purposes) that: (a) was not obtained or made as a direct or indirect result of a breach of (or in violation of) the Merger Agreement; and (b) is on terms and conditions that the Edge Board or the PDS Board, as applicable, determines in good faith, based on such matters that it deems relevant (including the likelihood of consummation thereof), as well as any written offer by the other party to the Merger Agreement to amend the terms of the Merger

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Agreement, and following consultation with its outside legal counsel and outside financial advisors, if any, are more favorable, from a financial point of view, to the Edge stockholders or the PDS stockholders, as applicable, than the terms of the transactions contemplated by the Merger Agreement.

### **Meetings of Stockholders**

Edge is obligated under the Merger Agreement to use commercially reasonable efforts to take all action necessary to call, give notice of and hold a meeting of its stockholders for the purposes of voting on the issuance of shares of Edge common stock in the merger and the reverse stock split of Edge common stock.

PDS is obligated under the Merger Agreement to obtain written consents of its stockholders sufficient to adopt the Merger Agreement and approve the merger and the others transactions contemplated thereby reasonably promptly, and no later than three business days following this registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, being declared effective by the SEC. The PDS board of director's recommendation that PDS stockholders approve the Merger Agreement and the transactions contemplated thereby shall not be withdrawn or modified (and the PDS Board shall not publicly propose to withdraw or modify such recommendation) in a manner adverse to Edge, and no resolution by the PDS Board or any committee thereof to withdraw or the PDS Board in a manner adverse to Edge or to adopt, approve or recommend (or publicly propose to adopt, approve or recommend) any alternative acquisition proposal shall be adopted or proposed.

### **Covenants; Conduct of Business Pending the Merger**

Edge has agreed that, except as permitted by the Merger Agreement, as required by law, or unless PDS shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement, Edge will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts. Edge has also agreed that, subject to certain limited exceptions, without the consent of PDS, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock; or repurchase, redeem or otherwise reacquire any shares of capital stock or other securities (except in connection with the payment of the exercise price (but not for withholding taxes except in respect of obligations that existed prior to October 1, 2018) incurred upon the exercise, settlement or vesting of any award granted under any Edge equity incentive plan);
- sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing with respect to: any capital stock or other security (except for Edge common stock issued upon the valid exercise or settlement of outstanding options or restricted stock units to purchase shares of Edge common stock); any option, warrant or right to acquire any capital stock or any other security of Edge; or any instrument convertible into or exchangeable for any capital stock or other security of Edge;
- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of Edge, or effect or become a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into any joint venture with any other entity;
- lend money to any person (except for advancement of expenses to employees, directors or consultants in the ordinary course of business); incur or guarantee any indebtedness for borrowed money; guarantee any debt



securities of others; or make any capital expenditure or commitment in excess of the amounts set forth in Edge operating budget delivered to PDS concurrently with the Merger Agreement;

- other than as required by law, adopt, establish, terminate or enter into any Edge employee benefit plan; cause or permit any Edge employee benefit plan to be amended; increase the amount of the wages,

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salary, commissions, benefits or other compensation or remuneration payable to any of its directors, officers or employees; increase the severance or change of control benefits offered to any current or new employees, directors or consultants; or hire, terminate (other than for cause) or give notice of termination (other than for cause) to any (x) officer, or (y) employee whose annual base salary is or is expected to be more than \$25,000 per year;

- recognize any labor union, labor organization or similar person;
- enter into any material transaction other than in the ordinary course of business;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any encumbrance with respect to such assets or properties, except in the ordinary course of business; make, change or revoke any tax election; fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making a material change to any tax return; settle or compromise any tax liability, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement, request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than in connection with any extension of time to file any tax return) or adopt or change any accounting method in respect of taxes;
- except as contemplated by the Merger Agreement, enter into, materially amend or terminate certain material contracts;
- make any expenditures, incur any liabilities, or discharge or satisfy any liabilities in amounts that exceed the limitations set forth in Edge's operating budget delivered to PDS concurrently with the execution of the Merger Agreement, in each case, in amounts that exceed the aggregate amount of the Edge budget by \$300,000;
- other than as required by law or U.S. GAAP, take any action to materially change its accounting policies or procedures;
- initiate any legal proceeding other than for the routine collection of bills, in such cases where Edge in good faith determines that failure to commence suit would result in the material impairment of a valuable aspect of Edge's business, provided that Edge consults with PDS prior to the initiation of such legal proceeding or for any claim related to or arising out of, or in respect of any breach of the Merger Agreement;
- settle any legal proceeding; or
- agree, resolve or commit to do any of the foregoing.

PDS has agreed that, except as permitted by the Merger Agreement, as required by law, or unless Edge shall have provided written consent, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement, PDS will conduct its business and operations in the ordinary course consistent with past practices and in compliance with all applicable laws, regulations and certain contracts. PDS has also agreed that, subject to certain limited exceptions, without the consent of Edge, it will not, during the period commencing on the date of the Merger Agreement and continuing until the earlier to occur of the closing of the merger and the termination of the Merger Agreement:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any shares of capital stock of PDS; or repurchase, redeem or otherwise reacquire any shares of capital stock or other securities of PDS (except for shares of PDS common stock from terminated employees, directors or consultants of PDS);
- except as required to give effect to anything in contemplation of the closing of the merger, amend the certificate of incorporation, bylaws or other charter or organizational documents of PDS, or effect or become a party to any merger, consolidation, share exchange, business combination, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction except as related to the proposed transactions under the Merger Agreement;

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- other than as contemplated by a Permitted Bridge Financing or a permitted post-measurement date financing, sell, issue, grant, pledge or otherwise dispose of or encumber or authorize any of the foregoing actions with respect to: any capital stock or other security of PDS (except for shares of PDS common stock issued upon the valid exercise of PDS options and PDS warrants); any option, warrant or right to acquire any capital stock or any other security of PDS; or any instrument convertible into or exchangeable for any capital stock or other security of PDS;
- form any subsidiary or acquire any equity interest or other interest in any other entity or enter into a joint venture with any other entity;
- lend money to any person (except for advancement of expenses to employees, directors or consultants in the ordinary course of business); incur or guarantee any indebtedness for borrowed money (other than a Permitted Bridge Financing or permitted post-measurement date financing); guarantee any debt securities of others; or make any capital expenditure or commitment in excess of \$100,000;
- other than as required by applicable law: adopt, establish, terminate or enter into any employee benefit plan; cause or permit any employee plan to be amended in any material respect; increase the amount of the wages, salary, commissions or other compensation or remuneration payable to, any of its directors, officers or employees, other than increases in base salary and annual cash bonus opportunities and payments made in the ordinary course of business in accordance with past practices; increase the severance or change of control benefits offered to any current or new employees, directors or consultants; or hire, terminate or give notice of termination to any (x) officer or (y) employee whose annual base salary is expected to be more than \$125,000 per year;
- recognize any labor union, labor organization, or similar person;
- enter into any material transaction other than in the ordinary course of business in accordance with past practices or as contemplated by a Permitted Bridge Financing or permitted post-measurement date financing;
- acquire any material asset or sell, lease or otherwise irrevocably dispose of any of its assets or properties, or grant any encumbrance with respect to such assets or properties, except in the ordinary course of business in accordance with past practices;
- sell, assign, transfer, license, sublicense or otherwise dispose of any material PDS intellectual property rights (other than pursuant to non-exclusive licenses in the ordinary course of business in accordance with past practices);
- make, change or revoke any tax election; fail to pay any income or other material tax as such tax becomes due and payable, file any amendment making any material change to any tax return; settle or compromise any income or other material tax liability, enter into any tax allocation, sharing, indemnification or other similar agreement or arrangement (other than customary contracts entered into in the ordinary course of business the principal subject of which is not taxes), request or consent to any extension or waiver of any limitation period with respect to any claim or assessment for any income or other material taxes (other than in connection with any extension of time to file any tax return) or adopt or change any material accounting method in respect of taxes;
- Other than as contemplated by a Permitted Bridge Financing or permitted post-measurement date financing, or as otherwise contemplated by the Merger Agreement, enter into, materially amend or terminate certain material contracts;
- take any action to materially change its accounting policies other than as required by law or U.S. GAAP;
- initiate any legal proceeding other than for the routine collection of bills, in such cases where PDS in good faith determines that failure to commence suit would result in the material impairment of a valuable aspect of PDS's business, provided that PDS consults with Edge prior to the initiation of such legal proceeding or for any claim related to or arising out of, or in respect of any breach of the Merger Agreement;
- settle any legal proceeding; or
- agree, resolve or commit to do any of the foregoing.

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### **Other Agreements**

Each of Edge and PDS has agreed to use its commercially reasonable efforts to:

- file or otherwise submit all applications, notices, reports and other documents reasonably required to be filed with a governmental entity with respect to the merger;
- satisfy the conditions precedent to the consummation of the transactions contemplated by the Merger Agreement;
- make all filings and other submissions and give all notices required to be made and given in connection with the merger;
- provide the other party with reasonable access during normal business hours to such party's personnel and assets and to all existing books, records, tax returns, work papers and other documents and information relating to such party and its subsidiaries;
- provide the other party with such copies of the existing books, records, tax returns, work papers, product data, and other documents and information relating to such party and its subsidiaries, and with such additional financial, operating and other data and information regarding such party and its subsidiaries as the other party may reasonably request;
- permit the other party's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of such party responsible for such party's financial statements and the internal controls of such party to discuss such matter as the other party may deem appropriate;
- make available to the other party copies of unaudited financial statements, material operating and financial reports prepared by senior management or the board of directors of such party, and any material notice, report or other document filed with or sent to or received from any governmental body in connection with the transactions contemplated by the Merger Agreement;
- obtain all consents, approvals or waivers reasonably required in connection with the transactions contemplated by the Merger Agreement;
- cause this proxy statement/prospectus/information statement to comply with the rules and regulations promulgated by the SEC, to respond promptly to any comments of the SEC or its staff and to have this proxy statement/prospectus/information statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC;
- cause this proxy statement/prospectus/information statement to be mailed to Edge's stockholders as promptly as practicable after this proxy statement/prospectus/information statement is declared effective; and
- lift any injunction prohibiting, or any other legal bar to, the merger or other transactions contemplated by the Merger Agreement.

Edge and PDS agreed that, among other things:

- Edge and PDS will use reasonable best efforts to file or otherwise submit all documents reasonably required to be filed with respect to the transactions contemplated by the Merger Agreement; Edge shall use commercially reasonable efforts to cause this proxy statement/prospectus/information statement to comply with the rules and regulations promulgated by the SEC, to respond promptly to any comments of the SEC or its staff and to have this proxy statement/prospectus/information statement declared effective under the Securities Act as promptly as practicable after it is filed with the SEC;
- For purposes of employee benefits provided under any benefit plans or arrangements after the closing of the merger, each employee who continues to be employed by Edge, PDS or their subsidiaries immediately following such closing shall be credited with his/her years of service with Edge, PDS or their subsidiaries. In addition, Edge shall cause all pre-existing condition exclusions and actively at work requirements of any benefit plans in effect after closing to be waived for any such employee;



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- Edge will use reasonable best efforts to keep this registration statement on Form S-4 effective as long as necessary to complete the merger;
- PDS will use commercially reasonable efforts to deliver a letter from PDS's independent accounting firm to Edge in a form customary in scope and substance for letters delivered by independent public accountants in connection with registration statements similar to this proxy statement/prospectus/information statement;
- Edge will use reasonable best efforts to maintain the listing of its common stock on the Nasdaq Stock Market;
- Edge shall use commercially reasonable efforts to prepare and submit to Nasdaq a notification form for the listing of the shares of Edge common stock to be issued pursuant to the Merger Agreement and to cause such shares to be approved for listing and shall, to the extent required by Nasdaq rules, to file an initial listing application for the Edge common stock on Nasdaq and to cause such listing application to be conditionally approved prior to the Effective Time;
- for a period of six years after the closing of the Merger, Edge and PDS as the surviving corporation in the merger will indemnify each of the directors and officers of Edge and PDS to the fullest extent permitted under applicable law; and
- Edge will maintain directors' and officers' liability insurance policies from and after the Effective Time and will also purchase a six-year prepaid tail policy for the non-cancellable extension of the directors' and officers' liability coverage of Edge's existing directors' and officers' insurance policies for a period of at least six years from the Effective Time.

**Termination of the Merger Agreement**

The Merger Agreement may be terminated at any time before the closing of the merger, whether before or after the required stockholder approvals to complete the merger, issue additional Edge common stock and consummate the reverse stock split of Edge common stock, as applicable, have been obtained, as set forth below:

- by mutual written consent duly authorized by the board of directors of each of Edge and PDS;
- by either Edge or PDS if the merger has not been consummated by June 23, 2019 (subject to a possible extension as provided in the Merger Agreement, referred to as the end date); provided, however, that this right to terminate the Merger Agreement will not be available to any party whose action or failure to act has been a principal cause of the failure of the merger to occur on or before such date and such action or failure to act constitutes a breach of the Merger Agreement, and in the event that a request for additional information has been made by any government authority, or in the event that the SEC has not declared effective the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, by the date that is 60 days prior to the end date, either party will be entitled to extend the end date for an additional 60 days by written notice to the other party;
- by Edge or PDS if a court of competent jurisdiction or governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that has the effect of permanently restraining, enjoining or otherwise prohibiting the merger;
- by Edge if PDS did not obtain the written consent of a requisite number of its stockholders necessary to adopt the Merger Agreement and approve the merger and related matters within three business days of the registration statement on Form S-4, of which this proxy statement/prospectus/information statement is a part, becoming effective, but this right to terminate the Merger Agreement will not be available to Edge once PDS obtains such approval;
- by Edge or PDS if the stockholders of Edge do not approve the issuance of shares of Edge common stock pursuant to the Merger Agreement at the Edge stockholders' meeting (including any adjournments and postponements thereof); provided, however, that this right to terminate the Merger Agreement will not be available to any party if such party's action or failure to act has been a principal cause of the failure and such action or failure to act constitutes a breach of the Merger Agreement and Edge may not terminate the Merger Agreement until the date that is 61 days after the date the initial Edge stockholders' meeting is held;



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- by PDS, at any time prior to the approval by Edge’s stockholders of the issuance of the shares of Edge common stock pursuant to the merger, if any of the following occurs (each, a triggering event ):
  - Edge fails to include in this proxy statement/prospectus/information statement its recommendation that the stockholders of Edge vote to approve the issuance of shares of Edge common stock pursuant to the Merger Agreement and the reverse stock split of Edge common stock;
  - the Edge Board approves, endorses or recommends any acquisition proposal, as defined in the section titled The Merger Agreement—Non-Solicitation ; or
  - Edge enters into any letter of intent or similar document or any contract relating to any acquisition proposal, other than a confidentiality agreement permitted pursuant to the Merger Agreement.
- by Edge or PDS if the other party to the Merger Agreement has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of the other party has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of time of such breach or inaccuracy, but if such breach or inaccuracy is curable by the end date, then the Merger Agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of written notice of such breach or inaccuracy and the intention to terminate;
- by PDS, at any time, upon the occurrence of any event, effect, change, circumstance or development that has had or would reasonably be expected to have had a material adverse effect on the business, condition (financial or otherwise), liabilities, assets or results of operations of Edge. The Merger Agreement provides that certain effects, events, changes, circumstances or developments shall not be considered a material adverse effect on Edge;
- by Edge, at any time, upon the occurrence of any event, effect, change, circumstance or development that has had or would reasonably be expected to have had a material adverse effect on the business, condition (financial or otherwise), liabilities, assets or results of operations of PDS. The Merger Agreement provides that certain effects, events, changes, circumstances or developments shall not be considered a material adverse effect on PDS; or
- by Edge, at any time, if Edge has received a superior offer (as defined above), Edge has complied with its obligations under the Merger Agreement to accept such superior offer, Edge concurrently terminates the Merger Agreement and enters into a definitive agreement that is contemplated or relates to an acquisition transaction (as defined above) that constitutes a superior offer and within two business days of such termination, Edge pays the applicable termination fees to PDS as contemplated by the Merger Agreement.

**Termination Fees**

***Fee payable by Edge***

Edge must pay PDS a termination fee of \$1.75 million if:

- the Merger Agreement is terminated by PDS (at any time prior to Edge’s stockholders’ approval of the Stock Issuance Proposal pursuant to the Merger Agreement) because a triggering event (as define above) occurs; or
- if the following events occur:
  - (i) either PDS or Edge terminates the Merger Agreement because the stockholders of Edge did not approve the Stock Issuance Proposal at the Edge stockholders’ meeting as described above under Termination of Merger Agreement, or (ii) PDS terminates the Merger Agreement because Edge has breached any of its representations, warranties, covenants or agreements contained in the Merger Agreement or if any representation or warranty of Edge has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied as of time of such breach or inaccuracy (subject to the cure period described above under Termination of Merger Agreement ); and



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an acquisition proposal with respect to Edge has been publicly announced or disclosed or otherwise communicated to Edge or the Edge Board after the date of the Merger Agreement but prior to the

- termination of the Merger Agreement; and within 12 months after the date of such termination of the Merger Agreement, Edge enters into a definitive agreement for a subsequent transaction (as defined below) in respect of such acquisition proposal.

A subsequent transaction is defined as

any merger, consolidation, amalgamation, share exchange, business combination, issuance of securities, acquisition of securities, reorganization, recapitalization, tender offer, exchange offer or other similar transaction:

- in which a party is constituent entity;
- in which a person or a group (as defined in the Exchange Act and the rules promulgated thereunder) of persons directly or indirectly acquires beneficial or record ownership of securities representing more than 50% of the outstanding securities of any class of voting securities of a party or any of its subsidiaries; or
- in which a party or any of its subsidiaries issues more than 50% of the outstanding securities of any class of voting securities of such party or any of its subsidiaries; or
- any sale, lease, exchange, transfer, license, acquisition or disposition of any business or business or businesses or assets that constitute or account for 50% or more of the consolidated book value or the fair market value of the assets of a party and its subsidiaries taken as a whole.

In addition, if the Merger Agreement is terminated by Edge because (a) Edge has received a superior offer (as defined above), (b) Edge has complied with its obligations under the Merger Agreement in order to accept such superior offer, and (c) Edge concurrently terminates the Merger Agreement and enters into a permitted alternative agreement with respect to such superior offer, then Edge shall pay to PDS a termination fee of \$1.75 million.

**Amendment**

The Merger Agreement may be amended with the approval of the respective board of directors of PDS, Merger Sub and Edge at any time, except that after the Merger Agreement has been adopted and approved by the stockholders of Edge or PDS, no amendment which by law requires further approval by the stockholders of Edge or PDS, as the case may be, shall be made without such further approval.

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**AGREEMENTS RELATED TO THE MERGER**

**Support Agreements and Written Consent**

***PDS***

Certain PDS stockholders are party to a support agreement with Edge, Echos Merger Sub and PDS pursuant to which, among other things, such stockholders agreed, solely in their capacity as a PDS stockholder, to vote all of their shares of PDS common stock in favor of the adoption and approval of the Merger Agreement and the transactions contemplated thereby and to acknowledge that the adoption and approval of the Merger Agreement is irrevocable. In addition, these PDS stockholders agreed not to, directly or indirectly, knowingly take any action that PDS is not permitted to take under the non-solicitation provisions of the Merger Agreement. The parties to these support agreements with Edge, Echos Merger Sub and PDS are:

- Asklepios Capital LLC
- DeLyle Bloomquist
- Frank Bedu-Addo, Ph.D.
- Gregory Conn
- Gregory Freitag
- Ian Postlethwaite
- Indiana 21<sup>st</sup> Century Fund, L.P.
- Michael King
- NetScientific Plc
- Sir Richard Sykes

The PDS stockholders that are party to a support agreement with Edge consist of the holders of a majority of the shares of PDS common stock outstanding on the record date and entitled to vote thereon (voting as a single class).

The holders of a sufficient number of shares of PDS common stock required to approve and adopt the Merger Agreement and approve the merger and related transactions are contractually obligated to approve and adopt the Merger Agreement. Following the effectiveness of the registration statement of which this proxy statement/prospectus/information statement is a part such holders will execute written consents to approve and adopt the Merger Agreement and approve the merger and related transactions.

