PROVECTUS BIOPHARMACEUTICALS, INC.
Form S-1/A
November 22, 2016
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As filed with the Securities and Exchange Commission on November 22, 2016

Registration No. 333-213986

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

PROVECTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	90-0031917
(State or other jurisdiction of incorporation)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification No.)

7327 Oak Ridge Hwy., Knoxville, Tennessee 37931

(Address of Principal Executive Offices)

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Timothy C. Scott

President

7327 Oak Ridge Hwy., Knoxville, Tennessee 37931

(Address of Principal Executive Offices)

(866) 594-5999

(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 the registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

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

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

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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

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CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[5]
Units, each consisting of (i) shares of common stock, par value $0.001 per share, and (ii) warrants to purchase one share of common stock (Units)	$21,000,000 (2)	$2,433.90
Non-transferable Rights to purchase Units[2]		
Common stock included as part of the Units	Included with Units above	
Warrants included as part of the Units[3]	Included with Units above	
Common stock issuable upon exercise of the Warrants included in the Units[1][4]	$23,100,000	$2,677.29
Pre-Funded Warrants in lieu of common stock included in Units[3]	Included with Units above	
Common stock issuable upon exercise of Pre-Funded Warrants[3][4]	Included with Units above	
Total	**$44,100,000**	**$5,111.19**

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933 (the Act) and assumes that the registrant elects to increase the size of the offering by 20% as discussed in the registration statement on Form S-1.

(2) Non-transferable Rights to purchase Units are being issued without consideration. Pursuant to Rule 457(g) under the Act, no separate registration fee is required for the Rights because the Rights are being registered in the same registration statement as the common stock of the registrant underlying the Rights.

(3) Pursuant to Rule 457(g) of the Act, no separate registration fee is required for the Warrants because the Warrants are being registered in the same registration statement as the common stock of the registrant issuable upon exercise of the Warrants.

(4) In addition to the shares of common stock set forth in this table, pursuant to Rule 416 under the Act, this registration statement also registers such indeterminate number of shares of common stock as may become issuable upon exercise of the Warrants as the same may be adjusted as a result of their customary anti-dilution provisions.

(5) $5,111.19 was previously paid on October 5, 2016.

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

SUBJECT TO COMPLETION, DATED NOVEMBER 22, 2016

PRELIMINARY PROSPECTUS

Subscription Rights to Purchase Up to Units

Consisting of an Aggregate of Up to Shares of Common Stock

and Warrants to Purchase Up to Shares of Common Stock

at a Subscription Price of $ Per Unit

We are distributing to holders of our common stock, par value $0.001 per share, at no charge, non-transferable subscription rights to purchase units. Each unit, which we refer to as a Unit and collectively as the Units, consists of shares of common stock and warrants representing the right to purchase one share of our common stock, which we refer to as the Warrants. Each whole Warrant will be exercisable for one share of our common stock. We refer to the offering that is the subject of this prospectus as the Rights Offering. In the Rights Offering, you will receive one subscription right for each shares of common stock owned at 5:00 p.m., Eastern Time, on , 2016, the record date of the Rights Offering, or the Record Date.

Each subscription right will entitle you to purchase one Unit, which we refer to as the Basic Subscription Right, at a subscription price per Unit of $, which we refer to as the Subscription Price; *provided, however*, that we may reduce the Subscription Price by up to 20% as provided herein. Each whole Warrant entitles the holder to purchase one share of common stock at an exercise price of $ per share from the date of issuance through its expiration five years from the date of issuance. If you exercise your Basic Subscription Rights in full, and any portion of the Units remain available under the Rights Offering, you will be entitled to an over-subscription privilege to purchase a portion of the unsubscribed Units at the Subscription Price, subject to proration, which we refer to as the Over-Subscription Privilege.

For certain investors whose subscriptions may result in the purchaser beneficially owning more than 4.99% of our outstanding common stock, such investors may elect to receive in the Rights Offering, in lieu of shares of common stock, certain pre-funded warrants, which we refer to as the Pre-Funded Warrants, to purchase the same amount of shares of common stock. Each Pre-Funded Warrant will have an exercise price of $0.01, and the subscription price per Unit for any such electing investors will be reduced to $ (which equals the Subscription Price for the other Units sold in the Rights Offering, less the $0.01 exercise price for each Pre-Funded Warrant). This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Warrants and the Pre-Funded

Warrants.

The Subscription Rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on , 2016, unless the Rights Offering is extended or earlier terminated by the Company in its sole discretion; *provided, however,* that we may not extend the expiration date of the Rights Offering by more than 30 days past the original expiration date. If you exercise your Subscription Rights, you may revoke such exercise before the expiration date of the Rights Offering by following the instructions herein. If the expiration date is extended, you may revoke your exercise of Subscription Rights at any time until the final expiration date as so extended. If we terminate the Rights Offering, all subscription payments received will be returned as soon as practicable thereafter without interest or deduction.

We have engaged Maxim Group LLC to act as the sole dealer-manager in the Rights Offering. We have not entered into any standby purchase agreement or other similar arrangement in connection with the Rights Offering. The Rights Offering is being conducted on a best-efforts basis and there is no minimum amount of proceeds necessary to be received in order for us to close the Rights Offering.

Shares of our common stock are listed on the NYSE MKT under the symbol PVCT, although NYSE MKT suspended trading in our common stock and commenced delisting procedures on October 13, 2016. We intend to appeal the NYSE MKT decision to commence delisting procedures, and on October 20, 2016, we submitted a request for a review of such delisting determination. Effective October 17, 2016, our common stock trades on the OTCQB under the symbol PVCT. On October 26, 2016, the closing sale price for our common stock was $0.06 per share. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. The Subscription Rights are non-transferrable and will not be listed for trading on the NYSE MKT or any other stock exchange or market. You are urged to obtain a current price quote for our common stock before exercising your subscription rights.

	Per Unit	**Total[(1)]**
Subscription price	$	$
Dealer-Manager fees and expenses[(2)]	$	$
Proceeds, before expenses, to us	$	$

(1) Assumes the Rights Offering is fully subscribed, but excludes proceeds from the exercise of Warrants included within the Units.

(2) In connection with this Rights Offering, we have agreed to pay to the dealer-manager a cash fee equal to 8% of the dollar amount of the Units sold to holders of Subscription Rights. We will provide to the dealer-manager upon completion of the Rights Offering a non-accountable expense allowance equal to $100,000 for expenses incurred in connection with the Rights Offering and other consideration described under Plan of Distribution. We advanced $30,000 against such non-accountable expense allowance to Maxim Group LLC upon its engagement as a dealer-manager; provided that Maxim Group LLC will promptly reimburse to us any portion of the advance not used for actual out-of-pocket expenses if the Rights Offering is not completed. See Plan of Distribution for more information.

Our board of directors is making no recommendation regarding your exercise of the Subscription Rights.

Investing in our securities involves a high degree of risk. You should carefully consider all of the information set forth in this prospectus, including the section entitled Risk Factors beginning on page 19 of this prospectus, before exercising your subscription rights.

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

the contrary is a criminal offense.

Dealer-Manager

Maxim Group LLC

The date of this prospectus is , 2016

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The distribution of this prospectus and the offering and sale of our securities in certain jurisdictions may be restricted by law. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus may contain forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as may, will, would, should, expects, plans, anticipates, could, intends, target, projects, contemplates, believe assume, intend, potential, continue or other similar words or the negative of these terms. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described under the caption Risk Factors herein. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Also, the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We have included important factors in the cautionary statements included in this prospectus, including under the caption entitled Risk Factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

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QUESTIONS AND ANSWERS RELATING TO THE RIGHTS OFFERING

The following are examples of what we anticipate will be common questions about the Rights Offering. The answers are based on selected information from this prospectus. The following questions and answers do not contain all of the information that may be important to you and may not address all of the questions that you may have about the Rights Offering. This prospectus contains more detailed descriptions of the terms and conditions of the Rights Offering and provides additional information about us and our business, including potential risks related to the Rights Offering, our common stock and our business. In this prospectus, all references to the Company, we, us and our refer to Provectus Biopharmaceuticals, Inc., a Delaware corporation, and its subsidiaries unless the context otherwise requires or where otherwise indicated.

Why are we conducting the Rights Offering?

We are conducting the Rights Offering:

- to raise additional capital for clinical development, including our ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma;
- for working capital; and
- for general corporate purposes.

What is the Rights Offering?