***Edge***

Certain Edge stockholders are party to a support agreement with Edge, Echos Merger Sub and PDS pursuant to which, among other things, such stockholders agreed, solely in their capacity as a stockholder, to vote all of their shares of Edge common stock in favor of the approval of the issuance of shares of Edge common stock pursuant to the Merger Agreement and the reverse stock split of Edge common stock. In addition, these Edge stockholders agreed not to, directly or indirectly, knowingly take any action that Edge is not permitted to take under the non-solicitation provisions of the Merger Agreement. The parties to these support agreements with Edge, Echos Merger Sub and PDS are:

- Brian A. Leuthner
- Andrew Saik
- Herbert J. Faleck, D.O.
- W. Bradford Middlekauff
- Alyssa J.S. Wyant
- Sol Barer, Ph.D.

- Liam Ratcliffe, M.D., Ph.D.

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- Robert Spiegel, M.D.
- R. Loch Macdonald, M.D., Ph.D.
- Isaac Blech
- Rosemary Crane
- James Loughlin

The stockholders of Edge that are party to a support agreement with Edge, Echos Merger Sub and PDS consist of the holders of an aggregate of 1,822,915 shares of Edge common stock, representing approximately 5.8% of the outstanding shares of Edge common stock as of September 30, 2018. These stockholders are solely comprised of the executive officers and directors of Edge.

**Lock-up Agreements**

*PDS*

As a condition to the closing of the merger, PDS's directors, executive officers and principal stockholders, who will beneficially hold 82% of the combined company's capital stock immediately following the closing of the merger, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for 180 days following the Effective Time, other than in the case of directors or officers who will not continue in such capacity with the combined company, who will be subject to such restrictions for 90 days following the Effective Time.

*Edge*

As a condition to the closing of the merger, Edge's directors and executive officers, who will beneficially hold 5.8% of the combined company's capital stock immediately following the closing of the merger, have entered into lock-up agreements, pursuant to which such parties have agreed not to, except in limited circumstances, transfer, grant an option with respect to, sell, exchange, pledge or otherwise dispose of, or encumber any shares of the combined company's common stock for 180 days following the Effective Time, other than in the case of directors or officers who will not continue in such capacity with the combined company, who will be subject to such restrictions for 90 days following the Effective Time.

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**MATTERS BEING SUBMITTED TO A VOTE OF EDGE STOCKHOLDERS**

**Edge Proposal No. 1 (the Stock Issuance Proposal): Approval of the Issuance of Common Stock in the Merger**

At the Edge special meeting, Edge stockholders will be asked to approve the issuance of shares of Edge common stock pursuant to the Merger Agreement. Immediately following the merger, it is expected that PDS securityholders will own approximately 70% of the outstanding capital stock of the combined company, and the Edge securityholders will own approximately 30% of the outstanding capital stock of the combined company, subject to adjustment as provided in the Merger Agreement.

The terms of, reasons for and other aspects of the Merger Agreement, the issuance of shares of Edge common stock pursuant to the Merger Agreement are described in detail in the other sections in this proxy statement/prospectus/information statement.

***Required Vote; Recommendation of Board of Directors***

Presuming a quorum is present, the affirmative vote of the holders of a majority of the shares of Edge common stock properly cast at the Edge special meeting is required for approval of this proposal.

**THE EDGE BOARD UNANIMOUSLY RECOMMENDS THAT THE EDGE STOCKHOLDERS VOTE FOR THE STOCK ISSUANCE PROPOSAL TO APPROVE THE ISSUANCE OF SHARES OF EDGE COMMON STOCK PURSUANT TO THE MERGER AGREEMENT.**

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### **Edge Proposal No. 2 (the Reverse Stock Split Proposal): Approval of the Amendment to the Certificate of Incorporation of Edge Effecting the Reverse Stock Split at a Ratio in the Range of 5-for-1 to 10-for-1**

#### *General*

At the Edge special meeting, Edge stockholders will be asked to approve the amendment to the certificate of incorporation of Edge effecting a reverse stock split of the issued shares of Edge common stock, at a ratio in the range of 5-for-1 to 10-for-1, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge stockholders, determined solely by the Edge Board following the special meeting. Upon the effectiveness of the amendment to the certificate of incorporation of Edge effecting the reverse stock split, or the split effective time, the issued shares of Edge common stock outstanding immediately prior to the split effective time will be reclassified into a smaller number of shares such that an Edge stockholder will own one new share of Edge common stock for each five to ten shares of issued common stock held by that stockholder immediately prior to the split effective time. The ultimate ratio will be based on a number of factors, including market conditions, existing and expected trading prices for Edge common stock and the listing requirements of the Nasdaq Global Select Market.

If both the Stock Issuance Proposal and the Reverse Stock Split Proposal are approved by the stockholders, the reverse stock split ratio shall be mutually agreed upon by Edge and PDS. In addition, the Edge Board may determine to effect the reverse stock split, if it is approved by the stockholders, even if the Stock Issuance Proposal is not approved, at a range of 5-for-1 to 10-for-1 determined solely by the Edge Board.

The form of the amendment to the certificate of incorporation of Edge to effect the reverse stock split, as more fully described below, will effect the reverse stock split but will not change the number of authorized shares of common stock or preferred stock, or the par value of Edge common stock or preferred stock.

#### *Purpose*

The Edge Board approved the proposal approving the amendment to the certificate of incorporation of Edge effecting the reverse stock split for the following reasons:

- the board of directors believes effecting the reverse stock split may be an effective means of maintaining the listing of the combined company's post-merger common stock on the Nasdaq Capital Market and avoiding a delisting of Edge common stock from the Nasdaq Global Select Market;
- the board of directors believes a higher stock price may help generate investor interest in Edge and help Edge attract and retain employees; and
- if the reverse stock split successfully increases the per share price of Edge common stock, the Edge Board believes this increase may increase trading volume in Edge common stock and facilitate future financings by Edge.

#### *Requirements for Nasdaq Listing*

Edge common stock is listed on the Nasdaq Global Select Market under the symbol EDGE. Edge intends to file an initial listing application under the reverse merger rules with The Nasdaq Stock Market LLC to seek listing on the Nasdaq Capital Market or other appropriate Nasdaq trading market upon the closing of the merger.

According to the applicable rules and regulations of Nasdaq, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-Nasdaq entity, resulting in a change of control of the issuer and potentially allowing the non-Nasdaq entity to obtain a Nasdaq listing. Accordingly, the listing standards of the Nasdaq Capital Market will require Edge to have, among other things, a \$4.00 per share minimum bid price upon the closing of the merger. Although the approval of the stock split is not a closing condition to consummate

the merger, if Edge's stockholders do not approve the Reverse Stock Split Proposal to effect the reverse stock split in connection with the closing of the merger, Edge has been advised that the Nasdaq will commence delisting procedures immediately following the closing of the merger.

If Edge's stockholders do not approve the Reverse Stock Split Proposal, the combined company's board of directors will immediately call for a second special meeting following the closing of the merger and request the stockholders of the combined company to approve a reverse stock split that will allow the combined company to remain in compliance with the listing requirements of The Nasdaq Stock Market LLC. If the Stock Issuance

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Proposal is not approved but the Reverse Stock Approval is approved, the Edge Board may nevertheless authorize a reverse split of its common stock at a ratio in the range of 5-for-1 to 10-for-1 as determined solely by the Edge Board in order to satisfy Edge's continued listing requirements on the Nasdaq Global Select Market.

One of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Edge's management being able to issue more shares without further stockholder approval. For example, before the reverse stock split, Edge's authorized but unissued shares immediately prior to the closing of the merger would be approximately [•] million compared to shares issued of approximately [•] million. If Edge effects the reverse stock split using a 1-for-10 ratio, its authorized but unissued shares immediately prior to the closing of the merger would be approximately [•] million compared to shares issued of approximately [•] million. The reverse stock split will not affect the number of authorized shares of Edge common stock and preferred stock, which will continue to be authorized pursuant to the certificate of incorporation of Edge, thus the reverse stock split will have the effect of increasing the number of authorized but unissued shares of Edge common stock. There are no shares of Edge preferred stock currently outstanding. Edge currently has no plans, commitments, arrangements, understandings or agreements to issue shares, other than pursuant to the Merger Agreement, and to satisfy obligations under the Edge stock options and restricted stock units from time to time as these stock options and restricted stock units, respectively, are exercised. The additional authorized shares of common stock will provide the combined company with the flexibility to consider and respond to future business opportunities and needs as they arise, including but not limited to, equity offerings; financings; potential strategic transactions, including mergers, acquisitions and business combinations; stock dividends; stock splits; grants under equity compensation plans; and other general corporate transactions.

***Potential Increased Investor Interest***

On December [•], 2018, Edge common stock closed at \$[•] per share. An investment in Edge common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, the Edge Board believes that most investment funds are reluctant to invest in lower priced stocks. The Edge Board believes that the anticipated higher market price expected to result from a reverse stock split will reduce, to some extent, the negative effects of the practices of brokerage houses and investors described above on the liquidity and marketability of Edge common stock.

There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of Edge common stock. Edge cannot predict whether the reverse stock split will increase the market price for Edge common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Edge common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of Edge common stock outstanding before the reverse stock split;
- the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks;
- the reverse stock split will result in a per share price that will increase the ability of Edge to attract and retain employees;
- the market price per share will either exceed or remain in excess of the \$1.00 minimum bid price as required by The Nasdaq Stock Market LLC for continued listing, that Edge will otherwise meet the requirements of The Nasdaq Stock Market LLC for inclusion for trading on the Nasdaq Global Select Market, including the \$4.00 minimum bid price upon the closing of the merger, or, if met, that the market price per share would remain above the minimum bid price for a sustained period of time; or



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- Edge would otherwise meet the Nasdaq listing requirements even if the per share market price of Edge common stock after the reverse stock split meets the required minimum bid price.

The market price of Edge common stock will also be based on performance of Edge and other factors, some of which are unrelated to the number of shares outstanding. If the reverse stock split is effected and the market

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price of Edge common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Edge may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Edge common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split.

***Criteria to be Used for Determining Whether to Implement the Reverse Stock Split***

In determining whether to implement the reverse stock split and which reverse stock split ratio to implement, if any, following receipt of stockholder approval of the Reverse Stock Split Proposal, Edge and/or PDS may consider, among other things, various factors, such as:

- the historical trading price and trading volume of Edge common stock;
- the then-prevailing trading price and trading volume of Edge common stock and the expected impact of the reverse stock split on the trading market for Edge common stock in the short- and long-term;
- the ability of Edge to continue its listing on the Nasdaq Global Select Market;
- which reverse stock split ratio would result in the least administrative cost to Edge; and
- prevailing general market and economic conditions.

The failure of Edge stockholders to approve the Reverse Stock Split Proposal could have serious, adverse effects on Edge and its stockholders. Edge could be delisted from the Nasdaq Global Select Market because shares of Edge common stock may continue to trade below the requisite \$1.00 per share bid price needed to maintain its listing. If Nasdaq delists Edge common stock, Edge shares may then trade on the OTC Bulletin Board or other small trading markets, such as the pink sheets. In that event, Edge common stock could trade thinly as a microcap or penny stock, adversely decrease to nominal levels of trading and be avoided by retail and institutional investors, resulting in the impaired liquidity of Edge common stock and making it difficult to raise additional capital if needed.

***Principal Effects of the Reverse Stock Split***

The amendment to the certificate of incorporation of Edge effecting the reverse stock split is set forth in *Annex B* to this proxy statement/prospectus/information statement.

The reverse stock split will be effected simultaneously for all outstanding shares of Edge common stock. The reverse stock split will affect all of the Edge stockholders uniformly and will not affect any stockholder's percentage ownership interests in Edge, except to the extent that the reverse stock split results in any of the Edge stockholders owning a fractional share. The reverse stock split will not change the terms of Edge common stock. After the reverse stock split, the shares of Edge common stock will have the same voting rights and rights to dividends and distributions and will be identical in all other respects to the Edge common stock now authorized, which is not entitled to preemptive or subscription rights, and is not subject to conversion, redemption or sinking fund provisions. Edge common stock issued pursuant to the reverse stock split will remain fully paid and nonassessable. The reverse split does not affect the total proportionate ownership of the combined company following the merger. The reverse stock split will not affect Edge continuing to be subject to the periodic reporting requirements of the Exchange Act.

As an example, the following table illustrates the effects of a 5-for-1 and a 10-for-1 reverse stock split (without giving effect to the treatment of fractional shares):

	<b>Prior to Reverse Stock Split</b>	<b>After 5-for-1 Reverse Stock Split</b>	<b>After 10-for-1 Reverse Stock Split</b>
Common stock outstanding	[•]	[•]	[•]

Common stock issuable pursuant to outstanding equity awards

[•] <sup>(1)</sup>

[•]

[•]

(1) All of such options have an exercise price higher than \$[•] per share, the closing price of Edge common stock on [•], 2018.

In addition, if the proposed reverse stock split is implemented, it will increase the number of Edge stockholders who own odd lots of fewer than 100 shares of common stock. Brokerage commission and other

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costs of transactions in odd lots are generally higher than the costs of transactions of more than 100 shares of common stock. Accordingly, the reverse stock split may not achieve the desired results of increasing marketability and liquidity of Edge common stock that have been described above.

After the effective date of the reverse stock split, Edge common stock would have a new committee on uniform securities identification procedures, or CUSIP number, a number used to identify Edge common stock.

Edge common stock is currently registered under Section 12(b) of the Exchange Act, and Edge is subject to the periodic reporting and other requirements of the Exchange Act. The proposed reverse stock split will not affect the registration of the common stock under the Exchange Act.

### ***Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates***

If the Edge stockholders approve the amendment to the certificate of incorporation of Edge effecting the reverse stock split, and if the Edge Board still believes that a reverse stock split is in the best interests of Edge and its stockholders, Edge will file the amendment to the certificate of incorporation with the Delaware Secretary of State at such time as the Edge Board has determined to be the appropriate split effective time. The Edge Board may delay effecting the reverse stock split without resoliciting stockholder approval. Beginning at the split effective time, each book-entry account representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

***Beneficial Owners of Common Stock.*** Upon the implementation of the reverse stock split, Edge intends to treat shares held by stockholders in street name (i.e., through a bank, broker, custodian or other nominee), in the same manner as registered stockholders whose shares are registered in their names. Banks, brokers, custodians or other nominees will be instructed to effect the reverse stock split for their beneficial holders holding Edge common stock in street name. However, these banks, brokers, custodians or other nominees may have different procedures than registered stockholders for processing the reverse stock split and making payment for fractional shares. If a stockholder holds shares of Edge common stock with a bank, broker, custodian or other nominee and has any questions in this regard, stockholders are encouraged to contact their bank, broker, custodian or other nominee.

***Registered Holders of Common Stock.*** Certain of Edge registered holders of common stock hold some or all of their shares electronically in book-entry form with Edge's transfer agent, Computershare Trust Company, N.A. These stockholders do not hold physical stock certificates evidencing their ownership of Edge common stock. However, they are provided with a statement reflecting the number of shares of Edge common stock registered in their accounts. If a stockholder holds registered shares in book-entry form with Edge's transfer agent, no action needs to be taken to receive post-reverse stock split shares or payment in lieu of fractional shares, if applicable. If a stockholder is entitled to post-reverse stock split shares, a transaction statement will automatically be sent to the stockholder's address of record indicating the number of shares of Edge common stock held following the reverse stock split.

### ***Fractional Shares***

No fractional shares will be issued in connection with the reverse stock split. Stockholders of record who otherwise would be entitled to receive fractional shares because they hold a number of pre-split shares not evenly divisible by the number of pre-split shares for which each post-split share is to be reclassified, will be entitled to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the common stock on the Nasdaq Global Select Market on the first trading day immediately following the split effective time. The ownership of a fractional interest will not give the holder thereof any voting, dividend, or other rights except to receive payment therefor as described herein.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Edge is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the split effective time may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Edge or the transfer agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

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### ***Accounting Consequences***

The par value per share of Edge common stock will remain unchanged at \$0.00033 per share after the reverse stock split. As a result, at the reverse stock split effective time, the stated capital on Edge's balance sheet attributable to Edge common stock will be reduced proportionately based on the reverse stock split ratio, from its present amount, and the additional paid-in capital account will be increased for the amount by which the stated capital is reduced. After the reverse stock split (and disregarding the impact of shares of Edge common stock issued in the merger), net income or loss per share, and other per share amounts will be increased because there will be fewer shares of Edge common stock outstanding. In future financial statements, net income or loss per share and other per share amounts for periods ending before the reverse stock split will be recast to give retroactive effect to the reverse stock split.

### ***Potential Anti-Takeover Effect***

Although the increased proportion of unissued authorized shares to issued shares could, under certain circumstances, have an anti-takeover effect, for example, by permitting issuances that would dilute the stock ownership of a person seeking to effect a change in the composition of the Edge Board or contemplating a tender offer or other transaction for the combination of Edge with another company, the reverse stock split proposal is not being proposed in response to any effort of which Edge is aware to accumulate shares of Edge common stock or obtain control of Edge, other than pursuant to the Merger Agreement, nor is it part of a plan by management to recommend a series of similar amendments to the Edge Board and stockholders. Other than the proposals being submitted to the Edge stockholders for their consideration at the Edge special meeting, the Edge Board does not currently contemplate recommending the adoption of any other actions that could be construed to affect the ability of third parties to take over or change control of Edge. For more information, please see the sections titled "Risk Factors-Risks Related to Edge Common Stock" and "Description of Edge Capital Stock-Anti-Takeover Effects of Provisions of Edge Charter Documents and Delaware Law."

### ***Material U.S. Federal Income Tax Consequences of the Reverse Stock Split***

The following discussion is a summary of material U.S. federal income tax consequences of a reverse stock split to U.S. Holders (as defined below) that hold shares of Edge common stock as capital assets for U.S. federal income tax purposes.

This summary does not address all aspects of U.S. federal income taxation that may be relevant to stockholders in light of their particular circumstances or to stockholders who may be subject to special tax treatment under the Code, including, without limitation dealers or traders in securities, commodities or foreign currency; banks, thrifts, insurance companies, and other financial institutions; traders that mark-to-market their securities; tax-exempt organizations or governmental organizations; small business investment companies; regulated investment companies; real estate investment trusts; tax-deferred or other retirement accounts; persons whose functional currency is not the U.S. dollar; persons who hold Edge common stock as part of a straddle, hedge, conversion transaction or other risk reduction transaction; persons who hold or receive Edge common stock pursuant to the exercise of compensatory stock options, the vesting of previously restricted shares of stock or otherwise as compensation; any entity or arrangement that is a partnership for U.S. federal income tax purposes; companies subject to the stapled stock rules; expatriated entities; certain former citizens or long-term residents of the United States; or persons subject to the alternative minimum tax or the 3.8% tax on net investment income.

This discussion is based on the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the IRS in effect as of the date hereof, all of which are subject to change, possibly with retroactive effect, or differing interpretations. Any such change may cause the U.S. federal income tax consequences of a reverse stock split to vary substantially from the consequences summarized

below. Edge has not sought any ruling from the IRS with respect to the statements made and the conclusions reached in this discussion, and there can be no assurance that the IRS will agree with these statements and conclusions.

The state and local tax consequences of a reverse split may vary as to each U.S. Holder, depending on the jurisdiction in which such U.S. Holder resides. This discussion should not be considered as tax or investment advice, and the tax consequences of a reverse stock split may not be the same for all U.S. Holders. U.S. Holders should consult their own tax advisors to understand their individual federal, state, local and foreign tax consequences to them of the reverse stock split.

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For purposes of this discussion, a U.S. Holder is a beneficial owner of shares of Edge common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or a trust if either a court within the United States is able to exercise primary supervision over the administration of such trust and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of such trust, or the trust has a valid election in effect under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds shares of Edge common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding shares of Edge common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

### *Tax Consequences of the Reverse Stock Split*

The reverse stock split should constitute a recapitalization for U.S. federal income tax purposes under Section 368(a)(1)(E) of the Code. As a result, a U.S. Holder of shares of Edge common stock should not recognize any gain or loss for U.S. federal income tax purposes as a result of a reverse stock split, except to the extent of any cash received in lieu of a fractional share of Edge common stock, as discussed below. A U.S. Holder's aggregate tax basis in shares of common stock received in a reverse stock split should equal the U.S. Holder's aggregate tax basis in the shares of Edge common stock exchanged in the reverse stock split, decreased by the amount of any tax basis allocable to a fractional share for which cash is received. In addition, each U.S. Holder's holding period for the shares of common stock the U.S. Holder receives in a reverse stock split should include the U.S. Holder's holding period for the shares of Edge common stock exchanged in the reverse stock split. U.S. Holders of shares of Edge common stock acquired on different dates and at different prices should consult their own tax advisors regarding the allocation of the tax basis and holding period of such shares.

### *Cash in Lieu of Fractional Shares*

In general, a U.S. Holder of shares of Edge common stock that receives cash in lieu of a fractional share of Edge common stock pursuant to the reverse stock split should recognize capital gain or loss equal to the difference between the amount of cash received and the U.S. Holder's tax basis in the shares of Edge common stock surrendered that is allocated to the fractional share of Edge common stock. Any such capital gain or loss will be treated as long term capital gain or loss if the U.S. Holder's holding period for shares of Edge common stock surrendered exceeded one year as of the effective time of the reverse stock split.

### *Information Reporting and Backup Withholding*

A U.S. Holder of shares of Edge common stock may be subject to information reporting and backup withholding on cash paid in lieu of fractional shares in connection with the reverse stock split, unless the U.S. Holder is an exempt recipient. Backup withholding generally will apply to such payments if the U.S. Holder fails to furnish a correct taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Each U.S. Holder of shares of Edge common stock should properly complete and sign, and deliver, an IRS Form W-9 in order to provide the information and



certification necessary to avoid backup withholding, or otherwise establish an applicable exemption in a manner acceptable to the paying agent. U.S. Holders of shares of Edge common stock should consult their own tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required

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information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

***Required Vote; Recommendation of Board of Directors***

The affirmative vote of the holders of a majority of the shares of Edge common stock outstanding on the record date for the Edge special meeting is required to approve the amendment to the certificate of incorporation of Edge effecting a reverse stock split at a ratio not to exceeding the range 5-for-1 to 10-for-1 of Edge common stock, with such specific ratio to be mutually agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge stockholders, determined solely by the Edge Board following the special meeting.

**THE EDGE BOARD UNANIMOUSLY RECOMMENDS THAT EDGE STOCKHOLDERS VOTE FOR THE REVERSE STOCK SPLIT PROPOSAL TO APPROVE THE AMENDMENT TO THE CERTIFICATE OF INCORPORATION OF EDGE EFFECTING THE REVERSE STOCK SPLIT AT A RATIO IN THE RANGE OF 5-for-1 to 10-for-1, with such specific ratio to be MUTALLY agreed upon by Edge and PDS or, if the Stock Issuance Proposal is not approved by Edge stockholders, determined SOLELY by the Edge Board following the special meeting.**

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**Edge Proposal No. 3 (the Equity Incentive Plan Proposal): Approval of the Amended and Restated Edge Therapeutics, Inc. 2014 Equity Incentive Plan**

*General*

On [ ], the Edge Board adopted, and recommended that the stockholders approve, the Amended and Restated Edge Therapeutics, Inc. 2014 Equity Incentive Plan, or the Restated Plan, the form of which is attached as *Annex C* to this proxy statement/prospectus/information statement, which amends and restates in its entirety the version of the plan currently in effect, or the Current Plan, which was adopted by the Edge Board and Edge s stockholders prior to Edge s initial public offering in September of 2014. If approved the Restated Plan will be effective upon the Effective Time. If the Stock Issuance Proposal is not approved, then this Equity Incentive Plan Proposal shall be withdrawn.

As of December 31, 2018, the Current Plan authorizes the issuance of 5,438,831 shares of Edge s stock, which is increased on each January 1<sup>st</sup> by the lesser of 4% of the number of shares of stock outstanding as of the immediately preceding December 31<sup>st</sup> or such lesser number of shares determined by the combined company s board of directors. Of this amount, a total of 226,243 shares have been issued as of December 31, 2018 and awards covering a total of 5,134,104 shares are subject to awards that are outstanding as of December 31, 2018, as of such date. As of December 31, 2018, there were a total of 31,449,989 shares of Edge s stock outstanding and an additional 7,747,960 shares of Edge s stock covered by outstanding options and restricted stock units, or Edge RSUs under all of Edge s equity plans and other agreements. No other types of awards are outstanding. If the maximum 4% evergreen increase is applied on January 1, 2019, the equity pool under the Current Plan will increase to approximately 26% of Edge s fully diluted shares as of December 31, 2018. In determining the number of Edge s fully diluted shares for this purpose, because the weighted average exercise price of Edge s outstanding options as of December 31, 2018 was \$6.18 (which is above the closing price of our common stock on [ ], 2018), Edge does not include [any] of Edge s options in this calculation but Edge does include all of Edge s outstanding Edge RSUs.

In connection with the Merger, Edge will be issuing new shares of Edge common stock to the stockholders of PDS and will be converting options to purchase shares of PDS common stock into options to purchase shares of common stock of the combined company, in each case, based on the exchange ratio determined under the Merger Agreement. It is expected that upon the closing of the Merger, there will be between [ ] and [ ] shares of Edge s stock outstanding and between an additional [ ] and [ ] shares covered by outstanding options. There are not expected to be any outstanding Edge RSUs upon closing of the Merger (Edge RSUs will be converted into shares of Edge common stock and are reflected in the figures in the immediately preceding sentence). As a result of the Merger, the percentage of shares remaining available for issuance under the Current Plan in relation to the number of Edge s Fully Diluted Shares upon the closing of the Merger would decrease to between approximately [ ]% and approximately [ ]% (even after factoring in the 4% evergreen increase on January 1, 2019). For this purpose, Fully Diluted Shares means [ ].

In order to be able to attract and retain employees, directors and consultants, it is essential that Edge is able to continue to offer a competitive equity compensation program. Contingent on the consummation of the Merger and on stockholder approval, the Edge Board has approved the Restated Plan, which authorizes the issuance of a number of shares equal to [ ]% of [ ]. The number of shares authorized for issuance under the Restated Plan upon the closing of the Merger is expected to be between [ ] and [ ] shares, but the exact number will not be known until the Merger is completed. Shares issued pursuant to awards granted under the Current Plan will be counted against the share limit in the Restated Plan.

The Restated Plan is identical to the Current Plan in all material respects, except as follows:

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Share Reserve: As described above, if this Equity Incentive Plan Proposal is approved by Edge's stockholders, the number of shares of stock authorized for awards under the Restated Plan will equal [\_\_\_\_]% of [\_\_\_\_\_]. Shares underlying any portion of an award granted under the Current Plan or the Restated Plan that is forfeited without the issuance of shares will be added back to the number of shares available for issuance under the Restated Plan, as described below in Summary of the Restated Plan – Shares of Stock Available for Awards (this concept is in Edge's Current Plan). All awards granted under the Current Plan will be deemed to have been granted under the Restated Plan and shares issued with respect to such awards will reduce the number of shares available for issuance under the Restated Plan.

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- Evergreen Provision: The Restated Plan does not include an evergreen provision that automatically increases the number of shares available for issuance pursuant to awards.
- Term: Unless terminated earlier, the Restated Plan will terminate on [ ] (the Current Plan was scheduled to terminate on August 27, 2024).
- Performance Goals: The Restated Plan retains the concept of performance goals, but revises certain language in the Current Plan regarding performance goals to account for changes in the tax law that have removed the exception under Section 162(m) of the Code that permitted Edge to deduct compensation paid to Edge’s named executive officers in excess of \$1 million if such compensation was performance-based.
- Incentive Stock Options, or ISOs: The Restated Plan increases the number of shares that may be issued upon the exercise of incentive stock options (within the meaning of Section 422 of the Code) from 2,000,000, to [\_\_\_\_\_].
- Individual Limit: The Restated Plan does not contain an annual limit on the number of shares that may be issued to an individual during any calendar year (the Current Plan includes an annual individual limit of 1,250,000 shares) as this limit was to allow us to issue awards under the exception under Section 162(m) of the Code that permitted us to deduct compensation paid to our named executive officers in excess of \$1 million if such compensation was performance-based.
- Non-Employee Director Limit: Under the Restated Plan, no non-employee director may be granted awards covering more than [\_\_\_\_\_] shares in any one calendar year.
- Non-Employee Directors of Subsidiaries: Non-employee directors of subsidiaries of Edge will be eligible to receive awards under the Restated Plan.

***Basis for Board of Directors Adoption of the Restated Plan***

Prior to adopting the Restated Plan, the Edge Board and the compensation committee of the Edge Board, or the Compensation Committee, considered the various aspects of the Restated Plan, including the number of shares authorized under the Restated Plan, the cost of issuing additional shares, the impact of share dilution on Edge’s existing stockholders and the central role of equity-based incentive compensation in the combined company’s executive compensation program. The Edge Board’s purposes in adopting the Restated Plan are to ensure the longevity, effectiveness and administrative flexibility of the long-term equity incentive component of the combined company’s executive compensation program and to update the terms of Edge’s equity program to reflect recent changes in the tax law that have eliminated the exception under Section 162(m) of the Code that permitted publicly-listed companies to deduct compensation paid to their named executive officers in excess of \$1 million if such compensation was performance based. The Edge Board and the Compensation Committee believe that it is essential to increase the number of shares Edge may issue under Edge’s equity compensation program following the closing of the Merger to reflect Edge’s expected new capitalization. If the Restated Plan is not approved by stockholders, the combined company will not have the flexibility to grant equity-based incentive compensation at levels that the Edge Board and the Compensation Committee believe to be critical to attracting, retaining and motivating the company’s service providers and to reward them for their contributions to the success of the combined company and the growth in value of its stock.

Based on the foregoing considerations, the Edge Board and the Compensation Committee concluded that it is in the best interests of the company and its stockholders for its stockholders to approve the Restated Plan. The Edge Board and the Compensation Committee determined that the costs to Edge’s stockholders of approving the Restated Plan would be outweighed by the benefits to be achieved by appropriately compensated and motivated employees, directors and consultants. If the Restated Plan is approved, the board of directors of the combined company and its compensation committee will continue to monitor and evaluate the benefits and risks to the company and its stockholders in granting the shares available for issuance under the Restated Plan.

TABLE OF CONTENTS**Outstanding Awards; Burn Rate**

The following table sets forth information regarding outstanding equity awards as of December 31, 2018 (and excludes awards that may be settled only in cash).

Unvested Shares of Restricted Stock Units ( Edge RSUs )	Weighted Average Remaining Vesting Period for Edge RSUs (Years) <sup>(1)</sup>	Vested but not Settled Edge RSUs	Outstanding Options	Weighted Average Exercise Price of Outstanding Options	Weighted Average Remaining Contractual Term of Outstanding Options (Years)
509,962	0.2	0	7,147,916	\$ 6.18	5.9

(1) All of these Edge RSUs will be settled for an equivalent number of shares of Edge's stock upon the closing of the Merger to the extent then outstanding.

The following table sets forth information regarding awards granted under the Current Plan during 2016, 2017 and 2018 (through December 31, 2018), the burn rate for each such year and the average burn rate over such period, in each case, for stock-settled awards. A company's burn rate is a measure of the speed at which the company uses shares available for grant under the company's equity compensation plans, and shows the potential dilutive effect of equity grants on the company's outstanding equity over the course of a year.

Year	Time-Based Edge RSUs Granted	Options Granted	All Other Awards Granted (excluding Options and Time-Based Edge RSUs)	Total Awards Granted	Weighted Average Number of Shares of Common Stock Outstanding	Burn Rate <sup>(1)</sup>
2018	601,394	2,322,906	—	2,924,300	31,239,075	9 %
2017	—	1,365,400	—	1,365,400	30,393,952	4 %
2016	—	1,211,400	—	1,211,400	28,864,216	4 %
3-Year Average	200,465	1,633,235	—	1,833,700	30,165,748	6 %

The burn rate is calculated as all time-based Edge RSUs and all option awards granted in a year, divided by the (1) weighted average number of shares of Edge common stock outstanding. All award types are counted on a one-for-one basis and cash settled awards are excluded.

**Best Practices**

The Restated Plan includes a number of features that will reinforce the alignment between the interests of participants in the Restated Plan and those of the combined company's stockholders. These provisions include, but are not limited to, the following:

*No Discounted Options or SARs.* Stock options and SARs may not be granted with exercise prices lower than the fair market value of the underlying shares on the grant date.

*No Repricing, Replacement or Buy Back without Stockholder Approval.* Edge may not reprice, replace or buy back any underwater stock option or SAR without stockholder approval.

*No Evergreen Provision.* Unlike the Current Plan, the Restated Plan does not contain an evergreen feature that automatically increases the number of shares available for issuance pursuant to awards. Therefore, Edge must obtain stockholder approval each time it desires to authorize additional shares for awards.

*No Liberal Share Recycling.* Any shares tendered in payment of an exercise price or the tax liability with respect to an award, including shares withheld from any such award, will not be available for future awards under the Restated Plan.

*Non-Employee Director Limit.* In the Restated Plan, no non-employee director may be granted awards covering more than [\_\_\_\_\_] shares in any one calendar year.

*Recoupment.* Awards granted under the Restated Plan (and all shares acquired thereunder) are subject to mandatory repayment and clawback pursuant to the terms of Edge's corporate governance guidelines, and as may otherwise be required under any federal or state laws or the listing requirements of any applicable securities exchange.

*No Transferability.* No Award may be transferred, assigned, pledged or encumbered by a participant except pursuant to the laws of descent and distribution or as approved by the Compensation Committee for estate planning or charitable purposes.

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*No Automatic Grants.* The Restated Plan does not provide for reload or other automatic grants to participants.

*No Tax Gross-Ups.* The Restated Plan does not provide for any tax gross-ups to participants.

### ***Summary of Restated Plan***

A summary of the Restated Plan is provided below. This summary is qualified in its entirety by the full text of the Restated Plan, a copy of which is attached to this Proxy Statement as *Annex C*. In the event of any inconsistency between this summary and the Restated Plan, the Restated Plan will control.

### ***General***

Under the Restated Plan, Edge may grant awards, or Awards, with respect to its common stock to employees and consultants of the combined company and its subsidiaries, as well as non-employee members of any board of directors or board of managers of the combined company or of its subsidiaries. Awards may consist of restricted stock, restricted stock units, or Edge RSUs, stock options, stock appreciation rights, or SARs, and other stock-based awards. Each Award will be governed by the provisions of the Restated Plan and the applicable Award agreement. The Restated Plan is not qualified under Section 401(a) of the Code and is not subject to the Employee Retirement Income Security Act of 1974, as amended. The Restated Plan will become effective upon the closing of the Merger, subject to its approval by Edge's stockholders.

### ***Purpose***

The general purpose of the Restated Plan is to provide an effective method of compensating employees and consultants and non-employee directors of the combined company and its subsidiaries and non-employee directors of the board of directors of the combined company, and to align the interests of these individuals with those of the company's stockholders. The Restated Plan will accomplish these goals by allowing eligible employees, consultants and directors of the combined company and its subsidiaries to receive Awards.

### ***Administration***

The Restated Plan is administered by Edge's Compensation Committee, which has the power to: (i) select the employees, consultants and non-employee directors who will receive Awards pursuant to the Restated Plan; (ii) determine the type or types of Awards to be granted to each participant; (iii) determine the number of shares of common stock to which an Award will relate, the terms and conditions of any Award granted under the Restated Plan, and all other matters to be determined in connection with an Award; (iv) determine the exercise price or purchase price (if any) of an Award; (v) determine whether, to what extent, and under what circumstances an Award may be cancelled, forfeited, or surrendered; (vi) determine whether, and to certify that, performance goals to which an Award is subject are satisfied; (vii) correct any defect or supply any omission or reconcile any inconsistency in the Restated Plan, and adopt, amend and rescind such rules, regulations, guidelines, forms of agreements and instruments relating to the Restated Plan as it may deem necessary or advisable; and (viii) construe and interpret the Restated Plan and make all other determinations as it may deem necessary or advisable for the administration of the Restated Plan. The Compensation Committee may delegate some or all of its powers to any of Edge's executive officers or any other person, other than its authority to grant Awards to certain individuals (such as board members and executive officers).

### ***Eligibility***

All of Edge's employees and consultants, all employees and consultants of Edge's subsidiaries, and all non-employee members of Edge's board of directors are eligible to receive Awards under the Restated Plan.



***Shares Available Under the Restated Plan***

Initially, Edge reserved an aggregate of 1,827,351 shares of Edge's common stock for issuance pursuant to the Current Plan. The number of shares available for issuance under the Current Plan was increased by 67,538, 1,152,433, 1,156,740, and 1,234,768 on each of January 1, 2015, January 1, 2016, January 1, 2017 and January 1, 2018 and is expected to be increased by [ ] shares on January 1, 2019. If this Equity Incentive Plan Proposal is approved by Edge's stockholders, the number of shares that will be available for grant pursuant

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to Awards under the Restated Plan will be [\_\_\_]% of [\_\_\_\_\_]. In addition, to the extent that awards granted under the 2010 Plan or the 2012 Plan are forfeited, terminate or are settled for any reason without an actual distribution of shares, the number of shares available for issuance under the Restated Plan will be increased by the number of shares underlying the portion of any such award that was so forfeited, terminated or settled. In addition, all awards granted under the Current Plan that are outstanding immediately following the Merger will be treated as if they were granted under the Restated Plan, and all shares issued in respect of such awards will reduce the number of shares available for issuance under the Restated Plan. If any shares subject to an Award granted under the Restated Plan or an award granted under the Current Plan are forfeited or such Award or award otherwise terminates or is settled for any reason without an actual distribution of shares to the participant, the shares subject to the portion of the Award or award that was forfeited, settled, or terminated will again be available for Awards under the Restated Plan.

Any shares tendered by a participant in payment of an exercise price for an Award or an award granted under the Current Plan or the tax liability with respect to an Award or an award granted under the Current Plan, including shares withheld from any such Award or award, will not be available for future Awards hereunder. Common stock awarded under the Restated Plan may be reserved or made available from Edge's authorized and unissued common stock or from common stock reacquired and held in Edge's treasury. Any shares of common stock issued by Edge through the assumption or substitution of outstanding grants from an acquired company shall not reduce the shares of common stock available for Awards under the Restated Plan.

The maximum number of shares that may be granted through the exercise of incentive stock options is [\_\_\_\_\_] shares. No non-employee director may be granted awards covering more than [\_\_\_\_\_] shares in any one calendar year.

***Awards — Generally***

Awards may be granted on the terms and conditions described below. In addition, the Compensation Committee may impose on any Award or the settlement or exercise thereof, at the date of grant or thereafter, such additional terms and conditions, not inconsistent with the provisions of the Restated Plan, as the Compensation Committee may determine, including without limitation terms requiring forfeiture of Awards in the event of the termination of service of the participant. The right of a participant to exercise or receive a grant or settlement of any Award, and the timing thereof, may be subject to such performance goals as may be determined by the Compensation Committee. Each Award will be evidenced by an Award agreement that will include additional terms and conditions that may be applicable to such Award.

***Awards — Performance Goals***

In the discretion of the Compensation Committee, any Award may be granted subject to performance goals that must be met by the end of a certain specified performance period. If the Compensation Committee determines that a change in the business, operations, corporate structure or capital structure of the company or any of its subsidiaries, or the manner in which the company or any subsidiary conducts its business, or other events or circumstances render any performance goals unsuitable, the Compensation Committee may modify such performance goal or the related minimum, target, maximum or other levels of achievement as it deems appropriate and equitable.

***Awards — Types of Awards***

***Restricted Stock.*** In a restricted stock award, a participant receives a grant of shares of common stock that are subject to certain restrictions, including forfeiture of such stock upon the happening of certain events. Unless otherwise provided in an award agreement, during the restriction period, holders of restricted stock will have all the rights of a stockholder with respect to the restricted stock, including, without limitation, the right to receive dividends (whether in cash or additional shares of common stock) and to vote shares of restricted stock, provided that any

dividends declared on restricted stock shall be subject to the same restrictions as the underlying restricted stock and any cash dividends shall be held by Edge and released to the participant upon the vesting of the underlying restricted stock.