We are distributing, at no charge, to record holders of our common stock, non-transferable Subscription Rights to purchase Units at a price of $ per Unit. The Subscription Rights will not be tradable. Each Unit consists of shares of common stock and Warrants representing the right to purchase one share of common stock. Upon closing of the Rights Offering, the common stock and Warrants will immediately separate. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. You will receive one Subscription Right to purchase one Unit for every shares of common stock that you owned as of 5:00 p.m., Eastern Time, on the Record Date. Each Subscription Right entitles the record holder to a Basic Subscription Right and an Over-Subscription Privilege. If the Rights Offering is oversubscribed (after taking into account all Over-Subscription requests), we may increase the size of the Rights Offering, in our sole discretion, by up to 20%, and we will allocate such increased amount pro rata among our stockholders who exercise both their Basic Subscription Right and their Over-Subscription Privilege. The Subscription Rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on , 2016, unless extended or earlier terminated by the Company in its sole discretion; provided, however, that we may not extend the expiration date of the Rights Offering by more than 30 days past the original expiration date.

What are the Basic Subscription Rights?

For every shares you owned as of the Record Date, you will receive one Basic Subscription Right, which gives you the opportunity to purchase one Unit, consisting of shares of common stock and Warrants to purchase one share of common stock for a price of $ per Unit. For example, if you owned 100 shares of common stock as of the Record Date, you will receive Subscription Rights and will have the right to purchase shares of our common stock and Warrants to purchase shares of our common stock for $ per Unit (or a total payment of $). You may exercise all or a portion of your Basic Subscription Rights or you may choose not to exercise any Basic Subscription Rights at all.

If you are a record holder of our common stock, the number of shares you may purchase pursuant to your Basic Subscription Rights is indicated on the enclosed Rights Certificate. If you hold your shares in the name of a broker, dealer, bank, or other nominee who uses the services of the Depository Trust Company, or DTC, you will

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not receive a Rights Certificate. Instead, DTC will issue one Subscription Right to your nominee record holder for every shares of our common stock that you beneficially own as of the Record Date. If you are not contacted by your nominee, you should contact your nominee as soon as possible.

What is the Over-Subscription Privilege?

If you exercise your Basic Subscription Rights in full, you may also choose to exercise your Over-Subscription Privilege to purchase a portion of any Units that the other record holders do not purchase through the exercise of their Basic Subscription Rights. You should indicate on your Rights Certificate, or the form provided by your nominee if your shares are held in the name of a nominee, how many additional Units you would like to purchase pursuant to your Over-Subscription Privilege.

If sufficient Units are available, we will seek to honor your Over-Subscription request in full. If Over-Subscription requests exceed the number of Units available, however, we will allocate the available Units pro rata among the record holders exercising the Over-Subscription Privilege in proportion to the number of shares of our common stock each of those record holders owned on the Record Date, relative to the number of shares owned on the Record Date by all record holders exercising the Over-Subscription Privilege. If this pro rata allocation results in any record holders receiving a greater number of Units than the record holder subscribed for pursuant to the exercise of the Over-Subscription Privilege, then such record holder will be allocated only that number of Units for which the record holder oversubscribed, and the remaining Units will be allocated among all other record holders exercising the Over-Subscription Privilege on the same pro rata basis described above. The proration process will be repeated until all Units have been allocated. See The Rights Offering Limitation on the Purchase of Units for a description of certain stock ownership limitations.

To properly exercise your Over-Subscription Privilege, you must deliver to the Subscription Agent the subscription payment related to your Over-Subscription Privilege before the Rights Offering expires. See The Rights Offering The Subscription Rights Over-Subscription Privilege. To the extent you properly exercise your Over-Subscription Privilege for an amount of Units that exceeds the number of unsubscribed Units available to you, any excess subscription payments will be returned to you within 10 business days after the expiration of the Rights Offering, without interest or deduction.

Broadridge Corporate Issuer Solutions, Inc., our Subscription Agent for the Rights Offering, will determine the Over-Subscription allocation based on the formula described above.

What are the terms of the Warrants?

Each Warrant entitles the holder to purchase one share of common stock at an exercise price of $ per share from the date of issuance through their expiration five years from the date of issuance. The Warrants will be exercisable for cash, or, solely during any period when a registration statement for the exercise of the Warrants is not in effect, on a cashless basis. After the one-year anniversary of the date of issuance, we may redeem the Warrants for $0.001 per Warrant if the volume weighted average price of our common stock is above $ per share, 250% of the exercise price, for each of 10 consecutive trading days.

Are the Warrants listed?

We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT.

What are the terms of the Pre-Funded Warrants?

The Pre-Funded Warrants will only be issued to certain investors whose subscriptions for Units in the Rights Offering may result in the purchaser beneficially owning more than 4.99% of our outstanding common

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stock following the consummation of the Rights Offering, and who elect to receive Pre-Funded Warrants in lieu of shares of common stock underlying the Units for which the investors have subscribed. You will not be eligible to elect to receive Pre-Funded Warrants, except to the extent that your beneficial ownership could exceed 4.99% of the shares of common stock outstanding following the consummation of the Rights Offering.

Each Pre-Funded Warrant entitles the holder to purchase one share of common stock at an exercise price of $0.01 per share, and the subscription price per Unit for any such electing investors will be reduced to $ (which equals the Subscription Price for the other Units sold in the Rights Offering, less the $0.01 exercise price for each Pre-Funded Warrant). Each Pre-Funded Warrant will be exercisable from the date of issuance through its expiration on , 2021. The Pre-Funded Warrants will be exercisable by paying the exercise price in cash or on a cashless basis in accordance with the terms of the Pre-Funded Warrants. The Pre-Funded Warrants will not be listed for trading on any stock exchange or market. The Pre-Funded Warrants do not confer upon the holder any voting or any other rights of a stockholder of the Company.

What are the requirements to list the Warrants on the NYSE MKT?

In order to satisfy the initial listing requirement for Warrants on the NYSE MKT, we must (i) issue at least 200,000 Warrants, (ii) maintain the listing of the common stock underlying the Warrants on NYSE MKT, (iii) have at least 100 public Warrant holders. In addition, NYSE MKT has advised us that NYSE MKT has a minimum price requirement to admit a new warrant of $0.20. There can be no assurance that we will be able to satisfy the requirements to list the Warrants on the NYSE MKT.

Will fractional shares be issued upon exercise of Subscription Rights or upon the exercise of Warrants?

No. We will not issue fractional shares of common stock in the Rights Offering. We will only distribute Subscription Rights to acquire whole Units, and rights holders will only be entitled to purchase a number of Units representing a whole number of shares and Warrants, rounded down to the nearest whole number of shares or Warrants, as applicable, a holder would otherwise be entitled to purchase. Any excess subscription payments received by the Subscription Agent will be returned within 10 business days after expiration of the Rights Offering, without interest or deduction.

What effect will the Rights Offering have on our outstanding common stock?

Based on shares of common stock outstanding as of , 2016 assuming no other transactions by us involving our common stock prior to the expiration of the Rights Offering, if the Rights Offering is fully subscribed shares of our common stock will be issued and outstanding and Warrants to purchase an additional shares of our common stock will be outstanding. The exact number of shares of common stock and Warrants that we will issue in this Rights Offering will depend on the number of Units that are subscribed for in the Rights Offering.

How was the Subscription Price determined?

Our board of directors determined the Subscription Price upon on the recommendation of a pricing committee comprised of two members of our board of directors. In determining the Subscription Price to recommend to our board of directors for approval, the pricing committee considered a number of factors, including:

the likely cost of capital from other sources;

the price at which our stockholders might be willing to participate in the Rights Offering;

historical and current trading prices for our common stock;

our need for liquidity and capital; and

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the desire to provide an opportunity to our stockholders to participate in the Rights Offering on a pro rata basis.

In conjunction with its review of these factors, the pricing committee also reviewed a range of discounts to market value represented by the subscription prices in various prior rights offerings of other public companies.

The Subscription Price is not intended to bear any relationship to the book value of our assets or our past operations, cash flows, losses, financial condition, net worth, or any other established criteria used to value securities. You should not consider the Subscription Price to be an indication of the fair value of our common stock offered in the Rights Offering.

We may, in our sole discretion, reduce the Subscription Price by up to 20%, and if we elect to reduce the Subscription Price per Unit, you may elect to receive (i) proportionally more Units based on the payment amount we received from you in connection with the exercise of your Subscription Rights or (ii) an amount in cash equal to the difference between your total payment amount at the original Subscription Price and the payment amount that would have been due for the number of Units for which you subscribed at the reduced Subscription Price. If you elect to receive cash in lieu of additional Units, the Company will remit such payment within 10 business days after the expiration date of the Rights Offering, without interest or deduction.