*Restricted Stock Units.* An Edge RSU is a grant of the right to receive a payment in Edge's common stock or cash, or in a combination thereof, equal to the fair market value of a share of Edge's common stock on the expiration of the applicable restriction period or periods. During such period or periods, the participant will

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generally have no rights as a stockholder with respect to any such shares. However, the Compensation Committee may provide in an Award that amounts equal to any dividends declared during the restriction period will be credited to the participant's account and deemed to be reinvested in additional Edge RSUs that will be subject to the same forfeiture restriction as the Edge RSUs to which the dividend equivalent payment relates.

*Stock Options.* Stock options granted under the Restated Plan may be either ISOs or non-qualified options. The exercise price of an option shall be determined by the Compensation Committee, but must be at least 100% of the fair market value of Edge's common stock on the date of the grant. If the participant owns, directly or indirectly, shares constituting more than 10% of the total combined voting power of all classes of Edge's stock or the stock of any subsidiary, the exercise price of an incentive stock option must be at least 110% of the fair market value of a share of common stock on the date the incentive stock option is granted. Each Award of an option shall specify the time or times at which the option may be exercised and any terms and conditions applicable to the option, including (i) a vesting schedule which may be based upon the passage of time, attainment of performance goals, or a combination thereof, (ii) whether the exercise price for an option shall be paid in cash, with shares of common stock, with a combination of cash and shares of common stock, or with other legal consideration, (iii) the methods of payment, which may include payment through cashless and net exercise arrangements, to the extent permitted by applicable law and (iv) the methods by which, and/or the time at which, common stock will be delivered or deemed to be delivered to a participant upon exercise of an option. The term of an option may not exceed ten years from the date of grant (or five years from the date of grant in the case of an incentive stock option granted to a participant who owns, directly or indirectly, shares constituting more than 10% of the total combined voting power of all classes of Edge's stock or the stock of any subsidiary).

*Stock Appreciation Rights.* A grant of a SAR entitles the holder to receive, upon exercise of the SAR, the excess of the fair market value of one share of Edge's common stock on the date of exercise over the grant price of the SAR as determined by the Compensation Committee. SARs will be settled either in cash, shares of common stock, or a combination of the foregoing. The grant price of a SAR may never be less than 100% of the fair market value of a share of common stock on the date of grant. The term of an SAR shall be no greater than ten years from the date of grant.

*Other Stock-Based Awards.* The Compensation Committee is authorized, subject to limitations under applicable law, to grant participants any type of Award that is payable in, or valued in whole or in part by reference to shares of Edge's common stock, and that is deemed by the Compensation Committee to be consistent with the purposes of the Restated Plan, including, without limitation, dividend equivalents, performance shares and performance units.

***Change in Control and other Corporate Transactions***

With respect to SARs and options outstanding on a change of control, the Compensation Committee in its discretion generally may (a) cancel any outstanding options or SARs in exchange for a cash payment in an amount equal to the excess, if any, of the fair market value of the common stock underlying the unexercised portion of the option or SAR as of the date of the change in control over the exercise price or grant price; (b) terminate any option or SAR, effective immediately prior to the change in control, provided that the participant has an opportunity to exercise his or her Award within a specified period following a written notice of the change in control; (c) terminate any options or SARs if the applicable performance goals were not satisfied as of the change in control; (d) require the successor or acquiring company (or its parents or subsidiaries) to assume any outstanding option or SAR or to substitute options or SARs with Awards involving the common equity securities of an acquirer or successor on terms and conditions necessary to preserve the rights of participants, or (e) take such other actions as the Compensation Committee believes may be appropriate. With respect to Edge RSUs or other Awards, the Compensation Committee generally may (a) provide in an Award agreement that, upon the occurrence of a change in control, any vested Edge RSUs and other Awards shall become immediately vested and/or payable, provided that if such Awards constitute non-qualified

deferred compensation (within the meaning of Code Section 409A) such change in control satisfies the requirements of Treasury Regulation Section 1.409A-3(i)(5)(v), (vi) or (vii); (b) with respect to any Edge RSUs or other Awards that do not constitute non-qualified deferred compensation, elect to settle such Edge RSUs and other Awards upon a change in control, (c) terminate any Edge RSUs or other Awards if the applicable performance goals were not satisfied as of the change in control, (d) require the successor or acquiring company (or its parents or subsidiaries), following a change in control, to assume such Edge RSUs and other Awards or to substitute such

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Awards with Awards involving the equity securities of the acquiring or successor company on terms and conditions so as to preserve the rights of participants, or (e) take such other actions as the Compensation Committee believes may be appropriate (including terminating such Awards for a cash payment equal to the fair market value of the underlying shares).

### *Certain Corporate Transactions*

In order to prevent dilution or enlargement of the rights of participants under the Restated Plan as a result of any stock dividend, recapitalization, forward stock split or reverse stock split, reorganization, division, merger, consolidation, spin-off, combination, repurchase or share exchange, extraordinary or unusual cash distribution or other similar corporate transaction or event that affects Edge's common stock, the Compensation Committee shall adjust (i) the number and kind of shares of common stock which may be issued in connection with Awards to participants, (ii) the number and kind of shares of stock issuable in respect of outstanding Awards, (iii) the aggregate number and kind of shares of common stock available under the Restated Plan, and (iv) the exercise or grant price relating to any Award. In addition, the Compensation Committee is authorized to make adjustments in the terms and conditions of, and the criteria included in, Awards, including any performance goals, in recognition of unusual or nonrecurring events (including, without limitation, events described above) affecting Edge or any subsidiary, or in response to changes in applicable laws, regulations, or accounting principles.

### *Termination of Employment or Other Service*

Unless otherwise provided in an Award agreement, upon a participant's termination of employment or other service with Edge, the unvested portion of such participant's Awards shall cease to vest and shall be forfeited and the vested portion of such participant's options and SARs shall remain exercisable by the participant or the participant's beneficiary or legal representative, as the case may be, for a period of (i) 30 days in the event of a termination by Edge or a subsidiary without cause, (ii) 180 days in the event of a termination due to death or disability and (iii) 30 days in the event of the participant's voluntary termination, but in all cases, not beyond the normal expiration date of the option or SAR. All of a participant's options and SARs, whether or not vested, shall be forfeited immediately upon such participant's termination by Edge or a subsidiary for cause.

### *Amendment and Termination*

The Restated Plan will automatically terminate on [        ]. In addition, prior to the automatic termination of the Restated Plan, the combined company's board of directors may amend, alter, suspend, discontinue, or terminate the Restated Plan without the consent of stockholders, except that any such action shall be subject to the approval of Edge's stockholders if such action would increase the number of shares subject to the Restated Plan or decrease the price at which Awards may be granted, or if stockholder approval with respect to such action is required by any applicable law or regulation or the rules of any stock exchange on which Edge's common stock may then be listed or quoted. The combined company's board of directors must also obtain stockholder approval in order to take any action that would result in the repricing, replacement or repurchase of any option, SAR or other Award. The combined company's board of directors may otherwise determine to submit such other changes to the Restated Plan for approval by Edge's stockholders in its discretion. Generally, without the consent of an affected participant, no amendment, alteration, suspension, discontinuation, or termination of the Restated Plan may materially and adversely affect the rights of such participant under any outstanding Award.

### *Recoupment*

Any Award granted under the Restated Plan will be subject to mandatory repayment by the participant to Edge pursuant to the terms of any company's clawback or recoupment policy that is directly applicable to the Restated Plan

and set forth in an Award agreement or as required by law.

***Transfer Restrictions***

The Restated Plan prohibits participants from pledging, encumbering, assigning or transferring any Award, right or interest under the Restated Plan, except for assignments or transfers that occur by way of the laws of descent and distribution. Awards and rights under the Restated Plan will be exercisable during the life of a participant only by the participant or his legal guardian. However, the Compensation Committee, may in its discretion, permit transfers of options, SARs and/or restricted stock to certain immediate family members of the participant, to trusts for the benefits of such family members and to partnerships in which such family members are the only partners.

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### *Foreign Nationals*

Without amending the Restated Plan, Awards may be granted to participants who are foreign nationals or are employed or providing services outside the United States or both, on such terms and conditions different from those specified in the Restated Plan as may, in the judgment of the Compensation Committee, be necessary or desirable to further the purpose of the Restated Plan. Moreover, the Compensation Committee may approve such supplements to, or amendments, restatements or alternative versions of, the Restated Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of the Restated Plan as in effect for any other purpose.

### *New Plan Benefits*

Because grants of awards will be made from time to time by the Compensation Committee to those persons whom the Compensation Committee determines in its discretion should receive grants of Awards, the benefits and amounts that may be received in the future by persons eligible to participate in the Restated Plan are not presently determinable. In connection with Lauren Wood's being hired as PDS's Chief Medical Officer, Ms. Wood's offer letter provided that she would receive a grant of options with respect to PDS's common stock. This grant has not yet been made. It is anticipated that this grant of options will be made under the Restated Plan on or after the Merger. It is anticipated that this grant of options to Ms. Wood will cover [\_\_\_] shares of the combined company's common stock.

### *Summary of U.S. Federal Income Tax Consequences*

The following discussion is a summary of certain U.S. federal income tax considerations that may be relevant to participants in the Restated Plan. This discussion is for general informational purposes only and does not purport to address specific federal income tax considerations that might apply to a participant based on his or her particular circumstances, nor does it address state, local or foreign income tax or other tax considerations that may be relevant to a participant.

**PARTICIPANTS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE PARTICULAR FEDERAL INCOME TAX CONSEQUENCES APPLICABLE TO THEM AS A RESULT OF PARTICIPATING IN THE RESTATED PLAN, AS WELL AS WITH RESPECT TO ANY APPLICABLE STATE, LOCAL OR FOREIGN INCOME TAX OR OTHER TAX CONSIDERATIONS.**

*Incentive Stock Options.* Upon the grant of an ISO, the option holder will not recognize any income. In addition, no income for federal income tax purposes will be recognized by an option holder upon the exercise of an ISO if the requirements of the Restated Plan and the Code are satisfied, including, without limitation, the requirement that the option holder remain employed by the combined company or a subsidiary during the period beginning on the date of grant and ending on the day three months (or, in the case of the option holder's disability, one year) before the date the option is exercised. If an option holder has not remained an employee of the combined company or a subsidiary during the period beginning on the date of grant of an ISO and ending on the day three months (or one year in the case of the option holder's disability) before the date the option is exercised, the exercise of such option will be treated as the exercise of a non-qualified option and will have the tax consequences described below in the section entitled Non-Qualified Options.

The federal income tax consequences upon a disposition of the shares acquired pursuant to the exercise of an ISO depends upon when the disposition of the shares occurs and the type of such disposition.

- If the disposition of such shares occurs more than two years after the date of grant of the ISO and more than one year after the date of exercise, any gain or loss recognized upon such disposition will be long-term capital gain or loss and the combined company or a subsidiary, as applicable, will not be entitled to any



income tax deduction with respect to such ISO.

If the disposition of such shares occurs within two years after the date of grant of the incentive stock option or within one year after the date of exercise, or a disqualifying disposition, the excess, if any, of the amount recognized over the option price will be treated as taxable income to the participant and, subject to Section

- 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a deduction equal to the amount of ordinary income recognized by the option holder. The amount of ordinary income recognized by the option holder in a disqualifying disposition (and the corresponding deduction to the combined company or a subsidiary, as applicable) is limited to the lesser of the gain

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on such sale and the difference between the fair market value of the shares on the date of exercise and the option price. Any gain recognized in excess of this amount will be treated as short-term or long-term capital gain (depending upon whether the shares have been held for more than one year). If the option price exceeds the amount recognized upon such a disposition, the difference will be short-term or long-term capital loss (depending upon whether the shares have been held for more than one year).

If a participant is subject to the Alternative Minimum Tax, or the AMT, the tax consequences to the participant may differ from those described above. Under the AMT, a taxpayer will be required to pay an alternative minimum tax if the taxpayer's tentative minimum tax (as defined in Section 55 of the Code) exceeds his or her regular tax for the year in question. For purposes of calculating the AMT, upon the exercise of an ISO, a taxpayer is required to include in his alternative minimum taxable income (as defined in Section 55 of the Code) for the taxable year in which such exercise occurs an amount equal to the amount of income the taxpayer would have recognized if the option had not been an ISO (i.e., the difference between the fair market value of the shares on the date of exercise and the option's exercise price). As a result, unless the shares acquired upon the exercise of the ISO are disposed of in a taxable transaction in the same year in which such option is exercised, the option holder may incur AMT as a result of the exercise of an ISO.

Except as provided in the paragraph immediately below, if an option holder elects to tender shares in partial or full payment of the option price for shares to be acquired upon the exercise of an ISO, the option holder will not recognize any gain or loss on such tendered shares. No income will be recognized by the option holder with respect to the shares received by the option holder upon the exercise of the ISO if the requirements of the Restated Plan and the Code described above are met. The number of shares received equal to the number of shares surrendered will have a tax basis equal to the tax basis of the surrendered shares. Shares received in excess of the number of shares surrendered will have a tax basis of zero. The holding period of the shares received equal to the number of shares tendered will be the same as such tendered shares' holding period, and the holding period for the excess shares received will begin on the date of exercise. Solely for purposes of determining whether a disqualifying disposition has occurred with respect to shares received upon exercise of the ISO, all shares are deemed to have a holding period beginning on the date of exercise.

If an option holder tenders shares that were previously acquired upon the exercise of an ISO in partial or full payment of the option price for shares to be acquired upon the exercise of another ISO, and each such exercise occurs within two years after the date of grant of such ISO or within one year after such shares were transferred to the option holder, the tender of such shares will be a disqualifying disposition with the tax consequences described above regarding disqualifying dispositions. The shares acquired upon such exercise will be treated as shares acquired upon the exercise of an ISO.

If the holding rules described above are not satisfied, gain recognized on the disposition of the shares acquired upon the exercise of an ISO will be characterized as ordinary income, and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction. The amount of such gain will be equal to the difference between the exercise price and the fair market value of the shares at the time of exercise. Special rules may apply to disqualifying dispositions where the amount recognized is less than the value at exercise. Any excess of the amount recognized upon such disposition over the fair market value at exercise will generally be long-term or short-term capital gain depending on the holding period involved. Notwithstanding the foregoing, in the event that the exercise of the option is permitted other than by cash payment of the exercise price, various special tax rules may apply.

*Non-Qualified Options.* An option holder will not recognize taxable income, and the combined company or a subsidiary, as applicable, is not entitled to a deduction, when a non-qualified option is granted. Upon the exercise of a non-qualified option, an option holder will recognize compensation taxable as ordinary income equal to the excess of

the fair market value of the shares received over the option price of the non-qualified option and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction. An option holder's tax basis in the shares received upon the exercise of a non-qualified option will be equal to the fair market value of such shares on the exercise date, and the option holder's holding period for such shares will begin at that time. Upon the subsequent sale of the shares received

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in exercise of a non-qualified option, the option holder will recognize short-term or long-term capital gain or loss, depending upon whether the shares have been held for more than one year. The amount of such gain or loss will be equal to the difference between the amount recognized in connection with the sale of the shares and the option holder's tax basis in such shares.

If a non-qualified option is exercised in whole or in part with shares held by the option holder, the option holder will not recognize any gain or loss on such tendered shares. The number of shares received by the option holder upon such an exchange that are equal in number to the number of tendered shares will retain the tax basis and the holding period of the tendered shares for capital gain purposes. The shares received by the option holder in excess of the number of shares used to pay the exercise price of the option will have a basis equal to the fair market value on the date of exercise and their holding period will begin on such date.

*Restricted Stock.* Upon the grant of an award of restricted stock, the shares are considered to be subject to a substantial risk of forfeiture for federal income tax purposes. If a participant who receives restricted stock does not make the election described below, the participant does not recognize any taxable income upon the receipt of restricted stock and the combined company or a subsidiary, as applicable, is not entitled to a deduction at such time. When the forfeiture restrictions with respect to the restricted stock lapse, the participant will recognize compensation taxable as ordinary income equal to the fair market value of the shares at that time, less any amount paid for the shares and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction. A participant's tax basis in restricted stock will be equal to the fair market value of such restricted stock when the forfeiture restrictions lapse, and the participant's holding period for the shares will begin on such date. Upon a subsequent sale of the shares, the participant will recognize short-term or long-term capital gain or loss, depending upon whether the shares have been held for more than one year at the time of sale. Such gain or loss will be equal to the difference between the amount recognized upon the sale of the shares and the tax basis of the shares in the participant's hands.

Participants receiving restricted stock may make an election under Section 83(b) of the Code to recognize compensation taxable as ordinary income with respect to the shares when such shares are received rather than at the time the forfeiture restrictions lapse. If the participant makes such an election, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction in the year of grant. The amount of such compensation income (and the corresponding deduction) will be equal to the fair market value of the shares when the participant receives them (valued without taking into account restrictions other than restrictions that by their terms will never lapse), less any amount paid for the shares. By making a Section 83(b) election, the participant will recognize no additional ordinary compensation income with respect to the shares when the forfeiture restrictions lapse, and will instead recognize short-term or long-term capital gain or loss with respect to the shares when they are sold, depending upon whether the shares have been held for more than one year at the time of sale. The participant's tax basis in the shares with respect to which a Section 83(b) election is made will be equal to their fair market value when received by the participant, and the participant's holding period for such shares will begin at that time. If the shares are subsequently forfeited, the participant will not be entitled to a deduction as a result of such forfeiture, but will be entitled to claim a short-term or long-term capital loss (depending upon whether the shares have been held for more than one year at the time of forfeiture) with respect to the shares to the extent of the consideration paid by the participant for such shares.

Generally, during the restriction period, dividends and distributions paid with respect to restricted stock will be treated as compensation taxable as ordinary income (not dividend income) received by the participant, and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries, as applicable, will receive a corresponding deduction. Dividend payments received with respect to shares of restricted stock for which a Section 83(b) election has been made or which are paid after the restriction period lapses generally will be treated and taxed as dividend income.

*SARs.* A participant will not recognize taxable income, and the combined company or a subsidiary, as applicable, is not entitled to a deduction, upon the grant of a SAR. Upon exercise or settlement of a SAR, a participant will recognize compensation taxable as ordinary income in an amount equal to the cash or the fair market value of the shares received and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction. A participant's tax basis in shares received upon the exercise of a SAR will be equal to the fair market value of such shares on the exercise date, and the participant's holding period for such shares will begin at that time. Upon the sale of shares received from the

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exercise of a SAR, the participant will recognize short-term or long-term capital gain or loss, depending on whether the shares have been held for more than one year. The amount of such gain or loss will be equal to the difference between the amount recognized in connection with the sale of the shares and the participant's tax basis in the shares.

*Edge RSUs.* A participant will not recognize taxable income upon the grant of Edge RSUs, and the combined company or a subsidiary, as applicable, is not entitled to a deduction upon such grant. When the award is settled and the participant receives cash or shares, the participant will recognize compensation taxable as ordinary income equal to the amount of cash received or the fair market value of the shares at that time (as applicable) and, subject to Section 162(m) of the Code, the combined company or one of its subsidiaries will be entitled to a corresponding deduction. A participant's tax basis in shares received at the end of a restriction period will be equal to the fair market value of the shares when the participant receives them, and the participant's holding period will begin on such date. Upon the sale of the shares received upon the settlement of restricted stock, the participant will recognize short-term or long-term capital gain or loss, depending upon whether the shares have been held for more than one year at the time of sale. Such gain or loss will be equal to the difference between the amount recognized upon the sale of the shares and the tax basis of the shares in the participant's hands. Dividend equivalents will be taxable to participants upon distribution as compensation, and accordingly, the participant will recognize ordinary income (not dividend income) in such amount and, subject to Section 162(m) of the Code, the combined company or a subsidiary, as applicable, will receive a corresponding deduction. In addition, as discussed below, Edge RSUs may be considered deferred compensation that must comply with the requirements of Section 409A of the Code in order to avoid early income inclusion and tax penalties.

*Withholding.* Participants will be responsible for making appropriate provision for all taxes required to be withheld in connection with any awards, including taxes relating to the vesting, exercise and transfer of shares pursuant to the Restated Plan. The combined company or a subsidiary is authorized to withhold from any payment relating to an Award under the Restated Plan, including from a distribution of common stock or any payroll or other payment due to a participant, withholding and other taxes due in connection with any transaction involving an award.

*Million Dollar Deduction Limit.* In 2017 and prior years, under Section 162(m) of the Code, a publicly-held corporation may not deduct compensation paid in any one taxable year in excess of \$1,000,000 to a covered employee unless the compensation properly qualifies as performance-based compensation subject to certain requirements. Prior to the amendment of Section 162(m) adopted by the Tax Cuts and Jobs Act, as described below, a covered employee for this purpose is the chief executive officer of the corporation and each of the three other most highly compensated officers of the corporation (other than the chief financial officer), as reported to stockholders under the Exchange Act.

The Tax Cuts and Jobs Act, passed by Congress in December 2017, eliminated the performance-based compensation exemption under Section 162(m) and revised the definition of covered employee. Therefore, for 2018 and going forward, compensation paid to Edge's chief executive officer, Edge's chief financial officer and to each of Edge's other named executive officers (as required to be disclosed in Edge's annual proxy statement pursuant to the Exchange Act) will not be deductible for federal income tax purposes to the extent such compensation exceeds \$1,000,000, regardless of whether such compensation would have been considered performance-based under prior law. This limitation on deductibility applies to each individual who is a covered employee (as defined in Section 162(m)) in 2017 or becomes a covered employee in any subsequent year, and continues to apply to each such individual for all future years, regardless of whether such individual remains a named executive officer. There is, however, a transition rule that allows performance-based compensation in excess of \$1,000,000 to continue to be deductible if the remuneration is provided pursuant to a binding contract which was in effect on November 2, 2017 and which was not subsequently materially modified.

*Nonqualified Deferred Compensation.* Section 409A of the Code contains certain restrictions on the ability to defer receipt of compensation to future tax years. Any award that provides for the deferral of compensation, such as Edge

RSUs that are settled more than two and one-half months after the end of the year in which they vest, must comply with Section 409A of the Code or else be subject to further adverse tax consequences. If the requirements of Section 409A of the Code are not met with respect to an award, all amounts deferred under the Restated Plan during the taxable year and all prior taxable years (to the extent not already included in gross income) will be included in the participant's taxable income in the later of the year in which such violation

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occurs or the year in which such amounts are no longer subject to a substantial risk of forfeiture, even if such amounts have not been actually received by the participant. In addition, the violation of Section 409A of the Code will result in an additional tax to the participant of 20% of the deferred amount plus applicable interest computed from the date the award was earned, or if later, the date on which it vested.

*Excess Parachute Payments.* If the vesting or payment of an award made to a disqualified individual (as defined in Section 280G of the Code) occurs in connection with a change in control of the combined company, such vesting or payment, either alone or when combined with other compensation payments which such disqualified individual is entitled to receive, may result in an excess parachute payment (as defined in Section 280G of the Code). Section 4999 of the Code generally imposes a 20% excise tax on the amount of any such excess parachute payment received by such disqualified individual and Section 280G of the Code would prevent the combined company or a subsidiary or affiliate, as applicable, from deducting such excess parachute payment.

**THE EDGE BOARD UNANIMOUSLY RECOMMENDS THAT THE EDGE STOCKHOLDERS VOTE “FOR” THE APPROVAL OF THE AMENDED AND RESTATED EDGE THERAPEUTICS, INC. 2014 EQUITY INCENTIVE PLAN.**



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### **EDGE BUSINESS**

#### **Pending Merger Agreement with PDS**

On November 23, 2018, Edge, Echos Merger Sub, Inc., a Delaware corporation, or Merger Sub, and PDS Biotechnology Corporation, a Delaware corporation, or PDS, that is a privately-held late 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. The Merger Agreement and the transactions contemplated hereby are described in detail elsewhere in this proxy statement/prospectus/information statement.

If the merger is completed, the business of Edge will become the business of PDS as described on page 146 under the caption PDS Business. 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.

#### **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

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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.

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, and expects to continue to explore, whether any third party(ies) would be interested in acquiring rights to EG-1962.

On April 17, 2018, 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 to serve as its financial advisor in the strategic review process. During the strategic alternatives process, Edge continued to finance its operations with its existing cash. In the near term, 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.

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. The Merger Agreement and the transactions contemplated hereby are described in detail elsewhere in this proxy statement/prospectus/information statement.

### **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 post-merger 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.

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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.

*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, Canada, China, Europe, Israel, Japan, Korea, New Zealand 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 Australia, Europe, Japan, New Zealand, Russia, Singapore, and the United Kingdom; 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, Europe, 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; a European patent application is pending.

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 and Canada. 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 products in its pipeline. 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 at Oakwood under either agreement.

### **Competition**

Edge has no current plans to further develop or commercialize its portfolio of products. However, to the extent a potential strategic transaction results in the further development of the candidates in its portfolio, potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and

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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 FDA 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's therapies obsolete or non-competitive before development and commercialization expenses can be recovered.

### **Government Regulation**

Government authorities in the U.S. 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 U.S., 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 U.S. 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 IND, which must become effective before clinical trials (trials in human subjects) in the U.S. 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.



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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 U.S., 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.

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 has [\_\_\_\_\_] 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

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EDGE. Edge is an emerging growth company under the Jumpstart Edge s 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

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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](http://www.sec.gov).

**Legal Proceedings**

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 alleges 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 EG-1962 would likely fail a futility analysis. The complaint is brought on behalf of all purchasers of Edge's common stock between December 27, 2017 and March 27, 2018, and seeks unspecified damages. None of Edge, Mr. Leuthner, or Mr. Saik has been served with the complaint and their time to respond has not yet expired. On December 7, 2018, Sam Kirkpatrick and Amos Bakouple were appointed lead plaintiffs. It is expected that the lead plaintiffs will file an amended complaint in early 2019 and that defendants will not need to respond to the current complaint. Edge and its executives intend to defend themselves vigorously in the action. There can be no guarantee as to the outcome or timing of any resolution.

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### **PDS BUSINESS**

#### **Overview**

PDS is a clinical-stage biotechnology company that seeks to develop and commercialize multi-functional cancer immunotherapy products that we believe will overcome limitations of immuno-oncology products and technologies that are currently on the market or in development.

Our mission is to apply the Versamune<sup>®</sup> platform, our proprietary and versatile immunotherapy technology, to develop a new generation of immuno-oncology products that are effective and safe across a broad range of cancer types. Our current development pipeline of cancer immunotherapy products are based on the Versamune platform, and can potentially be used both as monotherapies in early-stage disease and as a component of combination products with other leading technologies to provide effective treatment across a range of cancer types, including Human Papillomavirus (HPV)-based cancers, melanoma, colorectal, lung, breast and prostate cancers.

We seek to maintain high barriers to entry around our product candidates and the markets in which they are utilized by using a multiple layered approach to our patents, patent applications, and substantial know-how and trade secrets related to the Versamune platform. As of December 2018, we hold three (3) U.S. patents with granted claims directed to our platform technology, six (6) pending U.S. patent applications, five (5) issued foreign patents and three (3) pending foreign patent applications.

In preclinical studies, PDS has validated Versamune's novel multi-functional mechanism, which leads to a unique ability to induce high levels of tumor-targeting killer T-cells (CD8+) in vivo. This ability to overcome one of the most critical limitations of other immunotherapy technologies has been demonstrated in PDS's Phase 1/2a human clinical trial as described further below.

Key elements of PDS's clinical and commercial execution strategy are as follows:

1. Rapidly develop our lead product candidate, PDS0101, as monotherapy as a first line therapy for Cervical Intraepithelial Neoplasia (CIN2/3), and secondly in combination with Keytruda<sup>®</sup> as first and second line treatment of recurrent or metastatic head and neck cancer;
2. Validate our versatile immunotherapy technology, Versamune, by continuing development of the PDS0102, 0103, and 0104 programs in colorectal, melanoma, breast, lung, and prostate cancers;
3. Commercialize our wholly-owned product candidates, including PDS0101, if approved, through a targeted sales force in the United States, Canada and Europe and with potential strategic partnerships outside of these regions; and
4. Continue to seek to maintain high barriers to entry around our product candidates and the markets in which they are utilized by using our patents and know how around our Versamune<sup>®</sup> platform technology.

#### **Cancer Immunotherapy**

In the field of cancer immunotherapy, a well-documented and significant unmet need is the ability of therapies to safely induce in vivo an adequate number of highly active/polyfunctional CD8+ T-cells, coupled with the altering of the tumor microenvironment in order to limit its immune tolerance, in order to facilitate efficient tumor cell killing. Our data to date suggests that the Versamune<sup>®</sup> platform effectively promotes both of these critical immunotherapy characteristics, leading to strong antigen-specific CD8+ T-cell induction in a human clinical trial.

One of the most active areas of clinical testing in the field of cancer immunotherapy today is combining checkpoint inhibitors with other anti-cancer agents, with the goal of synergistic clinical efficacy compared with that of individual products. We believe that next generation of combination immunotherapy agents, especially those including both

checkpoint inhibitors and a second therapeutic agent, will need to have at least the following characteristics to achieve clinical and commercial success:

1. Induction of tumor infiltrating CD8+ T-cells;
2. Further alteration of the tumor microenvironment through activation of complimentary immunological mechanisms; and

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3. Lack of substantially higher combined toxicity than either component alone, in order to contribute a viable clinical application to cancer patients.

Most immunotherapies work by training or priming our T-cells to recognize specific disease-related proteins (cancer, bacterial or viral) displayed or expressed by diseased cells. The ultimate goal of immunotherapy treatment is to harness the power of the immune system to target and kill specific diseased cells, and thereby cure the underlying disease.

Immunotherapies have recently been recognized as having significant potential to treat a broad range of cancers and infectious diseases. Several cancer immunotherapies have now been approved by the FDA, and other promising immunotherapy technologies and products are in various stages of advanced clinical development.

Despite the promise demonstrated by current immunotherapy technologies, these products still face significant hurdles to achieving optimal therapeutic value. Some key obstacles faced by the current technologies are the following:

*Antigen Uptake by Dendritic Cells:* Antigens are particular proteins recognizable by the immune system that are uniquely or highly expressed/present in tumor cells but not present in normal healthy cells. The first critical step in generating an effective antigen-specific or antigen-targeting T-cell response is efficient uptake of particular antigens by dendritic cells, which are the key antigen presenting cells of the immune system. Proteins and peptides are not naturally highly taken up by dendritic cells, creating obstacles to effective T-cell response in existing immunotherapies. Versamune® has demonstrated the ability to promote antigen uptake by dendritic cells.

*Antigen Cross-Presentation and Killer (CD8+) T-Cell Priming:* Suboptimal ability to internalize, process/break-down and present tumor antigens to the immune system leads to ineffective activation or priming of killer T-cells. Dendritic cells are required to take up and process tumor antigens. These processed antigens then have to enter into an internal compartment of the cell, called the cytoplasm. The peptide's presence in the cytoplasm is necessary to allow smaller processed proteins (peptides) to be presented to killer T-cells via what is known as the Major Histocompatibility Complex (MHC) Class I pathway or to helper T-cells via the MHC Class II pathway. This is the process of T-cell priming. Current technologies have presented limited ability to adequately facilitate antigen presentation via the MHC Class I process *in vivo*, therefore leading sub-optimal killer T-cell priming and then weaker-than-optimal anti-tumor potency. Versamune® has demonstrated the ability to promote antigen processing and presentation via MHC Class I leading to effective CD8+ T-cell priming.

*Immune Activation:* Once T-cell priming has successfully occurred, a subsequent critical step is induction-specific immunological signals, including induction of certain chemokines and cytokines necessary for activation and proliferation of various classes of T-cells. Chemokines and cytokines are each a broad category of small proteins that are crucial for fighting off infections and other immune responses. Versamune® has demonstrated the ability to specifically activate the important type I interferon signaling pathway, leading to induction of the right phenotype of active CD8+ T-cells.

*Overcoming Immune Suppression:* A number of immune-suppressive mechanisms and cells naturally exist in humans that can increase in number within tumors. This results in the inhibition or blocking of ability of killer and helper T-cells to identify and kill the tumor cells. This state of immune tolerance must generally be overcome for T-cells to be effective in killing antigen-expressing cancer cells. In preclinical studies, Versamune® was demonstrated to alter the tumor micro-environment, making the tumors more susceptible to attack by T-cells.

*Complexity and Costs:* The relatively high formulation and manufacturing complexities, as well as related high costs, associated with most commercially available immunotherapies is well documented. For example, live vector-based cancer vaccines and dendritic cell vaccines require complex and expensive processes to enable manufacturing of live agent (virus or bacteria) products. Versamune® is based on synthetic positively charged lipids, which results in a much

simpler and less expensive manufacturing process than most other immunotherapy technologies.

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TABLE OF CONTENTS**Versamune® - A Next Generation Immunotherapy and Cancer Immunotherapy**

Based on the shortcomings described above, we believe that a next generation immunotherapy agent that can overcome those limitations is likely to address significant unmet needs. Below is a chart comparing Versamune®, a T-cell activating platform technology, to other cancer immunotherapy approaches. This table presents a general comparison and, in each category, PDS expects that there may be exceptions that display different characteristics. This table is not meant to represent every checkpoint inhibitor, cancer vaccine or CAR T-cell therapy, nor is it meant to imply that these are the only classes of immunotherapy.

\* Based on preclinical toxicology and efficacy studies and Phase 1 clinical data.

**Versamune® Platform**

Versamune® has been rationally designed and is based on synthetic positively charged (cationic) lipids. The structure of these lipids leads to spontaneous formation of nanoparticles in an aqueous medium. The nanoparticles are sized to promote efficient uptake by the antigen presenting cells of the immune system, the dendritic cells. The nanoparticles are combined with tumor antigens (proteins, peptides, DNA or RNA) and administered by subcutaneous injection.

## Figure 1: Versamune nanoparticles

The initial concept for Versamune® was first discovered and developed in 2005 by PDS's scientific founder, Professor Leaf Huang, at the University of Pittsburgh, School of Medicine. The Versamune® technology is based on the use of immune activating cationic (positively charged) lipids that spontaneously form liposomal nanoparticles in an aqueous medium. Huang, a world-renowned expert in liposome drug delivery and non-viral gene therapy, was familiar with the ability of cationic lipids to effectively deliver DNA into the cytoplasm of cells. PDS's targeted research and development efforts identified critical structural characteristics of bio-active lipids, and then refined and built upon that initial concept.

PDS's early development strategy was to assemble an expert team of third-party collaborators, with various and complementary areas of relevant expertise in immunology, molecular biology and tumor biology. This



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cross-functional team enabled PDS to develop and validate a unique platform encompassing and combining key attributes of the most promising immunotherapies, such as the live vectors and CAR T-cells, while also mitigating some of the most notable clinical shortcomings of those technologies. The resulting Versamune® technology is believed to induce active and potent disease-specific helper and killer T-cells, while simultaneously suppressing the tumor's defenses, thus becoming a key component in PDS' product pipeline that is projected to safely and effectively treat both early and late-stage cancers.

The unique ability of Versamune to incorporate the critical characteristics described above is due to the following:

1. The specific composition of the nanoparticles results in efficient binding and uptake of nanoparticles by dendritic cells, and leads to rapid internalization into the cell endosomes and destabilization of endosomal membranes, thus releasing contents into the cytoplasm where they can then access the MHC Class I presentation pathway. This allows for effective priming of CD8+ T-cells.
  - a. Delivery into the right compartments of the cell leads to effective processing of the antigen and cross presentation of the processed antigen to CD8+ T-cells, therefore overcoming a key limitation of vaccine technologies.
  - b. Endosomal destabilization and entry into the cytoplasm allows for presentation of the processed antigen to both CD8+ and CD4+ T-cells (MHC-I and MHC-II). This overcomes a key limitation of current immunotherapy.
2. The structure of the cationic lipids induces specific activation of the Type I interferon (IFN-1) signaling pathway and the related down-stream cytokines and chemokines. IFN-1 activation is known to be highly important in the activation and proliferation of CD8+ T-cells.
  - a. Localized induction of IFN-I at the injection site and within the lymph nodes restricts the cytokine and chemokine induction as well as resulting inflammation to the lymph nodes. Minimal systemic inflammation limits toxicity, and the lymph node-localized cytokine induction promotes T-cell potency. Specific/targeted activation specifically of the IFN-I pathway eliminates the non-specific immune activation induced by the current approaches and leads to induction of the correct/required phenotype of active polyfunctional T-cells that present effective tumor targeting and killing.
  - b.

### **PDS Clinical Development Plan**

Initially, PDS intends to demonstrate the application of the Versamune® platform's attributes:

- By applying PDS0101 as a monotherapy in first-line treatment of High Grade Cervical Intraepithelial Neoplasia (CIN2/3), and
- By applying PDS0101 as a more effective and safer combination therapy with Keytruda® in recurrent and metastatic head and neck cancer.

With additional financing, we plan to initiate clinical trials with PDS0102 (TARP-expressing cancers, e.g. prostate and breast cancers), PDS0103 (MUC-1 expressing cancers, e.g. colon, breast, lung and ovarian cancers) and PDS0104 (TRP2 expressing cancers, e.g. melanoma and glioma).

### **PDS 0101**

We believe PDS0101, our lead product candidate, can fundamentally improve patient outcomes and transform the management of HPV-related pre-cancers and cancers. PDS0101 utilizes Versamune®, PDS' proprietary and versatile multi-functional platform technology, and also includes various peptides from oncogenic strains of the HPV virus.

### **PDS0101 in Cervical Intraepithelial Neoplasia (CIN)**

HPV-induced cancers, including cervical cancer, are one of the few cancer types with a well-defined pre-cancerous stage. Pre-cancerous lesions are defined as low-grade squamous intraepithelial lesions, including early stage cervical intraepithelial neoplasia ( CIN1 ), and high grade squamous intraepithelial lesions, including

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late-stage cervical intraepithelial neoplasia ( CIN2/3 ). There are currently no FDA-approved therapeutic drugs available to treat HPV-induced pre-cancers. High grade dysplasia is treated with various forms of surgery, with the most predominant being the loop electrosurgical excision ( LEEP ) procedure. Low grade dysplasia is not currently treated, primarily due to the potentially debilitating side effects that occur in approximately 15% of surgery patients. Strong association has been found between these surgical treatments of HPV-related lesions and then risk of future infertility or subfertility diagnoses. The procedures have also been associated with an increased risk of cervical stenosis and spontaneous abortion.

The worldwide annual incidence of pre-cancerous cervical intraepithelial neoplasia ( CIN ) is about 1,400,000. The estimated annual incidence of CIN in the United States among females who undergo cervical cancer screening is about four percent for early stage CIN (CIN1), and five percent for late stage CIN (CIN2/3). It is estimated that over 300,000 women in the US are diagnosed annually with CIN2/3. In China, the prevalence of CIN2 is about 1.5% of the general female population and the prevalence of CIN3 is about 1.2% of the female population.

**PDS0101 + Keytruda® in HPV-positive recurrent or metastatic head and neck cancer**

We have a collaboration agreement with Merck and Co. to combine PDS0101 with Merck's checkpoint inhibitor, Keytruda®, in a Phase 2 human clinical trial to treat HPV-positive recurrent or metastatic head and neck cancer.

*HPV-Positive Head and Neck Cancer Including Oropharyngeal Squamous Cell Carcinoma:*

Head and neck cancers have been reported to be increasing in recent years, and have been described as a silent epidemic attributed to HPV infection. A recent study showed the overall prevalence of oral HPV infection to be 11.5% in men and 3.2% in women, or 11 million men and 3.2 million women in the United States. High-risk oral HPV-16 was over three times more common in men. Over 70% of oropharyngeal cancers are estimated to be HPV-associated in developed Western countries. It has been reported that about 90% of the OSCC tumors were positive for HPV-16. The US National Cancer Institute (NCI) estimated that in 2013 about 36,000 people in the US would be diagnosed with OSCC. For 2017 the projections were increased to 49,670 new cases with an estimated 9,700 deaths. The current treatment options are surgery, radiation, chemotherapy or a targeted therapy, including checkpoint inhibitors.

**PDS0101 Phase 1/2a Human Clinical Data**

PDS completed a Phase 1/2a trial of PDS0101, which was conducted at three sites in the United States. The study was an Open-label Escalating Dose Study to Evaluate the Safety, Tolerability, and Pharmacodynamics of PDS0101 in subjects with Cervical Intraepithelial Neoplasia (CIN) and high-risk Human Papillomavirus (HPV) infections. The study included 3 cohorts of 3 to 6 subjects each, based on a modified 3 + 3 dose-escalation study design.