In the event that we determine to reduce the subscription price, we will file with the Commission and mail to stockholders of record as of the record date for the Rights Offering a prospectus supplement disclosing the reduced subscription price. The expiration date of the Rights Offering will be no less than seven calendar days after the date of such prospectus supplement disclosing a reduction in subscription price.

The market price of our common stock may decline during or after the Rights Offering. You should obtain a current price quote for our common stock before exercising your Subscription Rights and make your own assessment of our business and financial condition, our prospects for the future, the terms of the Rights Offering, the information in this prospectus and the other considerations relevant to your circumstances. In addition, there is no established trading market for the Warrants to be issued pursuant to this Rights Offering, and the Warrants may not be widely distributed. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT.

Am I required to exercise all of the Basic Subscription Rights I receive in the Rights Offering?

No. You may exercise any number of your Basic Subscription Rights, or you may choose not to exercise any Basic Subscription Rights. If you do not exercise any Basic Subscription Rights, the number of shares of our common stock you own will not change. However, if you choose not to exercise your Basic Subscription Rights in full and other holders of Subscription Rights do exercise, your proportionate ownership interest in our company will decrease. If you do not exercise your Basic Subscription Rights in full, you will not be entitled to exercise your Over-Subscription Privilege.

How soon must I act to exercise my Subscription Rights?

If you received a Rights Certificate and elect to exercise any or all of your Subscription Rights, the Subscription Agent must receive your completed and signed Rights Certificate and payment for both your Basic Subscription

Rights and any Over-Subscription Privilege you elect to exercise before the Rights Offering expires on , 2016, at 5:00 p.m., Eastern Time. If you hold your shares in the name of a broker, dealer, bank, or other nominee, your nominee may establish a deadline before the expiration of the Rights Offering by which you must provide it with your instructions to exercise your Subscription Rights, along with the required subscription payment.

May I transfer my Subscription Rights?

No. The Subscription Rights may be exercised only by the stockholders to whom they are distributed, and they may not be sold, transferred, assigned or given away to anyone else, other than by operation of law. As a

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result, Rights Certificates may be completed only by the stockholder who receives the certificate. We do not intend to apply for the listing of the Subscription Rights on the NYSE MKT or any other securities exchange or recognized trading market.

Will our directors and executive officers participate in the Rights Offering?

To the extent they hold common stock as of the Record Date, our directors and executive officers will be entitled to participate in the Rights Offering on the same terms and conditions applicable to other Rights holders. While none of our directors or executive officers has entered into any binding commitment or agreement to exercise Subscription Rights received in the Rights Offering, Peter R. Culpepper, our Interim Chief Executive Officer and Chief Operating Officer, Timothy C. Scott, our President and a member of our board of directors, and Eric A. Wachter, our Chief Technology Officer and a member of our board of directors, have indicated an interest in participating in the offering.

Has the board of directors made a recommendation to stockholders regarding the Rights Offering?

No. Our board of directors is making no recommendation regarding your exercise of the Subscription Rights. Rights holders who exercise Subscription Rights will incur investment risk on new money invested. We cannot predict the price at which our shares of common stock and, if listed, the Warrants will trade after the Rights Offering. On October 26, 2016, the closing price of our common stock was $0.06 per share. The market price for our common stock may be above the Subscription Price or may be below the Subscription Price. If you exercise your Subscription Rights, you may not be able to sell the underlying shares of our common stock (or Warrants) in the future at the same price or a higher price. You should make your decision based on your assessment of our business and financial condition, our prospects for the future, the terms of the Rights Offering, the information contained in this prospectus and other considerations relevant to your circumstances. See Risk Factors for discussion of some of the risks involved in investing in our securities.

How do I exercise my Subscription Rights?

If you are a stockholder of record (meaning you hold your shares of our common stock in your name and not through a broker, dealer, bank, or other nominee) and you wish to participate in the Rights Offering, you must deliver a properly completed and signed Rights Certificate, together with payment of the Subscription Price for both your Basic Subscription Rights and any Over-Subscription Privilege you elect to exercise, to the Subscription Agent before 5:00 p.m., Eastern Time, on , 2016. If you are exercising your Subscription Rights through your broker, dealer, bank, or other nominee, you should promptly contact your broker, dealer, bank, or other nominee and submit your subscription documents and payment for the Units subscribed for in accordance with the instructions and within the time period provided by your broker, dealer, bank or other nominee.

What if my shares are held in street name ?

If you hold your shares of our common stock in the name of a broker, dealer, bank, or other nominee, then your broker, dealer, bank, or other nominee is the record holder of the shares you beneficially own. The record holder must exercise the Subscription Rights on your behalf. Therefore, you will need to have your record holder act for you.

If you wish to participate in this Rights Offering and purchase Units, please promptly contact the record holder of your shares. We will ask the record holder of your shares, who may be your broker, dealer, bank, or other nominee, to notify you of this Rights Offering.

What form of payment is required?

You must timely pay the full Subscription Price for the full number of Units you wish to acquire pursuant to the exercise of Subscription Rights by delivering to the Subscription Agent a:

personal check drawn on a U.S. bank;

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certified check drawn on a U.S. bank; or

wire transfer.

If you send payment by personal uncertified check, payment will not be deemed to have been delivered to the Subscription Agent until the check has cleared.

If you send a payment that is insufficient to purchase the number of Units you requested, or if the number of Units you requested is not specified in the forms, the payment received will be applied to exercise your Subscription Rights to the fullest extent possible based on the amount of the payment received.

When will I receive my new shares of common stock and Warrants?

The Subscription Agent will arrange for the issuance of the common stock and Warrants as soon as practicable after the expiration of the Rights Offering, payment for the Units subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms of the Rights Offering have been effected. All shares of common stock and Warrants that you purchase in the Rights Offering will be issued in book-entry, or uncertificated, form meaning that you will receive a direct registration (DRS) account statement from our transfer agent reflecting ownership of these securities if you are a holder of record of shares or warrants. If you hold your shares in the name of a broker, dealer, bank, or other nominee, DTC will credit your account with your nominee with the securities you purchase in the Rights Offering. Broadridge Corporate Issuer Solutions, Inc. is acting as the warrant agent in this offering and is also the transfer agent for our common stock.

When will I receive my Pre-Funded Warrants?

If you elect to receive any Pre-Funded Warrants, the Subscription Agent will arrange for the issuance of the Pre-Funded Warrants as soon as practicable after the expiration of the Rights Offering, payment for the Units subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms of the Rights Offering have been effected. All Pre-Funded Warrants will be issued in physical form.

After I send in my payment and Rights Certificate to the Subscription Agent, may I cancel my exercise of Subscription Rights?

Yes. If you exercise your Subscription Rights, you may revoke such exercise before the expiration date of the Rights Offering by following the instructions herein. If the expiration date is extended, you may revoke your exercise of Subscription Rights at any time until the final expiration date as so extended. See The Rights Offering Revocation Rights.

How much will our company receive from the Rights Offering?

Assuming that all Units are sold in the Rights Offering, we estimate that the net proceeds from the Rights Offering will be approximately $ million, based on the Subscription Price of $ per Unit, after deducting fees and expenses payable to the dealer-manager, and after deducting other expenses payable by us and excluding any proceeds received upon exercise of any Warrants. If all Warrants included in the Units are exercised at the exercise price of $ per share, we will receive an additional $ million. We intend to use approximately $15 million of the net proceeds from the exercise of Subscription Rights for clinical development, including approximately

$5 million to complete our ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma, approximately $5 million to complete our phase 1b/2 combination study of PV-10 and Merck s KEYTRUDA in late stage melanoma and approximately $5 million to complete our phase 1b/2 study of PV-10 in liver cancer, and we intend to use the remaining net proceeds for working capital and general corporate purposes. See Use of Proceeds.

Are there risks in exercising my Subscription Rights?

Yes. The exercise of your Subscription Rights involves risks. Exercising your Subscription Rights involves the purchase of additional shares of our common stock and Warrants to purchase shares of our common stock,

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and you should consider this investment as carefully as you would consider any other investment. The market price of our common stock may not exceed the Subscription Price, and the market price of our common stock may decline during or after the Rights Offering. The Warrants may not be listed on the NYSE MKT and, even if listed, a market for the Warrants may not develop. You may not be able to sell shares of our common stock or Warrants purchased in the Rights Offering at a price equal to or greater than the Subscription Price. In addition, you should carefully consider the risks described under the heading Risk Factors for discussion of some of the risks involved in investing in our securities.

Are there any conditions to the completion of the Rights Offering?