The study enrolled Cohort 1 and progressed through Cohort 3, with each subsequent cohort receiving a higher dose of PDS0101. Successive cohorts all receive a constant dose of the HPV-16 E6 and E7 antigens. Subjects were given three subcutaneous injections of PDS0101, three weeks apart, and blood was drawn 14-19 days after each injection, as well as 90 days after the last injection. HPV-specific CD8+ T-cells were quantified using both the Interferon-ELISPOT assay (quantifies all HPV-specific T-cells) and granzyme-b ELISPOT assay (specifically quantifies active HPV-specific CD8+ T-cells). Dosing and dose escalation were based on safety evaluation for determination of potential dose-limiting toxicity (DLT).

A total of 12 subjects were enrolled. There was a strong induction of active HPV-specific killer T-cells (CD8+) observed with quantifiable amounts of the CD8+ T-cells retrieved from patient blood as late as 14-19 days after treatment.



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Figure 2: CD8+ T-cell data generated in the phase 1/2a clinical trial

The CD8+ T-cells results seen in the Phase 1/2a study confirmed preclinical projections of high levels of active HPV-specific CD8+ T-cells. The results also confirmed preclinical projections of memory T-cell induction. Of note, T-cell responses were independent of patient genetic/HLA sub types.

No dose-limiting toxicities were observed, even at the highest tested dose of 10mg. A dose of approx. 3mg has been selected to move forward into the upcoming PDS0101 Phase 2b/3 clinical trials.

### **Other Development Programs**

#### **PDS0102 (TARP-expressing cancers) for the treatment of prostate and breast cancers**

**Prostate cancer:** Based on promising Phase 2 clinical trials run by the NCI using TARP antigens, PDS and the NCI are collaborating to develop a Versamune platform-based immunotherapy for prostate cancer.

Prostate cancer is the most common non-skin cancer in the United States. Over 30,000 men die from the cancer every year according to the Prostate Cancer Foundation, and over two million Americans currently have prostate cancer. A recent report projects that the prostate cancer market will grow at a compound annual growth rate of 9.5%, from \$7.6 billion in 2014 to \$13.6 billion by 2021.

#### **PDS0103 (MUC-1 expressing cancers) for the treatment of colorectal, breast, ovarian and lung cancers**

**PDS0103** is based on novel agonist antigens of the mucin-1 (MUC-1) oncogenic C-terminal region developed by the laboratory of Dr. Jeff Schlom, head of Tumor Biology at the NCI. MUC1 is highly expressed in multiple tumor types and has been shown to be associated with drug resistance and poor prognosis for a range of human tumors. The agonist peptides, compared to the native peptides, more efficiently enhance production of IFN- $\gamma$  by peptide activated human T cells, and also more efficiently lyse human tumor cell targets in an MHC-restricted manner. It is also known that high avidity T-cells can lyse targets with 1,000-fold lower peptide-MHC complexes. The enhancer agonist epitopes developed induce higher avidity T-cells than self-antigens and has been demonstrated to be a successful strategy to enhance number and avidity of T-cells for MUC-1 directed immunotherapy.

These MUC-1 antigens have been licensed from the NCI for use with Versamune<sup>®</sup> in ovarian, breast, colorectal and lung cancers.

We believe that an effective and safe immunotherapy targeting solid tumors expressing MUC-1 will gain rapid acceptance as a monotherapy in early-stage disease and initially as a combination therapy in later stage disease.

**Colorectal cancer (CRC):** Colorectal or colon cancer, includes cancerous growths in the colon, rectum and appendix. It is the third most common form of cancer and the second leading cause of cancer-related death in the Western world. Global Markets estimates the colorectal cancer market to grow at 3% annually from \$8.15 billion in 2015 to \$11 billion in 2025 in the eight major markets, US, UK, England, France, Italy, Japan, China and

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Germany. We believe that there is significant market opportunity for immunotherapy, especially in early stage CRC disease where there is a lack of novel treatments outside chemotherapy.

**Breast cancer:** Breast cancer is a leading cause of cancer-related mortality among women worldwide. IMS Health reports that sales of breast cancer treatments will increase by an average of 5.8% a year in nine major markets, increasing from a value of \$9.8 billion in 2013 to \$18.2 billion by 2023.

**Ovarian cancer:** Ovarian cancer is the most common cause of death from gynecological tumors. Nearly 60,000 cases of ovarian cancer are diagnosed in the following seven major markets (the United States, Japan, Germany, France, Italy, the United Kingdom and Spain) each year. The five-year survival rate of ovarian cancer patients remains below 20%. The American Cancer Society reports that in the US about 22,240 women will receive a new diagnosis of ovarian cancer, and about 14,000 women will die from ovarian cancer in 2018. We believe that there is a significant market opportunity for immunotherapy especially in early stage disease where there is a lack of novel treatments outside chemotherapy.

**Non-Small Cell Lung Cancer (NSCLC):** NSCLC is the leading cause of cancer-related mortality in the major pharmaceutical markets. There is still a clear unmet need in the treatment of NSCLC despite products such as Alimta<sup>®</sup>, Avastin<sup>®</sup>, Iressa<sup>®</sup> and Tarceva<sup>®</sup>. The NSCLC treatment market is expected to reach \$12.2 billion by 2025. Growth is expected to be driven by novel therapies entering the squamous cell carcinoma market segment, which is currently lacking effective treatment, unlike the non-squamous market segment.

### **PDS 0104 (TRP2 expressing cancers) for the treatment of melanoma**

PDS has completed preclinical work in advanced melanoma tumor models where we have observed the ability of PDS0104 to overcome immune suppression and inhibit growth of B16 melanoma tumors. Preclinical studies have also demonstrated a strong synergy between PDS0104 and checkpoint inhibitors, resulting in dramatically improved antitumor response and prolonged survival.

Melanoma is a malignant tumor of the melanocytes. Melanoma is primarily a skin tumor, although it may also occur less frequently in the melanocytes of the eye. It is currently the seventh most common cancer in the US. Melanoma comprises 5% of all skin cancers. The most common causes are exposure to ultra violet radiation from the sun, leading to damage to the DNA of the melanocytes of the skin, family history, an impaired immune system and atypical moles on the body. The American Cancer Society estimated that there will be about 91,270 new cases of melanoma in 2018, and over 9,000 deaths. No effective therapies existed for advanced cancer until the immunotherapy Yervoy<sup>®</sup> was approved by the FDA in March of 2011.

### **Versamune-Based Product Candidates**

The following table outlines PDS pipeline of product candidates.

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PDS is the sponsor of all of these clinical trials, and Merck and NCI referenced above are collaborators on such trials.

### **Commercialization of Product Candidates**

PDS retains worldwide rights to all of our product candidates. If our product candidates are approved, we intend to establish targeted commercialization and marketing capabilities for our products in the United States, Canada and Europe by developing a sales force that would focus on academic medical centers and large oncology clinics. For commercialization outside of the United States, Canada and Europe, we generally expect to enter into collaborations with strategic partners.

### **A Summary of the Current State-of-the-art**

Two approaches, dendritic cell vaccines and CAR T-cell immunotherapies, are the two commercial/FDA approved technologies that have presented the best promise to date in addressing other technologies' inability to effectively present antigens to the dendritic cells inside the body:

*Dendritic Cell Vaccines:* Dendritic cell vaccines eliminate the need to target and deliver antigens to dendritic cells *in-vivo*. In these products, immature dendritic cells or monocyte precursors of the patient's dendritic cells are removed from the patient's blood and cultured outside the body. The dendritic cells are then treated with tumor antigens, and matured dendritic cells are re-infused into the patient to present the processed antigen material to the patient's T-cells.

Recent data reported with Provenge<sup>®</sup>, a prostate cancer vaccine, suggests that its induced immune responses are long-lived, with strong T-cell responses still observed in most surviving patients at two years after treatment. Nevertheless, this approach does not appear to address the immuno-suppressive environment in tumors, or provide immune activation/stimulation necessary to enhance activity of primed T-cells. Importantly, recent studies have demonstrated that antigen uptake and processing is still suboptimal when dendritic cells are treated *ex-vivo*.

*CAR T-Cell Immunotherapy:* CAR T-cell immunotherapy is based on manipulating T-cells collected from patients' own blood. After collection, T-cells are genetically engineered to produce special receptors on their surface called chimeric antigen receptors (CARs). CARs are proteins that allow T-cells to recognize a specific protein (antigen) on tumor cells. These engineered CAR T-cells are then grown in the laboratory until they number in the billions. This expanded population of CAR T-cells is then intravenously infused into the patient. After the infusion, the T-cells are expected to multiply in the patient's body and, with guidance from their engineered receptor, recognize and kill cancer cells that display the antigen on their surfaces. Two CAR-T therapies have been approved to treat large B-cell lymphoma, Kymriah<sup>®</sup> and Yescarta<sup>®</sup>, and others are being tested in clinical trials.

CAR T-cell immunotherapy overcomes the need to perform *in-vivo* antigen processing and uptake by dendritic cells. Recent data in blood cancers have shown promising results with a high rate of complete remissions. These results confirm the ability or importance of killer T-cells in targeting and killing cancerous cells. Nevertheless, this approach does not appear to address the immuno-suppressive environment in solid tumors, and can cause significant side effects. Perhaps the most troublesome side effect is cytokine-release syndrome. The infused T-cells release cytokines, leading to a rapid and large presence in the bloodstream. This can cause dangerously high fevers and precipitous drops in blood pressure. Relatively high cost and complex manufacturing processes for CAR-T therapies may also limit the broader applicability of CAR T-cell immunotherapies in the long run.

Other promising approaches under evaluation in clinical trials are:

*Live Vectors:* This approach uses live vectors, predominantly live viruses or live bacteria, with added copies of a plasmid that encodes the protein antigen DNA sequence. The protein is then secreted by the virus or bacteria once

taken up by the dendritic cells. Studies have shown this approach can result in successful stimulation of T-cells and antibodies.

*Antibodies:* This approach uses dendritic cell targeting antibodies linked to tumor antigens in order to facilitate dendritic cell uptake of those antigens.

*Electroporation:* This approach involves generation of electrical pulses through the skin. This technology delivers antigenic DNA into the dendritic cells residing beneath the skin. The protein then has to be secreted



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by the dendritic cells once the DNA has been successfully delivered. Studies have shown this approach can result in successful stimulation of T-cells and antibodies.

Several of the technologies summarized above have not demonstrated the ability to effectively activate the necessary immunological mechanisms required to induce optimal killer T-cell responses. Additionally, many of these approaches do not activate mechanisms to combat or reduce immuno-suppressive cell populations within tumors. These drawbacks may lead to suboptimal responses, and the need to combine them with other technologies in the long run to improve their clinical responses.

Some efforts to address the immuno-suppressive environment have focused on developing antibodies focused on blocking immune checkpoints. These are known as the checkpoint inhibitors. Checkpoint inhibitors have had the most developmental attention and commercial success to date in the field of cancer immunotherapy. The function of checkpoint inhibitors is to block normal proteins on cancer cells, or the proteins on T-cells that respond to them. The result is to make cancer cells more visible to T-cells. This then helps generate a T-cell assault on the cancer. To date, more than six checkpoint inhibitors have received rapid approval from the U.S. Food and Drug Administration, or FDA. These include ipilimumab (Yervoy®), pembrolizumab (Keytruda®), and nivolumab (Opdivo®).

The development of each of the immunotherapies described below has encountered certain safety concerns:

*Adjuvant-Based Cancer Vaccines:* Adjuvant-based cancer vaccines appear to be quite well tolerated, with the most commonly reported adverse events being injection site reactions and systemic toxicities. These systemic inflammatory immune responses are sometimes caused by the use of the immune activators, known as adjuvants. Such adjuvants may have the potential to induce high cytokine levels in the blood, which can sometimes lead to severe side effects as a result of cytokine storms.

*Cytokine Therapies:* Products that administer cytokines present strong potential for high toxicity due to such cytokine storms.

*Live Vector-Based Cancer Vaccines:* Systemic toxicities have been reported with some live virus and bacteria technologies administered by intravenous infusion. Certain clinical trials have been suspended due to patient deaths suspected, but not confirmed, to have resulted from treatment-related toxicities.

*CAR T-Cells:* High numbers of infused T-cells can result in extremely high and debilitating systemic inflammation. In some recent clinical studies, patient deaths were reported as a result of high numbers of infused T-cells. These clinical trials were then suspended by the FDA.

*Checkpoint Inhibitors:* The use of checkpoint inhibitor antibodies to overcome tumor immune suppression is known to present the potential for triggering autoimmune disease.

### **Versamune® Mechanisms of Action (MOA)**

We believe that the Versamune platform has a multi-functional mechanism of action, or MOA, which is responsible for its strong antigen-specific T-cell activity, that could potentially lead to clinical confirmation of efficacy. PDS continues to further study and validate some of these detailed molecular signaling mechanisms.

The section below summarizes studies that have been performed to confirm the mechanisms by which the Versamune-based products elicit strong anti-tumor responses apparently without the toxicities typical of current immunotherapy.



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Figure 3: Summary of the versatile and multi-functional mechanism of the Versamune® platform that leads to demonstrated anti-tumor activity

*Antigen Uptake*

The critical first step in the process of effectively priming T-cells is uptake of disease-related antigens in the formulation. Versamune® exploits the well-studied function of dendritic cells to take up particulate matter, and no targeting mechanisms are therefore believed to be required to facilitate this uptake. The positive charge of Versamune® leads to enhanced association with negatively charged cell surfaces, resulting in high internalization by the dendritic cells.

To confirm this effective uptake by dendritic cells, a number of in-vivo confirmatory studies were successfully completed:

- A bio-distribution study in mice demonstrated that, four hours after subcutaneous injection of Versamune®, 80% of dendritic cells in a draining lymph node (where dendritic cells interact with T-cells) had taken up Versamune®. This study also demonstrated that dendritic cells had been effectively activated and matured by Versamune®.
- Pharmacokinetic and absorption, distribution and excretion studies, in both rats and monkeys, demonstrated an extremely low presence of PDS0101 in the blood circulation (bio-availability 5-6%) after subcutaneous administration. These studies also demonstrated an extremely low presence of PDS0101 in all key organs of the body, with predominant presence in the lymphatic system. These studies confirmed effective uptake of the immunotherapy by the dendritic cells, and a subsequent high presence in the lymphatic system where effective interaction with T-cells can occur.

**Example 1: *In-vitro* studies performed to examine the ability of Versamune® to promote antigen uptake and processing by bone marrow-derived dendritic cells (BMDC):**

The protein ovalbumin (OVA) was used as a model antigen. Uptake of OVA into BMDC was visualized using Alexa 647-OVA. BMDC were incubated for various times with Versamune® and Alexa 647-OVA or Alexa 647 OVA alone followed by measurement of Alexa 647-OVA fluorescence by flow cytometry. Although some Alexa 647-OVA uptake was observed in BMDC incubated with Alexa 647-OVA alone, uptake was dramatically enhanced in the presence of Versamune®. Notably, Versamune® facilitated significant uptake within the first 10 minutes and continued throughout the hour (Figure 4).

Presumably, OVA uptake mediated by Versamune® would deliver OVA into acidic endosomes where OVA processing would be expected to occur. To evaluate processing, PDS utilized DQ-OVA, which is a heavily fluorescent OVA that self- quenches in the intact molecule, but fluoresces when degraded. Incubation of BMDC with DQ-OVA and Versamune® resulted in a significant shift to red fluorescence indicative of extensive processing and endosomal accumulation. Incubation of BMDC with DQ-OVA and the potent adjuvant LPS did not result in enhanced processing (Figure 5). Thus, in this study, Versamune® promoted rapid protein uptake and processing in BMDC, presumably in the endosomal compartments.

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**Figure 4: Versamune® enhances protein uptake by dendritic cells**

Bone marrow derived dendritic cells were incubated with Alexa-647 conjugated ovalbumin admixed with sucrose or Versamune® (R-DOTAP) nanoparticles for indicated times and the association of ovalbumin with BMDCs was represented as mean fluorescence intensity.

**Figure 5: Versamune® enhances processing of antigen by dendritic cells**

Bone marrow derived dendritic cells were incubated with DQ conjugated ovalbumin admixed with sucrose or Versamune® nanoparticles or LPS (1µg/ml) for indicated times and the association of ovalbumin with BMDCs was represented as mean fluorescence intensity.

DQ-Ovalbumin processing at 60 minutes was measured by assessing the fluorescence in the FITC channel (FL1H) and the fluorescence in the PE-channel (FL2H) which represents the ovalbumin processing.

To further examine the ability of Versamune® to influence cross presentation of antigens to killer T-cells (CD8+) by dendritic cells, studies were performed utilizing the B3Z T cell hybridoma, which expresses a T-cell receptor specific for the CD8-specific SL9 peptide of ovalbumin presented by H-2K<sup>b</sup>. B3Z cells express a reporter lacZ gene under the control of the nuclear factor of activated T cells (NFAT) promoter providing a rapid and sensitive assay for the processing and presentation of SL9 antigen by dendritic cells. BMDCs were incubated with a long ovalbumin peptide (OVA<sub>241-270</sub>) containing the SL9 epitope formulated with Versamune® nanoparticles or sucrose buffer for 1hr at 37°C to load the peptide on to BMDCs. Excess peptide was removed by washing and BMDCs were then co-cultured with B3Z cells overnight. The efficiency of SL9 peptide cross presentation by BMDCs was measured using a colorimetric lacZ detection assay. While incubation of BMDC with peptide alone resulted in some cross presentation to B3Z cells, the addition of Versamune® nanoparticles resulted in maximal stimulation with approximately 100-fold less peptide (Figure 6). These results suggested that Versamune® potently enhances cross presentation of antigens to CD8+ T-cells.

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**Figure 6: Versamune® promotes antigen cross-presentation to killer T-cells (CD8+) *in-vitro***

BMDCs were pulsed for 10 minutes with indicated concentrations of OVA (241-270) peptide admixed with sucrose (green) or Versamune® (red) and co-cultured with B3Z cells overnight and lacZ production by OVA peptide-stimulated B3Z was measured using lacZ colorimetric assay.

Overall the studies summarized in Example 1 demonstrate the ability of Versamune® to potentially overcome a significant limitation of current immunotherapeutic approaches, which is the sub-optimal uptake, processing and cross-presentation of antigens resulting in weak induction of tumor-targeting killer T-cells.

*Antigen Presentation*

One of the most important characteristics of the Versamune®-based lipids is their ability to facilitate entry of antigens into the cytoplasm of dendritic cells, and subsequent efficient presentation to T-cells leading to effective T-cell priming. This characteristic is expected to help the Versamune®-based products overcome one of the most significant obstacles facing the field of cancer immunotherapy.

The use of cationic lipids in cancer and infectious disease immunotherapy has gained significant attention due to the work of Prof. Leaf Huang and the unique properties of these lipid particles in delivering their content effectively into antigen presenting cells such as dendritic cells.

To confirm that Versamune® facilitates antigen presentation to CD8+ (killer) and CD4+ (helper) T-cells via MHC Class I and Class II, respectively, a number of in-vivo and in-vitro confirmatory studies were performed.

**Example 2: In-vivo studies to confirm the ability of Versamune® to perform cross presentation to CD8+ T-cells**

To directly examine cross presentation *in vivo* following Versamune® administration with antigen, these studies utilized an adoptive transfer model in which OT1 T-cell receptor (TCR) transgenic T cells specific for the CD8 epitope SL9 of OVA presented by H-2K<sup>b</sup> were labeled with carboxy fluorescein succinimidyl ester (CFSE), a fluorescent cell staining dye and transferred into normal C57BL/6 mice.

Activation and proliferation of OT1 cells in the adoptive transfer mice requires *in-vivo* processing of whole OVA into the SL9 epitope and presentation on the H-2K<sup>b</sup> MHC class I molecule, i.e. cross presentation. Mice were then injected in the footpad with 1µg of whole OVA admixed with either sucrose or Versamune®. Proliferation of the transgenic T cells in the draining popliteal lymph node was assessed by flow cytometry measuring CFSE dilution in the transgenic T cells.