The only condition to completion of the Rights Offering is the availability of a sufficient number of authorized shares of common stock under our certificate of incorporation, as amended. We are holding a special meeting of stockholders on November 28, 2016 to vote on proposals to (1) approve and adopt an amendment to our certificate of incorporation, as amended, to increase the number of authorized shares of common stock that we are authorized to issue from 400,000,000 to 1,000,000,000 shares and (2) authorize our board of directors to amend our certificate of incorporation, as amended, to effect a reverse stock split of our common stock at a ratio of between 1-for-10 and 1-for-50, such ratio to be determined by our board of directors in its sole discretion. We are not requiring a minimum subscription to complete the Rights Offering.

Can the board of directors terminate or extend the Rights Offering?

Yes. Our board of directors may decide to terminate the Rights Offering at any time and for any reason before the expiration of the Rights Offering. We also have the right to extend the Rights Offering for additional periods in our sole discretion; provided, however, that we may not extend the expiration date of the Rights Offering by more than 30 days past the original expiration date. We do not presently intend to extend the Rights Offering. We will notify stockholders and the public if the Rights Offering is terminated or extended by issuing a press release announcing the extension no later than 9:00 a.m., Eastern Time, on the next business day after the most recently announced expiration date of the Rights Offering. We may also decide, in our sole discretion, to increase the size of the Rights Offering by up to 20% if the Rights Offering is oversubscribed (after taking into account all Over-Subscription requests), and we will allocate such increased amount pro rata among our stockholders who exercise both their Basic Subscription Right and their Over-Subscription Privilege.

If the Rights Offering is not completed or is terminated, will my subscription payment be refunded to me?

Yes. The Subscription Agent will hold all funds it receives in a segregated bank account until completion of the Rights Offering. If we do not complete the Rights Offering, all subscription payments received by the Subscription Agent will be returned as soon as practicable after the termination or expiration of the Rights Offering, without interest or deduction. If you own shares in street name, it may take longer for you to receive your subscription payment because the Subscription Agent will return payments through the record holder of your shares.

How do I exercise my Rights if I live outside the United States?

The Subscription Agent will hold Rights Certificates for stockholders having addresses outside the United States. To exercise Subscription Rights, foreign stockholders must notify the Subscription Agent and timely follow other procedures described in the section entitled The Rights Offering Foreign Stockholders.

What fees or charges apply if I purchase shares in the Rights Offering?

We are not charging any fee or sales commission to issue Subscription Rights to you or to issue shares of common stock or Warrants to you if you exercise your Subscription Rights. If you exercise your Subscription Rights through a broker, dealer, bank, or other nominee, you are responsible for paying any fees your broker, dealer, bank, or other nominee may charge you.

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What are the U.S. federal income tax consequences of receiving and/or exercising my Subscription Rights?

For U.S. federal income tax purposes, we do not believe you should recognize income or loss in connection with the receipt or exercise of Subscription Rights in the Rights Offering. You should consult your tax advisor as to the tax consequences of the Rights Offering in light of your particular circumstances. For a detailed discussion, see Material U.S. Federal Income Tax Consequences.

To whom should I send my forms and payment?

If your shares are held in the name of a broker, dealer, bank, or other nominee, then you should send your subscription documents and subscription payment to that broker, dealer, bank, or other nominee. If you are the record holder, then you should send your subscription documents, Rights Certificate, and subscription payment to the Subscription Agent by hand delivery, first class mail or courier service to:

By Mail:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS Re-Organization Dept.

P.O. Box 1317

Brentwood, NY 11717

By Hand Delivery or Overnight Courier Excluding USPS:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS IWS

51 Mercedes Way

Edgewood, NY 11717

You or, if applicable, your nominee are solely responsible for completing delivery to the Subscription Agent of your subscription documents, Rights Certificate and payment. You should allow sufficient time for delivery of your subscription materials to the Subscription Agent and clearance of payment before the expiration of the Rights Offering at 5:00 p.m. Eastern Time on , 2016.

Whom should I contact if I have other questions?

If you have other questions or need assistance, please contact the Information Agent or the dealer-manager for the Rights Offering:

Maxim Group LLC

405 Lexington Avenue

New York, New York 10174

Attention Syndicate Department

Email: syndicate@maximgrp.com

Telephone: (212) 895-3745

Broadridge Corporate Issuer Solutions, Inc.

(844) 695-1509

(720) 414-6879 (toll number)

Who is the dealer-manager?

Maxim Group LLC will act as dealer-manager for the Rights Offering. Under the terms and subject to the conditions contained in the dealer-manager agreement, the dealer-manager will use its best efforts to solicit the exercise of Subscription Rights. We have agreed to pay the dealer-manager certain fees and other consideration for acting as dealer-manager and to reimburse the dealer-manager for certain out-of-pocket expenses incurred in connection with the Rights Offering. The dealer-manager is not underwriting or placing any of the Subscription Rights or the shares of our common stock or Warrants being issued in the Rights Offering and is not making any recommendation with respect to such Subscription Rights (including with respect to the exercise or expiration of such Subscription Rights), shares of common stock or Warrants.

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PROSPECTUS SUMMARY

This summary highlights the information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information that you should consider before deciding whether to exercise your Subscription Rights. You should carefully read this entire prospectus, including the information contained under the heading Risk Factors, and all other information included in this prospectus in their entirety before you decide to exercise your Subscription Rights.

Provectus Biopharmaceuticals, Inc.

Overview

We are a development-stage biopharmaceutical company that is primarily engaged in developing ethical pharmaceuticals for oncology and dermatology indications. Our goal is to develop alternative treatments that are safer, more effective, less invasive and more economical than conventional therapies. We develop and intend to license or market and sell our two prescription drug candidates, PV-10 and PH-10. We also hold patents and other intellectual property which we believe may be used in over-the-counter products, which we refer to as OTC products, and various other non-core technologies. We have transferred all our intellectual property related to OTC products and non-core technologies to our subsidiaries and have designated such subsidiaries as non-core to our primary business of developing our oncology and dermatology prescription drug candidates.

Prescription Drugs

We focus on developing our prescription drug candidates PV-10 and PH-10. We are developing PV-10 for treatment of several life threatening cancers including metastatic melanoma, liver cancer, and breast cancer. We are developing PH-10 to provide minimally invasive treatment of chronic severe skin afflictions such as psoriasis and atopic dermatitis, a type of eczema. We believe that our prescription drug candidates will be safer and more specific than currently existing products. All of our prescription drug candidates are in either the pre-clinical or clinical trial stage.

The table below sets forth our two prescription drug candidates and our progress in developing those candidates for the indications shown:

PV-10	Phase 3 study in progress: Opened recruitment in April 2015
Melanoma*	Phase 1 and 2 studies completed, full reports submitted
	Orphan drug status obtained in January 2007
PV-10 +	Phase 1b/2 study initiated September 2015
Pembrolizumab	

PV-10 **Melanoma (Method of Action)**	Phase 1 study to detect immune cell infiltration into melanomas treated with PV-10 has now finished recruiting
	Data published in peer-reviewed journal May 2016
PV-10 **Cancers of the Liver**	Orphan drug status obtained in April 2011
	Phase 1 patient accrual and treatment completed
	Phase 1 protocol expansion (September 2012 into 2017)

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	Data communicated in 2015
	Phase 1b/2 commencement expected late 2016 / early 2017
PV-10	Phase 1 study completed
Breast Cancer	
	Further clinical development is being planned
PH-10	Phase 2c randomized study completed and full report submitted to FDA
Psoriasis	
	Toxicity study R&D for advanced studies 2012 to 2016
PH-10	Phase 2 mechanism of action study initiated in January 2015 by leading research facility
Psoriasis (Mechanism of Action)	
	Phase 2 study recruitment began in Q1 2015
	Phase 2 study recruitment completed in Q3 2015
	Phase 2 study data being compiled for FDA end of Phase 2 meeting
PH-10	Phase 2 study completed and full report submitted to FDA
Atopic Dermatitis	
	Toxicity study R&D for advanced studies 2012 to 2016

* In addition to clinical trials, patients enrolled in the Compassionate Use Program for PV-10 are also receiving PV-10 treatments.

Corporate Information

On April 23, 2002, Provectus Pharmaceutical, Inc., a Nevada corporation and a merger blank check public company, acquired Provectus Pharmaceuticals, Inc., a privately-held Tennessee corporation (PPI), by issuing 6,680,000 shares of common stock of Provectus Pharmaceutical to the stockholders of PPI in exchange for all of the issued and

outstanding shares of PPI, as a result of which Provectus Pharmaceutical changed its name to Provectus Pharmaceuticals, Inc. and PPI became a wholly-owned subsidiary of us. On December 16, 2013, Provectus Pharmaceuticals, Inc. was reincorporated in Delaware and changed its name to Provectus Biopharmaceuticals, Inc.

Our principal executive offices are located at 7327 Oak Ridge Highway, Knoxville, TN 37931, and our telephone number is 1-866-597-5999. Our website address is www.provectusbio.com. The information on, or accessible through, our website is not part of, and is not incorporated into, this prospectus and should not be considered part of this prospectus.

Recent Developments

As disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, from time to time, we receive subpoenas and/or requests for information from governmental agencies with respect to our business. As we have previously disclosed, the Company received a subpoena from the staff of the Securities and Exchange Commission related to the travel expense advancements and reimbursements received by H. Craig Dees, our former Chairman and Chief Executive Officer. At this time, the staff s investigation into this matter remains ongoing. The Company is continuing to cooperate with the staff but cannot predict with any certainty what the outcome of the foregoing may be.

On August 30, 2016, we closed a public offering of 240,000 shares of our Series B Convertible Preferred Stock, par value $0.001 per share, which we refer to as the Preferred Stock (which shares are initially convertible into an

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aggregate of 24,000,000 shares of our common stock), and warrants, which we refer to as the August 2016 Warrants, initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of $0.275 per share of common stock. The Preferred Stock and August 2016 Warrants were sold together at a price of $25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in gross offering proceeds of $6,000,000 to us before the payment of placement agent fees and expenses related to the offering.

The conversion feature embedded within the Preferred Stock is subject to anti-dilution price protection upon the issuance of equity or equity-linked securities within 60 trading days from the date of issuance of the Preferred Stock at an effective common stock purchase price of less than the conversion price then in effect, subject to certain exceptions as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, which we refer to as the Certificate of Designation. In addition, if the conversion price in effect on the 60th trading day following the date of issuance of the Preferred Stock exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the Preferred Stock and ending on the 60th trading day following the date of issuance of the Preferred Stock (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Conversion Price, then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive additional shares of common stock equal to the number of shares of common stock that would have been issued assuming for such purposes the Adjusted Conversion Price were in effect at such time less the shares issued at the then Conversion Price (subject to being held in abeyance based on beneficial ownership limitations); provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

The August 2016 Warrants expire on August 30, 2021. The exercise price of the August 2016 Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, if the exercise price in effect on the 60th trading day following the date of issuance of the August 2016 Warrants exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the August 2016 Warrants and ending on the 60th trading day following the date of issuance of the August 2016 Warrants (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Exercise Price, then (i) the exercise price shall be reset to the Adjusted Exercise Price (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the August 2016 Warrants, and (ii) the number of shares of common stock issuable upon exercise of the August 2016 Warrants will be reset to equal the number of shares of common stock issuable upon conversion of Preferred Stock after giving effect to the Adjusted Conversion Price or Adjusted Exercise Price, as applicable. If a holder of August 2016 Warrants exercises its August 2016 Warrants prior to such repricing, then such holder will receive shares of common stock equal to the difference between the exercise price and the Adjusted Exercise Price; provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

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Summary Consolidated Financial Data

	Nine months ended September 30 (Unaudited)		Years ended December 31				
	2016	2015	2015	2014	2013	2012	2011
	(all amounts in thousands except per share data)						
Consolidated Statement of Operations Data:							
Gain on settlement net of discount	$	$	$	$ 4,178	$	$	$
Operating expenses							
Research and development	6,874	7,537	11,380	5,809	4,267	5,677	9,479
General and administrative	12,455	7,453	13,274	11,002	8,761	8,661	11,962
Total operating loss	(19,329)	(14,991)	(24,654)	(12,633)	(13,028)	(14,338)	(21,441)
Other income, net	(98)	141	152	2,390	(14,670)	1,769	2,006
Net loss	(19,427)	(14,850)	(24,502)	(10,243)	(27,698)	(12,569)	(19,435)
Dividend paid in-kind to preferred shareholders	(2,257)						
Deemed dividend	(727)						
Dividends on preferred stock					(1,188)	(183)	(247)
Net loss applicable to common stockholders	$ (22,411)	$ (14,850)	$ (24,502)	$ (10,243)	$ (28,886)	$ (12,752)	$ (19,682)
Basic and diluted loss per common share	$ (0.10)	$ (0.08)	$ (0.13)	$ (0.06)	$ (0.22)	$ (0.11)	$ (0.19)
Weighted average number of common shares outstanding basic and diluted	213,723	192,604	195,662	175,828	132,001	112,987	105,725

	As of September 30 (Unaudited)	As of December 31				
	2016	2015	2014	2013	2012	2011
	(all amounts in thousands)					
Consolidated Balance Sheet Data:						
Cash, cash equivalents and marketable securities	$ 5,178	$ 14,179	$ 17,392	$ 15,696	$ 1,222	$ 7,705
Patents, net	2,409	2,913	3,584	4,255	4,926	5,598

Other assets	3,098	3,348	5,208	57	56	47
Total assets	10,686	20,440	26,184	20,008	6,204	13,350
Current liabilities	5,376	4,123	848	513	511	263
Long-term liability			147	12,866	1,300	3,067
Preferred stock					2	4
Common stock	244	205	185	160	118	110
Additional paid-in capital	205,289	196,908	181,299	152,520	122,626	115,690
Accumulated deficit	(200,223)	(180,796)	(156,294)	(146,051)	(118,353)	(105,784)
Total stockholders equity	5,310	16,317	25,190	6,629	4,393	10,020

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Rights Offering Summary

The following summary describes the principal terms of the Rights Offering, but is not intended to be complete. See the information under the heading The Rights Offering in this prospectus for a more detailed description of the terms and conditions of the Rights Offering.

Securities to be offered	We are distributing to you, at no charge, one non-transferable Subscription Right to purchase one Unit for every shares of our common stock that you owned on the Record Date. Each Unit consists of shares of common stock and Warrants to purchase one share of common stock. For certain investors whose subscriptions may result in the purchaser beneficially owning more than 4.99% of our outstanding common stock, such investors may elect to receive in the Rights Offering, in lieu of shares of common stock, certain pre-funded warrants, which we refer to as the Pre-Funded Warrants, to purchase the same amount of shares of common stock. If you do not wish to exceed the ownership threshold, you may elect to receive a Pre-Funded Warrant in lieu of any shares of common stock underlying the Units for which you have subscribed. You will not be eligible to elect to receive Pre-Funded Warrants, except to the extent that your beneficial ownership could exceed 4.99% of the shares of common stock outstanding following the consummation of the Rights Offering. Each Pre-Funded Warrant will have an exercise price of $0.01, and the subscription price per Unit for any such electing investors will be reduced to $ (which equals the Subscription Price for the other Units sold in the Rights Offering, less the $0.01 exercise price for each Pre-Funded Warrant). The Pre-Funded Warrants do not confer upon the holder any voting or any other rights of a stockholder of the Company.
Size of Offering	Units.
Subscription Price	$ per Unit. The Subscription Price per Unit will be determined by our board of directors or pricing committee prior to the effectiveness of the registration statement of which this prospectus is a part. We may, in our sole discretion, reduce the Subscription Price by up to 20%, and if we elect to reduce the Subscription Price per Unit, you may elect to receive (i) proportionally more Units based on the payment amount we received from you in connection with the exercise of your Subscription Rights or (ii) an amount in cash equal to the difference between your total payment amount at the original Subscription Price and the payment amount that

would have been due for the number of Units for which you subscribed at the reduced Subscription Price. If you elect to receive cash in lieu of additional Units, the Company will remit such payment within 10 business days after the expiration date of the Rights Offering, without interest or deduction. In the event that we determine to reduce the subscription price, we will file with the Commission and mail to stockholders of record as of the record date for the Rights Offering a prospectus

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	supplement disclosing the reduced subscription price. The expiration date of the Rights Offering will be no less than seven calendar days after the date of such prospectus supplement disclosing a reduction in subscription price. See The Rights Offering Subscription Price.
Warrants	Each whole Warrant entitles the holder to purchase one share of common stock at an exercise price of $ per share from the date of issuance through its expiration five years from the date of issuance. The Warrants will be exercisable for cash, or, solely during any period when a registration statement for the exercise of the Warrants is not in effect, on a cashless basis. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. After the one-year anniversary of the date of issuance, we may redeem the Warrants for $0.001 per Warrant if the volume weighted average price of our common stock is above $ per share, 250% of the exercise price, for each of 10 consecutive trading days.
Pre-Funded Warrants	Each Pre-Funded Warrant entitles the holder to purchase one share of common stock at an exercise price of $0.01 per share, and the subscription price per Unit for any such electing investors will be reduced to $ (which equals the Subscription Price for the other Units sold in the Rights Offering, less the $0.01 exercise price for each Pre-Funded Warrant). Each Pre-Funded Warrant will be exercisable from the date of issuance through its expiration on , 2021. The Pre-Funded Warrants will be exercisable by paying the exercise price in cash or, solely during any period when a registration statement for the exercise of the Warrants is not in effect, on a cashless basis. The Pre-Funded Warrants will not be listed for trading on any stock exchange or market. The Pre-Funded Warrants do not confer upon the holder any voting or any other rights of a stockholder of the Company. See Description of Securities Options and Warrants Pre-Funded Warrants Issuable in the Rights Offering.
Record Date	5:00 p.m., Eastern Time, , 2016.
Basic Subscription Rights	Your Basic Subscription Right will entitle you to purchase one Unit at the Subscription Price.