The draining lymph nodes (DLN) draining the Versamune® and OVA footpads were noticeably enlarged, and this was reflected in an increased total cell number isolated per lymph node. There was also a significant increase in total OT-1, both divided and undivided in the Versamune® and OVA-treated mice compared to OVA alone (Figure 7).

Thus, Versamune® facilitated MHC class I cross presentation of whole protein to CD8+ T cells in the draining lymph node when administered subcutaneously. Similar results were obtained utilizing class-II

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OVA-specific transgenic T-cells demonstrating that Versamune<sup>®</sup> facilitated MHC class II presentation of whole protein to CD4+ T cells in the draining lymph node when administered subcutaneously.

### **Figure 7: Versamune<sup>®</sup> (R-DOTAP) promotes antigen cross presentation *in-vivo* leading to superior proliferation of OT-1 CD8+ T-cells**

Total number of antigen specific cells in the draining popliteal lymph nodes in each vaccinated mouse were enumerated using hemocytometer and antigen specific CD8 T cell expansion was measured by CFSE dilution assay and total number of OT-1 CD8T cells.

#### *Immune Activation*

The ability of certain structurally-specific cationic lipids to act as potent immune activators was first reported by Prof. Leaf Huang. Subsequent studies have identified the fact that the cationic lipids activate (or upregulate) the type I interferon genes. The type I interferon signaling pathway is well documented to be highly important in activation and proliferation of killer T-cells. PDS's studies have demonstrated that cationic lipids utilize certain pathways to upregulate type I interferons.

To better understand how the cationic lipids induce potent immune activation without the typically observed inflammatory toxic side effects, a number of further studies were performed.

### **Example 3: Studies to understand the immunological effects of Versamune<sup>®</sup> and resulting T-cell responses**

To examine the immunostimulatory effect of Versamune<sup>®</sup> in the draining lymph node, mice were injected with Versamune<sup>®</sup> nanoparticles in the footpad and inflammatory gene expression was monitored in purified CD11c dendritic cells from the draining or non-draining popliteal lymph nodes after 4h or 24h by Nanostring multiplex analysis.

Among the inflammatory genes examined, the strongest genes up-regulated were those involved in the type I interferon pathway. These included IFN  $\gamma$ , IFN  $\alpha$ , CXCL10, and Stat 1. No induction of classical NF  $\kappa$ B dependent cytokines was observed (Figure 8). This result suggested that Versamune<sup>®</sup> is capable of inducing type I IFN in dendritic cells.

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To directly examine type I IFN production by DC, BMDC were incubated with Versamune® or LPS as a positive control for 18h and type I IFN was measured in the B16-Blue bioassay. There was a significant dose dependent induction of type I IFN in BMDC by Versamune®.

### **Figure 8: Versamune® (R-DOTAP) administration induces *in-vivo* lymph node production of Type I interferons known to be critical for CD8+ T-cell activation.**

Mice were injected with Versamune® or sucrose in the foot pad and draining popliteal lymph nodes were harvested from each mouse and CD11c cells from pooled lymph nodes were sort purified. Relative gene expression from sort purified CD11c cells from Versamune® or LPS injected mice were analyzed using Nano string technology.

#### Cytokine/Chemokine Induction:

In preclinical studies, cytokine and chemokine induction were observed within lymph nodes within 24 hours of a single subcutaneous injection, and persisted for at least 5 days. This is important as cytokines and chemokines are known to be important in the activation and proliferation of T-cells (Figure 9). A separate study performed to evaluate the effect of Versamune® on induction of 20 key cytokines and chemokines demonstrated that, unlike a traditional T-cell activating immunotherapy used as a positive control, that Versamune® injection led to negligible increase in blood cytokine levels above normal baseline levels. This finding was important for 2 reasons:

1. Localized cytokine induction within the lymph nodes at the site of required T-cell activation could enhance activation of primed T-cells.
2. Localized induction of cytokines within the lymph node with negligible presence in the blood circulation minimizes potential for systemic toxicities, and improves clinical tolerability of the immunotherapy.

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**Figure 9: Single subcutaneous injection of PDS0101 leads to sustained and elevated levels of the important CD8+ T-cell activating chemokine CCL2 (MCP-1).**

On day 0, mice (n=3) were injected with PDS0101 formulation.

On the indicated days, the mice were sacrificed and the draining lymph nodes collected.

The draining lymph nodes were homogenized in 100 µl ELISA buffer (10% FBS in PBS) and then analyzed by ELISA assay.

Activation and Proliferation of T-Cells:

As noted above, Versamune® was demonstrated to induce production of various chemokines in lymph nodes. Chemokines play a major role in selectively recruiting monocytes, neutrophils, and T-cells. It was demonstrated that, within a few hours of administering Versamune®, significant T-cell infiltration into the lymph nodes results.

Administration of Versamune® resulted in a visible increase in DLN size of wild type mice and this was due to a steady increase in total cell number over a seven-day period (Figure 10). This increase in total cell number was found to be dependent on the ability of Versamune® to induce type I IFN signaling, as this effect was greatly reduced in IFN R knock-out mice which are devoid of type I interferons.

Type I IFN is known to inhibit lymphocyte egress from lymphoid organs through the up-regulation of CD69, which in turn, inhibits the sphingosine 1 phosphate receptor required for lymphocyte egress. It has now been demonstrated that administration of Versamune® induces type I IFN in the lymph nodes, which in turn, up-regulates CD69 in T cells and natural killer cells resulting in their accumulation in the lymph nodes. This effect facilitates effective interaction of T-cells with dendritic cells leading to effective priming of T-cells.

When Versamune® is administered together with an antigen, strong T-cell priming to recognize the particular antigen, activation and proliferation is facilitated. Figure 11 shows a comparison of T-cell activation between Versamune® and the potent immune activator GM-CSF, demonstrating higher levels of CD8+ T-cell induction by Versamune®.



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**Versamune® administration induces production of chemoattractant chemokines leading to infusion of T-cells into the draining lymph nodes in vivo.** B6 mice were injected with Versamune® or sucrose and draining lymph nodes were harvested from each mouse, and enzymatically digested lymph nodes were assessed for the total cell number at indicated times. Total infiltrating T cells are shown.

Quality of induced T-Cells:

A qualitative factor now known to be highly important in the ability of T-cells to lyse, or kill, infected cells is the quality or potency of T-cells. T-cell quality is directly related to its polyfunctionality, or its ability to induce more than one cytokine. In order to better understand the strength of Versamune®-induced immune responses and their clinical relevance, head-to-head comparisons were made with promising adjuvant-based therapeutic vaccine formulations which had shown promise in preclinical and clinical studies.

We first compared a prototype Versamune®-MUC1 formulation (PDS0103) to two emulsion-based adjuvants in clinical development. Montanide is a proprietary emulsion adjuvant currently being used in peptide-based cancer vaccines. Another potent emulsion-based combination adjuvant formulation specifically designed to induce strong *in-vivo* CD8 T cell responses consists of the 4-adjuvant combination of incomplete Freund's adjuvant, IL-12, GM-CSF, and HBV<sub>128-140</sub> helper epitope (IFA-Cyt). Mice receiving PDS0103 showed strong responses to both V1A and V2A CD8+ stimulatory. In contrast IFA-Cyt generated an equivalent strong response only to V2A, and Montanide induced responses were significantly lower for both V1A and V2A peptides.

Next, the polyfunctionality (ability to produce multiple cytokines) of induced antigen specific CD8 T cells was assessed by measuring their ability to produce cytokines interferon-gamma (IFN- $\gamma$ ), tumor necrosis factor-alpha (TNF- $\alpha$ ) or interleukin-2 (IL-2) by intracellular cytokine staining. In this assay, it was observed that Versamune®-based formulations stimulated the highest percentages of polyfunctional antigen specific CD8 T cells compared to the other two tested emulsion-based lipid formulations (Figure 13), suggesting that Versamune® may induce not only a higher number of CD8 T-cells *in-vivo*, but also potentially qualitatively superior T cells (higher potency) compared to other typical immunotherapy approaches.

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**Figure 11:**

**Versamune® induces high levels of HPV-specific CD8+ T-cells in-vivo.**

Groups of C57BL/6J mice (n=5) were treated with the indicated formulation containing HPV CD8 T cell epitopes mixed with Versamune, GMCSF, or sucrose on day 0 and boosted on day 7. Antigen specific CD8 T cell responses in spleen were assessed 7 days after the second injection by ELISPOT assay.

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**Figure 12: Versamune® (R-DOTAP) formulations containing multiple MUC-1 tumor associated antigens (PDS0103) induce quantitatively superior CD8 T cells responses.**

Groups of AAD mice (n=6) were injected with the indicated formulations containing MUC-1 CD8 T cell epitope antigens on day 0 and boosted on day 7. MUC-1 specific CD8 T cell responses in the spleen were assessed 7 days after the second injection by ELISPOT assay. (A) Number of V1A, V2A, C1A, and C2A specific IFN $\gamma$  producing cells in spleens from mice injected with human muc-1 peptides. (C) Number of V1A, and V2A specific IFN $\gamma$  producing cells in spleen from mice vaccinated with Versamune®, IFN-Cyt or Montanide formulations containing Human MUC-1 peptides.

**Figure 13:  
Versamune® (R-DOTAP) formulations containing multiple MUC-1 tumor associated antigens (PDS0103) induce qualitatively superior CD8 T cells responses.**

Groups of AAD mice (n=6) were injected with the indicated formulations containing MUC-1 CD8 T cell epitope antigens on day 0 and boosted on day 7. Fraction of V1A or PMA/Ionomycin (positive control) stimulated cells in spleen producing multi-cytokine (IFN $\gamma$ , TNF $\alpha$ , and IL-2) among the IFN $\gamma$  producing cells. PMA/Ionomycin is a commonly used *in-vitro* stimulant used to induce cytokine production by T-cells for research purposes.

Enantiomeric Specificity of the Cationic Lipids: Cationic lipids exist as 50:50 racemic mixtures of two asymmetric molecules, each called an enantiomer. Enantiomers are referred to as chiral, meaning they have identical physical and chemical structure and are mirror images of each other. Each of the enantiomers can be regarded as separate chemical entities if they can be demonstrated to possess different biological activity. PDS discovered that the R-enantiomer of the cationic lipid DOTAP is the immuno-active component of the mixture, with the S-enantiomer having weaker immune activating capability. R-DOTAP is the active ingredient now used

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in Versamune®. PDS's products are the first pharmaceutical products to contain a pure cationic lipid enantiomer, and its use in cancer immunotherapy is protected by several issued patents.

### *Altering the Tumor Microenvironment to Overcome Immune Suppression*

The demonstrated ability of Versamune® to induce effective regression of established tumors strongly suggested that cationic lipids, such as R-DOTAP, could facilitate an altering of the tumor micro-environment sufficient to break tumor immune tolerance and induce killing of tumor cells.

#### **Example 4: Studies to understand the effect of the Versamune®-based immunotherapy on the tumor's microenvironment:**

To better understand Versamune®-induced changes within the tumor microenvironment, TC-1 tumor bearing B6 mice were subcutaneously injected on day 0 and day 7 with a Versamune®-based formulation containing a multi-epitope HPV peptide antigen (KF18) and assessed the effector (T-cell) and suppressor T cell (immune suppressive regulatory T-cells) recruitment to the tumor microenvironment on day 26. For comparison, a GMCSF adjuvant-based formulation that has been shown to induce strong CD8+ T cell immune responses *in vivo* in a clinical setting was also evaluated for comparative purposes. ELISPOT analysis (Figure 11) of CD8+ specific T cells (RF9) showed that tumor-bearing mice treated with the Versamune®-based formulation induced a superior sIFN- $\gamma$  ELISPOT response to the RF9 CD8 T cell epitope detected in the spleens 7 days after the second injection.

Mice treated with GMCSF and KF18 stimulated a modest antigen specific T cell ELISPOT response, while, as expected, no response was observed with KF18 antigen alone, GMCSF, or Versamune® alone. To evaluate the tumor microenvironment during Versamune® induced tumor regression, groups of mice were treated with Versamune® and an HPV multi-peptide mixture containing KF18, with or without GMCSF.

To assess the cell types present within the tumor after various treatments, tumors were removed, enzymatically digested and cell populations analyzed by flow cytometry. CD4 helper T-cells, RF9-specific CD8 killer T-cells, FOXP3+ immune suppressive regulatory T-cells (Treg) were analyzed.

Versamune® and HPV peptide treated mice showed the highest percentage of CD8+ T cells within the tumor, and about 50% of these cells were RF9 specific. GMCSF and antigen, or antigen alone did not induce significant CD8 or CD8-RF9 specific T cell infiltration into the tumors. The CD8/CD4 ratio was highest in the Versamune® and HPV mix group and the Treg/RF9 specific T cell ratio within the tumors was dramatically lower in the Versamune® and HPV mix groups (Figure 3F-H).

These data collectively suggest that Versamune®-based formulations induced a quantitatively superior antigen specific T cell response and the cells were actively recruited to the tumors in large numbers promoting anti-tumor responses and eventually alter the tumor's microenvironment to promote regression and elimination of established tumors.

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**Figure 14:**

**Versamune® efficiently alters effector T-cell to immune suppressor T cell ratio within the tumor, therefore promoting tumor regression.**

Groups of C57BL/6J mice (n=5) were injected with the indicated formulation containing a HPV peptide antigen mixed with Versamune®, Versamune® plus GM-CSF, GMCSF, or sucrose on day 0 and injected again on day 7. Mice (n=10) were implanted subcutaneously with  $1 \times 10^5$  TC-1 tumor cells and were given a single dose of each formulation when the tumors reached an average diameter of 4-5 mm on day 11 and tumor growth was monitored. The mice (n=5) were euthanized 8 days post treatment when the mice showed initial signs of regression and the tumors were processed to assess tumor infiltrating cells. Ratio of CD4/CD8 cells and ratio of immune suppressive Treg cells/RF9 CD8+ positive cells in the enzymatically digested tumor cell suspension were evaluated. Data represent mean  $\pm$  SEM from each group (n= 5) and experiments are repeated at least 3 times with similar results.

**Discussion of the effects of the studied attributes of Versamune® on tumor regression**

T-cell-inducing immuno-therapeutic approaches to date have primarily focused on optimizing antigen-specific CD8 T cell induction. These approaches include designs to enhance antigen delivery, uptake and presentation of antigen including approaches such as the use of DNA, viral or intracellular bacterial vectors, nanoparticles, targeting of the antigen to DC through conjugation or pulsing DC in vitro with antigen.

Most of these approaches also include immunostimulatory compounds, typically toll-like-receptor, or TLR, agonists designed to induce the desired cytokine production. Still others include recombinant cytokines like IL-2, IL-12 or GMCSF. PDS's demonstration that the Versamune® platform functions as an activator of the type I interferon pathway explains the ability of Versamune® formulations to induce potent responses without inclusion in the formulation of extraneous cytokines or TLR agonists.

One of the most effective cancer vaccines reported to date consists of:

- 1) Anti-tumor antibody
- 2) IL-2
- 3) Lipid modified peptide
- 4) CpG, and
- 5) Anti-PD1 checkpoint inhibitor.

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This complex multi-component immunotherapy induced strong CD8+ T-cell responses and tumor regression in the HPV-positive TC-1 mouse model. However, in the absence of anti-PD1 checkpoint blockade, this product did not induce complete regression of a TC-1 tumor using the same RF9 peptide antigen as in PDS studies.

In contrast, Versamune® nanoparticles, formulated with HPV peptide antigen KF18, effected complete regression of large TC-1 tumors with a single subcutaneous injection (Figure 15). PDS studies support the projection that Versamune® nanoparticles, combined with protein or peptide antigens, may possess the critical properties for a powerful CD8+ T-cell immunotherapy. These include:

- Effective antigen delivery to the antigen presenting cells of the immune system
- Antigen uptake and cross presentation to CD4+ and CD8+ T-cells
- Intrinsic and specific immunostimulatory properties through activation of type I interferons; and
- Formation of an antigen depot without the severe injection site reactions observed with emulsions and other approaches.

### **Figure 15:**

**Versamune® (R-DOTAP) efficiently alters effector to suppressor T cell ratio promoting effective regression of HPV-positive TC-1 tumors.**

Groups of C57BL/6J mice (n=10) were implanted subcutaneously with  $1 \times 10^5$  TC-1 tumor cells and were given a single dose of a formulation containing HPV CD8 T cell epitopes mixed with Versamune®, Versamune® plus GM-CSF, GMCSF, or sucrose when the tumors reached an average diameter of 4-5 mm on day 11 and tumor growth was monitored. Tumor regression only occurred in the formulations containing Versamune®. Addition of GMCSF to Versamune® appeared to provide no additional benefit.

### Anti-Tumor Efficacy in Advanced and Immuno-Suppressive B16F10 Model:

PDS utilized the aggressive subcutaneous B16F10 animal model in order to study Versamune® anti-tumor efficacy in a well-documented and extremely highly immuno-suppressive tumor microenvironment. This study was a follow-up to above described studies showing potent anti-tumor activity in HPV-positive TC-1 tumors with single doses.

The advanced B16F10 solid tumor model is rarely used in cancer immunotherapy development. More often, the prophylactic model is evaluated, where treatment occurs prior to inoculation with B16F10 tumor cells with the goal of preventing establishment of tumors. This is because once the tumors become well-established, various immune-suppressive mechanisms develop in tumors that are able to suppress T-cell activity. This suppression results in a lack of T-cell anti-tumor effect.

This study utilized an advanced tumor model, with  $3 \times 10^5$  B16F10-luc cells subcutaneously inoculated into mice, to ensure that all mice had established and measurable tumors within 6 days of tumor cell inoculation.

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Examples of reported B16F10 studies using selected other immunotherapeutic technologies:

- *Dendritic cell vaccine:* Dendritic cells pulsed with Trp2 peptide were ineffective in both prophylactic and therapeutic B16F10 tumor models.  
*Intracellular antigen delivery:* HIV TAT protein transduction domain was conjugated to a 472 amino acid sequence from the Trp2 protein or to the Trp2 peptide, and evaluated in a prophylactic model. Both showed better tumor prevention (not therapeutic) compared to the dendritic cell vaccine. This was suggested to be the result of successful intra-cellular delivery of Trp2 by the TAT domain enabling access to the MHC class I pathway.
- *Live virus delivery:* The recombinant adeno-associated virus (rAAV) carrying Trp2 cDNA delivered 22 days before tumor challenge was unable to induce any delay in tumor growth. The addition of other adjuvants, including CpG oligonucleotides and imiquimod failed to provide additional benefit.
- *Adoptive T-cell transfer:* Utilizing Trp2 peptide specific T-cells, adoptive T-cell transfer showed no ability to inhibit tumor growth when studied in the advanced solid tumor model (inoculation of  $2 \times 10^5$  B16F10 cells). However, in the commonly used in-vivo CTL assay to monitor T-cell activity, nearly 98% specific lysis (killing) of injected non-tumor Trp2-expressing targets occurred. This study confirmed the ability of T-cells to identify the antigen-expressing cells and also confirmed the role of the immune-suppressive tumor environment in limiting T-cell efficacy.

In PDS's published study, a single dose of 300nmole Versamune® with 75nmole Trp2 peptide led to a significant increase in the presence of active CD8+ T-cells (IFN- $\gamma$  secreting) and inhibition of tumor growth.

The ability of Versamune® to facilitate intracellular delivery of the Trp2 peptide, and to break the immune tolerance developed by the B16F10 tumor model after only one dose, strongly suggests that Versamune® may potentially provide a superior approach to currently available technologies.

### Combination Immunotherapy

One common clinical goal of administration of immunotherapies to cancer patients is to spark a self-sustaining attack against cancer cells by the T cells, thereby producing long-term clinical benefit. Currently, there are approximately 2,000 immunotherapeutic agents in development. Some cancer patients respond better to the immunotherapies than others, due in part to the factors described above.

The limitations of current immunotherapy technologies as cancer monotherapies are now resulting in increasing testing of multiple cancer drugs in combination. As a result, combination immunotherapy is now generally believed to be the latest frontier in cancer research, and over a thousand such combination therapy clinical trials are currently ongoing. Due to the ability of the checkpoint inhibitors to alter the tumor's immune suppressive environment by blocking the immune checkpoints, the vast majority of the combination trials involve checkpoint inhibitors. However, due to the known need for CD8+ T-cell induction, checkpoint inhibitors have only generally been proven to be optimally clinically successful in a minority of treated patients to date.