Over-Subscription Privilege	If you exercise your Basic Subscription Rights in full, you may also choose to purchase a portion of any Units that are not purchased by our other stockholders through the exercise of their Basic Subscription Rights, subject to proration described elsewhere in this prospectus.

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Expiration Date	The Subscription Rights will expire at 5:00 p.m., Eastern Time, on , 2016. We reserve the right to extend the expiration date in our sole discretion; provided, however, that we may not extend the expiration date of the Rights Offering by more than 30 days past the original expiration date.
Procedure for Exercising Subscription Rights	To exercise your Subscription Rights, you must take the following steps: If you are a record holder of our common stock, you must deliver payment and a properly completed Rights Certificate to the Subscription Agent to be received before 5:00 p.m., Eastern Time, on , 2016. You may deliver the documents and payments by first class mail or courier service. If you use first class mail for this purpose, we recommend using registered mail, properly insured, with return receipt requested. If you are a beneficial owner of shares that are registered in the name of a broker, dealer, bank, or other nominee, you should instruct your broker, dealer, bank, or other nominee to exercise your Subscription Rights on your behalf. Please follow the instructions of your nominee, who may require that you meet a deadline earlier than 5:00 p.m., Eastern Time, on , 2016.
Delivery of Shares and Warrants	As soon as practicable after the expiration of the Rights Offering, the Subscription Agent will arrange for the issuance of the shares of common stock and Warrants purchased pursuant to the Rights Offering. All shares of common stock and Warrants that are purchased in the Rights Offering will be issued in book-entry, or uncertificated, form meaning that you will receive a direct registration, or DRS, account statement from our transfer agent reflecting ownership of these securities if you are a holder of record of shares of our common stock. If you hold your shares in the name of a bank, broker, dealer, or other nominee, DTC will credit your account with your nominee with the securities you purchased in the Rights Offering.
Non-Transferability of Subscription Rights	The Subscription Rights may not be sold, transferred, assigned or given away to anyone. The Subscription Rights will not be listed for trading on any stock exchange or market.

Transferability of Warrants	The Warrants will be separately transferable following their issuance and through their expiration five years from the issuance date.
No Board Recommendation	Our board of directors is not making a recommendation regarding your exercise of the Subscription Rights. You are urged to make your decision to invest based on your own assessment of our business and financial condition, our prospects for the future, the terms of the Rights Offering, the information in this prospectus and other information relevant to your circumstances. Please see Risk Factors for a discussion of some of the risks involved in investing in our securities.

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Director and Officer Participation in Rights Offering	While none of our directors or executive officers has entered into any binding commitment or agreement to exercise Subscription Rights received in the Rights Offering, Peter R. Culpepper, our Interim Chief Executive Officer and Chief Operating Officer, Timothy C. Scott, our President and a member of our board of directors, and Eric A. Wachter, our Chief Technology Officer and a member of our board of directors, have indicated an interest in participating in the Rights Offering.
Revocation	Exercises of Subscription Rights may be revoked prior to the expiration date of the Rights Offering (as such expiration date may be extended as provided herein) by following the instructions provided herein. See Rights Offering Revocation Rights.
Use of Proceeds	Assuming that all Units are sold in the Rights Offering, after deducting fees and expenses payable to the dealer-manager, and after deducting other expenses payable by us and excluding any proceeds received upon exercise of any Warrants issued, we estimate the net proceeds of the Rights Offering will be approximately $ million. We intend to use approximately $15 million of the net proceeds from the exercise of Subscription Rights for clinical development, including approximately $5 million to complete our ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma, approximately $5 million to complete our phase 1b/2 combination study of PV-10 and Merck s KEYTRUDA in late stage melanoma and approximately $5 million to complete our phase 1b/2 study of PV-10 in liver cancer, and we intend to use the remaining net proceeds for working capital and general corporate purposes. See Use of Proceeds.
Material U.S. Federal Income Tax Consequences	For U.S. federal income tax purposes, we do not believe you should recognize income or loss upon receipt or exercise of a Subscription Right. You should consult your own tax advisor as to the tax consequences of the Rights Offering in light of your particular circumstances. See Material U.S. Federal Income Tax Consequences.
Extension and Termination	Although we do not presently intend to do so, we may extend the Rights Offering for additional time in our sole discretion; provided, however, that we may not extend the expiration date of the Rights Offering by more than 30 days past the original expiration date. Our board of directors may for any reason terminate the Rights Offering at any time before the completion of the Rights Offering. If the Rights Offering is oversubscribed (after taking into account all Over-Subscription requests), we may increase the size of the Rights Offering, in our sole discretion, by

	up to 20%, and we will allocate such increased amount pro rata among our stockholders who exercise both their Basic Subscription Right and their Over-Subscription Privilege.
Subscription Agent and Information Agent	Broadridge Corporate Issuer Solutions, Inc.

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Questions	If you have any questions about the Rights Offering, please contact the Information Agent, Broadridge Corporate Issuer Solutions, Inc., at (844) 695-1509 (toll free) or (720) 414-6879 (toll number) or our dealer-manager, Maxim Group LLC, at (212) 895-3745 or by email at: syndicate@maximgrp.com.
Market for Common Stock	Our common stock is listed on the NYSE MKT under the symbol PVCT, although NYSE MKT suspended trading in our common stock and commenced delisting procedures on October 13, 2016. We intend to appeal the NYSE MKT decision to commence delisting procedures, and on October 20, 2016, we submitted a request for a review of such delisting determination. Effective October 17, 2016, our common stock trades on the OTCQB under the symbol PVCT. See Market Price of our Common Stock and Dividend Policy.
Risk Factors	Before you exercise your Subscription Rights to purchase Units, you should be aware that there are risks associated with your investment, and you should carefully read and consider risks described in the section captioned Risk Factors together with all of the other information included in this prospectus.
Dealer-Manager	Maxim Group LLC.
Distribution arrangements	Under the terms and subject to the conditions contained in the dealer-manager agreement, the dealer-manager will use its best efforts to solicit the exercise of Subscription Rights. We have agreed to pay the dealer-manager certain fees for acting as dealer-manager and to reimburse the dealer-manager for certain out-of-pocket expenses incurred in connection with this Rights Offering. The dealer-manager is not underwriting or placing any of the Subscription Rights or the Units, shares of common stock, Warrants or Pre-Funded Warrants being issued in this Rights Offering, and does not make any recommendation with respect to such Subscription Rights (including with respect to the exercise or expiration of such Subscription Rights), Units, shares of common stock, Warrants or Pre-Funded Warrants. See Plan of Distribution for a discussion of the fees and expenses to be paid to the dealer-manager.

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RISK FACTORS

Investing in the Rights Offering and our securities involves risk. Before making an investment in the Rights Offering and our securities, you should carefully consider the risks described below, together with the other information included in this prospectus, and the risks we have highlighted in other sections of this prospectus. The risks described below are those which we believe are the material risks we face. Any of the risks described below could significantly and adversely affect our business, prospects, financial condition and results of operations. As a result, the trading price of our common stock could decline, and you may lose part or all of your investment. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.

Risk Factors That May Affect Our Business

We are an early stage company, have no prescription drug products approved for commercial sale, have incurred substantial losses, and expect to incur substantial losses and negative operating cash flow for the foreseeable future.

We are an early stage company that has no prescription drug products approved for commercial sale. We have never generated any substantial revenues and may never achieve substantial revenues or profitability. As of September 30, 2016, we have incurred net losses of $201 million in the aggregate since inception in January 2002. We expect to incur substantial losses and negative operating cash flow for the foreseeable future. We may never achieve or maintain profitability, even if we succeed in developing and commercializing one or more of our prescription drug candidates, OTC products, or non-core technologies. We also expect to continue to incur significant operating expenditures and anticipate that our operating and capital expenses may increase substantially in the foreseeable future as we:

- continue to develop and seek regulatory approval for our prescription drug candidates PV-10 and PH-10;
- seek licensure of PV-10, PH-10, our OTC products, and our other non-core technologies;
- further develop our non-core technologies;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative operating cash flow for the foreseeable future as we fund our operating losses and any future capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

All of our existing prescription drug candidates are in early stages of development. It may be several years, if ever, until we have a prescription drug product available for commercial resale. If we do not successfully develop and license or commercialize our prescription drug candidates, or sell or license our OTC products or non-core technologies, we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

We need additional capital to conduct our operations and commercialize and/or further develop our prescription drug candidates in 2017 and beyond, and our ability to obtain the necessary funding is uncertain.

We estimate that our existing capital resources are sufficient to fund our current and planned operations for the remainder of 2016. However, we will need additional capital in 2017 and beyond as we continue to develop and seek commercialization of our prescription drug candidates. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our expanding phase 2 atopic dermatitis and psoriasis results, which continue

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to be developed. We potentially may license PV-10 depending on the timing for the optimal deal structure for our stockholders. We are also focusing on PV-10 geographic licensing and partnering opportunities in such countries as China and India. We are also focusing on potential co-development partnering opportunities with combination of PV-10 and immune checkpoint blockade or systemic immunotherapy agents. We intend to also proceed as rapidly as possible with the sale or licensure of our OTC products and other non-core technologies. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to both the licensure of PH-10 and PV-10, and the sale or licensure of our OTC products and non-core technologies, we cannot assure you that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

We have based our estimate of capital needs on assumptions that may prove to be wrong, and we cannot assure you that estimates and assumptions will remain unchanged. For example, we are currently assuming that we will continue to operate without any significant staff or other resources expansion. We intend to acquire additional funding through this Rights Offering, and we may also seek capital from public or private equity or debt financings or other financing sources that may be available. Such additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our products, product candidates, and technologies that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate one or more of our programs, any of which could have a material adverse effect on our business and may impair the value of our patents and other intangible assets.

There is substantial doubt as to our ability to continue as a going concern.

Our cash and cash equivalents were $5,178,076 at September 30, 2016, compared with $14,178,902 at December 31, 2015. As of November 15, 2016, we had cash and cash equivalents of $3,093,445. We continue to incur significant operating losses, and management expects that significant on-going operating expenditures will be necessary to successfully implement our business plan and develop and market our products. These circumstances raise substantial doubt about our ability to continue as a going concern. Implementation of our plans and our ability to continue as a going concern will depend upon our ability to develop PV-10 and raise additional capital.

Management believes that we have access to capital resources through possible public or private equity offerings (including this Rights Offering), exchange offers, debt financings, corporate collaborations or other means. In addition, we continue to explore opportunities to strategically monetize our lead drug candidate, PV-10, through potential licensing transactions, although there can be no assurance that we will be successful with such plans. We have historically been able to raise capital through equity offerings, although no assurance can be provided that we will continue to be successful in the future. If we are unable to raise sufficient capital through this Rights Offering or otherwise, we may be forced to implement significant cost cutting measures as early as the fourth quarter of 2016.

Our prescription drug candidates are at an intermediary stage of development and may never obtain U.S. or international regulatory approvals required for us to commercialize our prescription drug candidates.

We will need approval of the FDA to commercialize our prescription drug candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our prescription drug candidates in those jurisdictions.

We are continuing to pursue clinical development of our most advanced prescription drug candidates, PV-10 and PH-10, for use as treatments for specific conditions. The continued and further development of these prescription drug candidates will require significant additional research, formulation and manufacture

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development, and pre-clinical and extensive clinical testing prior to their regulatory approval and commercialization. Pre-clinical and clinical studies of our prescription drug candidates may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical drug and medical device products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including the following:

- a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials,
- a product may fail to receive necessary regulatory clearance,
- a product may be too difficult to manufacture on a large scale,
- a product may be too expensive to manufacture or market,
- a product may not achieve broad market acceptance,
- others may hold proprietary rights that will prevent a product from being marketed, and
- others may market equivalent or superior products.

Satisfaction of the FDA s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

We do not expect any prescription drug and other product candidates that we are developing to be commercially available without a partner. Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized products. Further, after commercial introduction of a new product, discovery of problems through adverse event reporting could result in restrictions on the product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Even if we comply with all FDA requests, we cannot be sure that we will ever obtain regulatory clearance for any of our prescription drug or other product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

We are subject to securities class action lawsuits and shareholder derivative lawsuits that could adversely affect our business. This litigation, and potential similar or related litigation, could result in substantial damages and may divert management s time and attention from our business.

Beginning on May 27, 2014, three putative securities class action lawsuits (the Federal Class Actions) were commenced in the United States District Court for the Middle District of Tennessee against us, and H.

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Craig Dees, Timothy C. Scott and Peter R. Culpepper, (the Defendants), alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The Federal Class Actions allege, among other things, that the defendants made false and materially misleading statements and failed to disclose material information regarding our application to the FDA for breakthrough therapy designation (BTD) of PV-10.

On July 9, 2014, the Company and the Federal Class Action plaintiffs filed joint motions to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee consolidated the Federal Class Actions and transferred them to the United States District Court for the Eastern District of Tennessee. Since the consolidation and transfer of the Federal Class Actions, several shareholders have filed motions seeking their appointment as the Lead Plaintiff to direct the class action litigation. The United States District Court for the Eastern District of Tennessee scheduled a hearing for November 11, 2014 to determine which shareholder should be appointed Lead Plaintiff.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint) in the Class Action Case, alleging that the Defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTD, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

On June 5, 2015, the Defendants filed their Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response). Pursuant to order of the Court, the Defendants replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions between the parties continued. On January 28, 2016, a settlement terms sheet (the Terms Sheet) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Federal Class Actions.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Securities Litigation, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier agreed to pay the total amount of $3.5 million (the Settlement Funds) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Securities Litigation. The Company has determined that it is probable that the Company will pay $1.85 million of the total, which has been accrued at December 31, 2015 and was paid in March 2016. The insurance carrier will pay $1.65 million of the total directly to the plaintiff s trust escrow account and it will not pass through the Company. Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Securities Litigation will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Securities Litigation and the Securities Litigation will be fully concluded. If the court does not give final approval of the settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the

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Terms Sheet and includes the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement further provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Securities Litigation.

On April 7, 2016, the court in the Securities Litigation held a hearing on preliminary approval of the settlement, entered an order preliminarily approving the settlement, ordered that the class be notified of the settlement as set forth in the Stipulation of Settlement, and set a hearing on September 26, 2016 to determine whether the proposed settlement is fair, reasonable, and adequate to the class; whether the class should be certified and the plan of allocation of the Settlement Funds approved; whether to grant Lead Plaintiff s request for expenses and Lead Plaintiff s counsel s request for fees and expenses; and whether to enter judgment dismissing the Securities Litigation as provided in the Stipulation of Settlement. On September 16, 2016, the Lead Plaintiff notified the court that approximately 6,300 stockholders did not receive notification of the proposed settlement until late August 2016 because of the delayed receipt of potential Settlement Class Member information from a number of brokers. As a result, on September 22, 2016, the parties filed a joint motion requesting that the court extend the deadlines to file a Proof of Claim, request exclusion from the settlement, or file an objection to the settlement, and that the court schedule a continued settlement hearing. The court granted the motion, cancelling the settlement hearing that had been set for September 26 and re-setting the hearing to take place on December 12, 2016. The court set a new deadline of November 10, 2016 for objections and requests for exclusion, and November 25, 2016 for submitting proofs of claim. If the settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

In addition, on June 4, 2014, a shareholder derivative lawsuit captioned *Hurtado v. Provectus Biopharmaceuticals, Inc., et al.* was filed derivatively on behalf of the Company against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant in the United States District Court for the Middle District of Tennessee (the Hurtado Shareholder Derivative Lawsuit). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties, and (ii) abuse of control, both claims based on the Plaintiff s allegations that the Individual Defendants recklessly permitted the Company to disclose false and misleading information and failed to implement adequate controls and procedures to ensure the accuracy of the Company s disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the Hurtado Shareholder Derivative Lawsuit to the United States District Court for the Eastern District of Tennessee and, in light of the pending Federal Class Actions, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee.