Thus far, nivolumab with ipilimumab, which targets PD-1 and CTLA-4 respectively, is the only checkpoint-inhibitor combination approved for clinical use. It was approved to treat metastatic melanoma by the FDA in 2015. In a published study report, this combination was shown to delay tumor progression in melanoma by a median of 11.5 months, almost twice as long as in those on nivolumab alone, and almost four times as long as in people treated with only ipilimumab (Larkin, J. . Then, in October 2017, in a published study report, researchers demonstrated that this combination extended survival times: people with melanoma lived longer on the combined treatments, with 58% still alive after three years compared with 52% of those treated with nivolumab alone.

However, these improved survival rates were paired with reports of increased toxicity. Almost 60% of people taking the combination experienced severe side effects such as colitis or diarrhea — three times as many as those treated with nivolumab, and twice as many as those treated with ipilimumab.

PDS believes that rational design of combination immunotherapies using agents that promote synergy with each other and reduced potential for compounded toxicity would substantially improve potential for combination therapies to deliver improved clinical benefit for cancer patients. PDS believes that the fact that Versamune® appears to activate the appropriate combination of immunological pathways that promote strong CD8+ T-cell

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induction, while also altering the tumor's microenvironment to make the tumor more susceptible to T-cell attack, makes it an ideal complement to the checkpoint inhibitors to enhance their potency. In addition, the differences in mechanism of action between Versamune® and checkpoint inhibitors, as well as the initial demonstrated safety profile of Versamune®, suggests that these combinations may be much better tolerated by patients than many or most other combination therapies involving checkpoint inhibitors.

**Example 5: Studies to understand the effect of Versamune®-based immunotherapy combined with a checkpoint inhibitor in a difficult-to treat preclinical tumor model:**

To determine if checkpoint inhibitors enhanced the anti-tumor response of Versamune®, preclinical studies were performed employing the B16F10 melanoma model. B16F10 is a notoriously difficult tumor to successfully treat with antigen-specific immunotherapy, and monotherapy. One reason is that many of the antigens targeted are self-antigens to which there is some degree of immune tolerance. A previous study performed by PDS demonstrated that TRP2 antigen dose was important in the ability of R-DOTAP to break the tumor's immune tolerance, and a 75µmol dose was demonstrated to inhibit tumor growth but did not induce regression.

The Versamune® plus Trp2 formulation was shown to induce a strong CD8 T cell response. Trp2 is a 9aa tyrosinase related peptide presented by the H-2K<sup>b</sup> molecule (Trp2<sub>180-188</sub>: SVYDFVWL). Subcutaneous injection with Versamune® and Trp2 resulted in strong CD8+ T-cell ELISPOT responses whereas Trp2 alone did not elicit any T-cell response (Figure 16A). To determine whether anti-PD1 treatment synergized with Versamune® and Trp2 treatment in slowing the growth of B16 melanoma, mice were implanted with B16F10 melanoma and injected with Versamune® and Trp2 when tumors reached a size of 3mm. In addition, some groups received 5 injections of anti-PD1 antibody.

Treatment with Versamune® and Trp2 resulted in some slowing of tumor growth compared to naïve or anti-PD1 only groups, which demonstrated no impact on tumor growth.

When Versamune® and Trp2 vaccination was combined with anti-PD1 treatment a synergistic effect was apparent resulting in a dramatic inhibition of tumor growth and an extension of survival (Figure 16 B-C). Tumor growth rate was observed to increase upon halting the anti-PD1 treatment.

These results strongly suggest an effective immunotherapeutic synergy between the Versamune® T-cell activating platform and the checkpoint inhibitors. Versamune® may therefore potentially be successfully combined with a checkpoint inhibitor in human combination immunotherapy strategies. One such trial is anticipated to begin in the second half of 2019.



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**Figure 4: Versamune® (R-DOTAP) synergizes with anti-mouse PD1 checkpoint inhibitor treatment to significantly alter B16 melanoma tumor growth *in vivo*.** Groups of C57BL/6J mice (n=5) were treated with the Versamune® plus TRP2 nanoparticles or TRP2 mixed in sucrose buffer on day 0 and boosted on day 7. A) Antigen specific CD8+ T cell responses in spleen were assessed 7 days after the second vaccination by ELISPOT assay. B-C) Mice were implanted subcutaneously with  $1 \times 10^5$  B16.F10 tumor cells and were subcutaneously injected with two doses of Versamune® plus TRP2 nanoparticles on day 5 and 12 after tumor implant. For anti-mouse PD1 therapy, each mouse received five doses of 200 µg of anti-mouse PD1 antibody delivered i.p. at 3-day intervals starting on day 5 after tumor implant. B) Mean tumor volume  $\pm$  SEM (n=5) in vaccinated or naïve mice. C) Survival over the course of the study.

### **Research and Development Strategy**

PDS focuses on developing a relatively low-risk path to successful clinical development and proof of concept ( POC ). To accomplish this, PDS formed collaborations with a number of experts in tumor biology, immunology and immuno-oncology. These partnerships have historically reduced PDS development and clinical trial expenses. Partnerships also have provided and continue to provide PDS with expert clinical collaborators, who have been intricately involved the design of PDS upcoming Phase 2 clinical trials.

Extensive preclinical studies were performed to understand how cationic lipids interact with the immune system to prime CD8+ T-cell responses. Upon obtaining a good understanding of the immunology of the lipids and their interaction with tumor antigens, PDS optimized and evaluated PDS0101 for safety in extensive toxicology studies. Once safety was confirmed in preclinical models, PDS0101 was subsequently studied in a Phase 1/2a human clinical trial in order to confirm safety and to confirm induction of strong HPV-specific CD8+ T-cell responses in humans.

Based on the successful Phase 1/2a human clinical trial, which corroborated the preceding preclinical data, PDS established clinical supply agreements and collaborations with leaders in the field of immuno-oncology, including the NIH/NCI and Merck & Company, Inc. ( Merck ).

### **Facilities & Manufacturing**

PDS is currently located at the Princeton Innovation Center BioLabs, 303A College Road East, Princeton, NJ 08540, which provides first-rate development facilities for biotech companies. All animal toxicology and efficacy testing is done via third party contracts and collaborations in order to provide maximum flexibility and to minimize operational costs and overhead. This approach allows for independent validation of PDS s data, and PDS believes it has historically been a cost-efficient way to progress its development programs.

PDS does not intend to incur the costs of building, staffing and maintaining manufacturing facilities in the near term. The PDS management team has extensive formulation, manufacturing and operations expertise, including past senior executive management roles in contract drug development and manufacturing. The team plans to utilize its expertise and knowledge to identify suitable contract manufacturers who will be capable of efficiently manufacturing PDS s products.

### **Competition**

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While PDS believes that the Versamune platform provides it with competitive advantages, PDS faces competition from many different sources, including biotechnology and



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pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that PDS may commercialize will have to compete with existing products and therapies as well as new products and immunotherapies that may become available in the future.

There are other organizations working to improve existing immunotherapies, vaccines or delivery methods, or to develop new vaccines, immunotherapies or delivery methods for its selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of the Versamune platform, if approved.

PDS anticipates that it will face intense and increasing competition as new immunotherapies enter the market and advanced technologies become available. PDS expects any products that it develops and commercializes to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

PDS's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that it may develop. PDS's competitors may obtain FDA or other regulatory approval for their products more rapidly than it may obtain approval for its products, which could result in PDS's competitors establishing a strong market position before it is able to enter the market. In addition, the ability of PDS to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

There is currently no approved HPV therapeutic product available for sale globally. PDS has performed an evaluation of HPV therapeutic products in development and considers the products utilizing effective antigen delivery systems to the dendritic cells to be its closest competitors. Some have shown significant promise in on-going clinical studies. PDS believes its top clinical-stage competitors include Advaxis, Transgene, ISA Pharmaceuticals, and Inovio. PDS also has considered companies developing closely related products as competitors, including Etubics, Vaccibody, Admedus, Cel-Sci, Neo-ImmuneTech, Kite Pharma, Immune Design, Dynavax, Bavarian Nordic, Seattle Genetics, and Selecta Biosciences.

### **Intellectual Property**

PDS strives to protect and enhance the proprietary technology, inventions and improvements that are commercially important to its business, including seeking, maintaining, and defending patent rights. PDS also relies on trade secrets relating to its platform and on know-how, continuing technological innovation to develop, strengthen and maintain its proprietary position in the vaccine field. In addition, PDS relies on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. PDS also utilizes trademark protection for its company name, and expects to do so for products and/or services as they are marketed.

PDS has developed numerous patents and patent applications and owns substantial know-how and trade secrets related to its Versamune® platform. As of December, 2018, PDS holds three (3) U.S. patents with granted claims directed to its platform technology and six (6) pending patent applications. These issued patents will expire in 2025, 2031 and 2031. Should the more recently submitted patents currently in prosecution be issued, these will expire in 2033 through 2037 assuming no patent term extensions are granted. As of December, 2018, PDS holds five (5) issued foreign patents and four (4) pending foreign patent application, most of which are issued in multiple countries including Europe, Japan and Australia, and all of which cover compositions of matter and methods of use related to its platform technology. These issued patents will expire in 2031-2034, or later if patent term extension applies.

#### *Licensed Patents*

Licensed Patent Families 1 and 2 cover the Versamune<sup>®</sup>-based product candidates, as they are directed to the currently utilized Versamune<sup>®</sup> ingredient, (R)-DOTAP and its crystal forms, manufacturing methods, and pharmaceutical compositions using the compounds. PDS Biotechnology has an exclusive worldwide license from Merck & Cie to Licensed Patent Families 1 and 2, which are owned by Merck Patent GmbH, for use in the Company's immunotherapy compositions and immunotherapies. Merck & Cie has informed the Company that it has rights to license these patent families through an intra-company agreement with Merck Patent GmbH.

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Licensed Patent Families 1-2 (which cover (R)-DOTAP compositions and crystal forms and methods of use) are also of significance to the Company's future commercial endeavors in using (R)-DOTAP to develop additional immunotherapies and immune modulators.

Licensed Patent Families 3 and 4 are licensed from the US government, and are directed to mucin-1 ( MUC-1 ) antigens to be used by the Company in future cationic lipid immunotherapy or vaccine products. Such immunotherapies can be used for treating a range of cancers, including colon, breast, ovarian, lung and pancreatic cancers.

### **Material Agreements**

#### ***Cooperative Research and Development Agreement for Intramural-PHS Clinical Research with The U.S. Department of Health and Human Services.***

Effective February 2, 2016, PDS entered into a Cooperative Research and Development Agreement (the *CRADA* ) with the U.S. Department of Health and Human Services, as represented by the National Cancer Institute ( *NCI* ), pursuant to which the parties agreed to perform certain research and development activities as defined by the exhibited Research Plan. The principal goal of the CRADA is to determine whether PDS's Versamur® immunotherapeutic technology will be effective for enhancing delivery of cancer vaccines or viral vaccines or other immunotherapies developed by the Vaccine Branch, Center for Cancer Research, NCI, in mouse models and in human clinical trials.

The term of the CRADA is five (5) years, starting February 2, 2016. Pursuant to Appendix A, PDS agreed to provide up to \$1,000,000 but no less than \$500,000 during the first year of the CRADA and up to \$1,000,000 but no less than \$750,000 per year for the remaining years of the CRADA for NCI to use in connection with acquiring technical, statistical, and administrative support for the clinical research activities, as well as to pay for supplies and travel expenses and, upon consent of the parties, to acquire support for a postdoctoral research fellow to conduct additional preclinical studies. The CRADA may be terminated by either party at any time by mutual written consent. Either party may unilaterally terminate the CRADA at any time by providing sixty (60) days written notice. If PDS terminates prior to the completion of all approved or active study protocol(s) pursuant to the CRADA, PDS must supply enough study test product to complete these study protocol(s) unless termination is for safety reasons. If the CRADA is mutually or unilaterally terminated by PDS before its expiration, PDS must pay non-cancellable obligations for personnel for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever is sooner. If PDS suspends development on the test article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, NCI may continue development. In such event, PDS must transfer all information necessary to enable NCI to contract for the manufacture of the test article and grant NCI a nonexclusive, irrevocable, worldwide, paid-up license regarding same.

#### ***Cost Reimbursement Agreement with University of Kentucky Research Foundation - I.***

Effective November 1, 2015, PDS entered into a Cost Reimbursement Agreement (the *Cost Reimbursement Agreement* ) with the University of Kentucky Research Foundation ( *UKRF* ), pursuant to which UKRF agreed to test PDS's preclinical and clinical-stage formulations based on HPV, TARP, MUC-1, Melanoma, WT1 and influenza antigens as specified more fully in the statement of work attached thereto in exchange for an amount not to exceed \$188,350. The Cost Reimbursement Agreement terminated on June 30, 2016 unless extended by written mutual agreement of parties or is terminated by one of the parties. Either party may terminate the Cost Reimbursement Agreement for any reason with thirty (30) days written notice.

#### ***Cost Reimbursement Agreement with University of Kentucky Research Foundation - II.***

Effective November 1, 2015, PDS entered into a Cost Reimbursement Agreement (the "Cost Reimbursement Agreement") with the University of Kentucky Research Foundation ("UKRF"), pursuant to which UKRF agreed to perform a study of the mechanism of action of cationic lipids to better understand how they improve the activity of vaccines in exchange for an amount not to exceed \$19,849. The Cost Reimbursement Agreement terminated on June 30, 2016 unless extended by the written mutual agreement of the parties or is terminated by one of the parties. Either party may terminate the Cost Reimbursement Agreement for any reason with thirty (30) days written notice.

TABLE OF CONTENTS***Patent License Agreement with National Institutes of Health.***

Effective January 5, 2015, PDS entered into a Patent License Agreement (the "Patent License Agreement") with the National Institutes of Health ("NIH") an agency within the Department of Health and Human Services ("HHS"), pursuant to which NIH granted PDS a nonexclusive license to certain patent rights for the development of a therapeutic cancer vaccine specifically in combination with PDS's proprietary Versamun® technology for ovarian and pancreatic cancers. The Patent License Agreement expires when the last licensed patent expires, if the Patent License Agreement is not terminated prior to that date. NIH may terminate the Patent License Agreement if PDS is in default in the performance of any material obligation under the Patent License Agreement. PDS may unilaterally terminate the Patent License Agreement in any country or territory upon sixty (60) days written notice.

PDS agreed to pay NIH: (a) a noncreditable, nonrefundable royalty in the amount of \$30,000 upon execution of the Patent License Agreement; (b) a nonrefundable minimum annual royalty of \$5,000; (c) earned royalties of two percent (2%) on net sales, reducible by a half percent (0.5%) for any earned royalties PDS must pay to third parties; (d) benchmark royalties as follows: (i) \$25,000 upon successful completion of Phase 2 Clinical Trials of a licensed product for ovarian cancer within each licensed territory; (ii) \$50,000 upon initiation of the first Phase 3 Clinical Trial of a licensed product for ovarian cancer within each licensed territory; (iii) \$750,000 upon the first commercial sale in the licensed territory utilizing and/or directed to licensed product(s) and/or licensed process(es) within the licensed patent rights for ovarian cancer; (iv) \$25,000 upon successful completion of Phase 2 Clinical Trials of a licensed product for pancreatic cancer within each licensed territory; (v) \$50,000 upon initiation (first patent dosed) of the first Phase 3 Clinical Trial of a licensed product for pancreatic cancer within each licensed territory; (vi) \$750,000 upon the first commercial sale in the licensed territory utilizing and/or directed to licensed product(s) and/or licensed process(es) within the licensed patent rights for pancreatic cancer; and (e) additional sublicensing royalties for each sublicense required to be approved by NIH of four percent (4%) on the fair market value of any consideration received for granting such sublicense.

***DOTAP Chloride Enantiomer License Agreement with Merck Eprova AG.***

Effective November 1, 2008, PDS entered into a DOTAP Chloride Enantiomer License (the "DOTAP License Agreement") with Merck Eprova AG ("EPRO"), pursuant to which PDS obtained a license from EPRO technology to undertake development of products relating to the R-enantiomer and S-enantiomer of Dotap Chloride for worldwide commercialization in a composition and method of inducing an immune response in a subject by administering at least one cationic lipid with or without an antigen. The DOTAP License Agreement expires on a licensed product-by-licensed product and country-by-country basis until the expiration of the obligation to pay royalties applicable to such licensed product in such country. PDS has the right to unilaterally terminate the DOTAP License Agreement (in its entirety or on a licensed product-by-licensed product or country-by-country basis) at any time for any reason upon nine (9) months prior written notice. In the event PDS is acquired, merged, re-organized or assigns all of its assets to a third party, PDS's successor will pay EPRO CHF 100,000. If PDS's successor elects not to develop the technology further within one (1) year, PDS's successor will pay EPRO a minimum of CHF200,000 or two percent (2%) of the value of the gross business transaction, whichever is greater.

***Clinical Trial Collaboration and Supply Agreement with MSD International GmbH.***

Effective May 19, 2017, PDS entered into a Clinical Trial Collaboration and Supply Agreement (the "CTCSA") with MSD International GmbH ("Merck") pursuant to which PDS and Merck agreed to collaborate in a Phase 2 clinical trial to evaluate the safety, and preliminary efficacy of the concomitant and/or sequenced administration of the combination of a Merck compound (i.e., pembrolizumab, a humanized anti-human PD-1 monoclonal antibody) and a PDS compound (i.e., PDS0101, a cationic lipid-based therapeutic vaccine encapsulating HPV peptides) in patients with recurrent or metastatic head and neck cancer and high-risk human papillomavirus-16 (HPV 16) infection after

failure with platinum-based chemotherapy. The term of the CTCSA commenced on May 19, 2017 and shall continue until the earlier of (i) delivery of the a final study report and (ii) Study Completion (i.e., upon database lock of the Study results) plus three (3) months, or until terminated by either party. In the event the CTCSA is terminated by Merck upon a material breach by PDS, PDS must reimburse Merck for its direct manufacturing costs, such as manufacturing fees, raw materials, direct labor, freight and duty, factory overhead costs and its indirect manufacturing costs, such as allocations of indirect factory overhead and site support costs.



TABLE OF CONTENTS**Government Regulation and Product Approval**

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those PDS is developing. PDS's product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, its activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

**U.S. Product Development Process**

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on PDS. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an investigational new drug application, or an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any product candidate in humans, the product enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor

must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed

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clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, PDS cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND and also require IRB approval. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in seriously ill subjects.
- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population generally at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators of potential safety risks, from clinical trials or any other source, including for serious and unexpected adverse events and serious and unexpected suspected adverse reactions, any findings from other studies suggesting a significant risk in humans exposed to the drug, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but no later than within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not

be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an

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unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

### *U.S. Review and Approval Processes*

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. For approved drugs, including BLA-licensed biological products, PDUFA also imposes an annual PDUFA program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on BLAs for products designated as orphan drugs, unless the application for the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP

requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than PDS interprets the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

### ***Post-Approval Requirements***

Any products for which PDS receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also

subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings

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and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of its product candidates under development.

### *Other U.S. Healthcare Laws and Compliance Requirements*

In the United States, PDS's activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. PDS's practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. However, the lack of uniform court interpretation of the anti-kickback statute makes compliance with the law difficult. Violations of the federal anti-kickback statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

The Criminal Healthcare Fraud statute, 18 U.S.C. § 1347 prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The qui tam provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. government. Recently, several

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pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

PDS may be subject to data privacy and security regulations by both the federal government and the states in which it conducts its business. HIPAA, as amended by the HITECH Act, and its respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year and up to an aggregate of \$1 million per year for knowing failures. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, PDS must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing,

pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of PDS's activities are potentially subject to federal and state consumer protection and unfair competition laws.

If PDS operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, PDS may be subject to penalties, including without

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limitation, civil, criminal and/or administrative penalties; damages; fines; disgorgement; exclusion from participation in government programs, such as Medicare and Medicaid; injunctions; private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow it to enter into government contracts; contractual damages; reputational harm; administrative burdens; diminished profits and future earnings; and the curtailment or restructuring of its operations; any of which could adversely affect PDS's ability to operate its business and its results of operations.

*Coverage, Pricing and Reimbursement*

Significant uncertainty exists as