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit) against the Individual Defendants. Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy s allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that PV-10 would qualify for BTD.

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Individual Defendants and against the Company as a nominal defendant (the Foley Shareholder Derivative Lawsuit). The Foley Shareholder Derivative Lawsuit asserts the exact same facts and legal claims as the Montiminy Shareholder Derivative Lawsuit.

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Individual Defendants, and against the

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Company as a nominal defendant (the Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. (the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit, the Foley Shareholder Derivative Lawsuit and the Donato Shareholder Derivative Lawsuit are collectively referred to as the Shareholder Derivative Lawsuits).

In each of the four Shareholder Derivative Lawsuits, the Company is a nominal defendant only. As such, the plaintiffs seek relief from the Individual Defendants, but not the Company itself. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company s purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA.

While the parties to the Securities Litigation were negotiating and documenting the Stipulation of Settlement in the Securities Litigation, the parties to the Hurtado, Montiminy, and Foley Shareholder Derivative Lawsuits, through counsel, engaged in settlement negotiations as well. On or about April 11, 2016, the parties entered into a Stipulation of Settlement, which was filed with the United States District Court for the Eastern District of Tennessee on April 29, 2016.

Pursuant to the Stipulation of Settlement, the parties agreed to settle the cases, contingent upon the approval of the court. The Company agreed to implement certain corporate governance changes, including the adoption of a Disclosure Controls and Procedures Policy, and to use its best efforts to replace one of its existing directors with an independent outside director by June 30, 2017. The Company has adopted a Disclosure Controls and Procedures Policy and is evaluating its options with respect to a replacement independent outside director. The Company agreed to pay from insurance proceeds the amount of $300,000 to plaintiffs counsel in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits. The insurance carrier will pay directly to the plaintiff s trust escrow account and it will not pass through the Company. Notice of the proposed settlement will be provided to shareholders as set forth in the Stipulation of Settlement. If the court enters final approval of the settlement, the Individual Defendants will be released from any and all claims in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

The United States District Court for the Eastern District of Tennessee preliminarily approved the settlement by order dated June 2, 2016. Pursuant to this court order, the notice to the class was filed with the Securities and Exchange Commission, published on the Company s website, and posted on plaintiffs counsel s websites by June 13, 2016. On August 26, 2016, the court held a final hearing on the fairness of the settlement and entered an order approving the settlement and dismissing the action with prejudice.

We believe that the resolution of these suits will not result in a material adverse effect to our consolidated financial statements. However, due to the inherent uncertainties that accompany litigation of this nature, there can be no assurance that we will be successful, and an adverse resolution of any of the lawsuits could have a material adverse effect on our consolidated financial statements. Furthermore, these actions may divert management s time and attention from our business, and we could be forced to expend significant resources and pay significant costs and expenses, including legal fees, in connection with defending the lawsuits.

Our former Chief Executive Officer and Chairman of the Board of Directors received travel expense advancements, which may be deemed a violation of Section 402 of the Sarbanes-Oxley Act of 2002 and/or other federal securities laws.

Our internal control testing for the period ended December 31, 2015 identified inadequate supporting documentation and lack of adequate review for the travel advances and expense reimbursements to Dr. Dees.

In February 2016, the Audit Committee initiated a review of Company procedures, policies and practices, including travel expense advancements and reimbursements to Dr. Dees. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in

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conducting the investigation. As part of the investigation, the Committee reviewed the Company s financial policies and procedures, including management expenses. The Audit Committee concluded that Dr. Dees did not produce receipts for most of the travel expense advances he received from 2013 to 2015, and that some receipts produced by Dr. Dees during this period appear to have been altered.

Section 402 of the Sarbanes Oxley Act of 2002 prohibits personal loans to a director or executive officer of a public company. If the SEC were to commence an investigation or institute proceedings to enforce a violation of this statute or other federal securities laws as a result of the travel advances to Dr. Dees, we may become a party to litigation or proceedings over these matters, and the outcome of such litigation or proceedings (including criminal, civil or administrative sanctions or penalties by the SEC), alone or in addition to the costs of litigation, may materially and adversely affect our business. The Company is unable to predict the extent of its ultimate liability with respect to the advances to Dr. Dees.

We have identified a material weakness in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. We cannot assure you that additional material weaknesses or significant deficiencies do not exist or that they will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Based on the results of management s assessment and evaluation of our internal controls, our principal executive officer and principal financial officer concluded that our internal control over financial reporting was not effective due to the material weakness described below.

The Company has identified the following material weakness related to its travel expense advancement and reimbursement policies and procedures to Dr. Dees: (1) the documentation provided for an expenditure was not sufficient to support the authorization of such expenditure, (2) only the check register and not the supporting documentation was obtained by an executive officer approving the expenses incurred by another executive officer, and (3) there was not adequate reconciliation of travel advances to actual expenses. As a result, our management also has concluded that our disclosure controls and procedures are not effective such that the information relating to our Company required to be disclosed in the reports we file with the SEC (a) is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and (b) is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

We continue to aggressively remediate the material weakness in our internal controls over financial reporting. To do so, we have put in place more clearly defined, tighter controls, including a clear process for limiting, approving and documenting travel advances and expenses and appropriately managing them. Specifically, we have:

- Adopted a control enhancement to require the provision of all invoice copies along with the check register for appropriate approval, including all travel reimbursements separately approved;

Established a policy so travel advances are no longer permitted; and

Implemented a more formal and detailed travel and expense policy.

In addition, we have replaced the independent consulting group previously utilized by management to aid in our documentation and testing of internal controls over financial reporting and appointed John Glass as our Interim Chief Financial Officer to assist in the organization and strategic operation of the Company as to its procedures and daily operations of the Company. We are also in the process of implementing many of the other recommendations made by counsel to the Audit Committee to remediate these issues, including the identification

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and recruitment of a permanent Chief Executive Officer and any other positions necessary. We believe the foregoing actions will continue to improve our internal control over financial reporting as well as our disclosure controls and procedures. We will continue to monitor the effectiveness of our internal control over financial reporting in the area affected by the material weakness discussed above, and will perform any additional procedures, as well as implement any new resources and policies, deemed necessary by our management to remediate the material weakness.

If we do not successfully remediate the material weakness described above, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results on a timely basis or prevent fraud, which could cause our reported financial results to be materially misstated and require restatement which could result in the loss of investor confidence, delisting or cause the market price of our common stock to decline.

We did not obtain and may not obtain or maintain the benefits associated with breakthrough therapy designation.

On March 21, 2014, we submitted a request for breakthrough therapy designation (BTD) to the FDA for PV-10 in the treatment of metastatic melanoma in the United States. The FDA denied the request in May 2014, but stated that a new request may be submitted if we obtain new clinical evidence that supports BTD. Accordingly, we are not entitled to the benefits of BTD, including expedited development and review of PV-10 in the treatment of melanoma.

If we resubmit such request for BTD, we may not be granted BTD, or even if granted, we may not receive the benefits associated with BTD. This may result from a failure to maintain breakthrough therapy status if PV-10 is no longer considered to be a breakthrough therapy. For example, a drug s development program may be granted BTD using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where BTD is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When BTD is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a BTD program.

We depend on the successful completion of clinical trials for our product candidates, including PV-10. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.

Before obtaining regulatory approval for the sale of our product candidates, including PV-10, we must conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

In October 2012, we presented final top-line data from the phase 2 trial of PV-10 for metastatic melanoma, and in March 2014, applied for BTD with the FDA, which was subsequently denied pending new clinical evidence that supports BTD. We (i) are conducting an expanded phase 1 trial for PV-10 for metastatic liver cancer, which is expected to be completed in early 2015; (ii) have completed a phase 1 clinical study for PV-10

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for recurrent breast cancer; (iii) are conducting a phase 1 trial for PV-10 in an investigator initial study to ascertain the feasibility of detecting immune cell infiltrates in injected melanoma tumors which is expected to be completed in early 2015; (iv) are conducting a phase 2 clinical trial for mechanism of action of PH-10 for psoriasis; (v) have completed multiple phase 2 clinical trials for PH-10 for psoriasis and atopic dermatitis; and (vi) expect to commence a phase 3 clinical trial to assess response to intralesional PV-10 versus that of systemic chemotherapy in patients with disease confined to cutaneous and subcutaneous sites. Meetings with scientific advisors, investigators and advocates in the field have led us to expect a starting date for the phase 3 clinical study sometime in the first quarter of 2015. However, we have never conducted a phase 3 clinical trial. The positive results we have seen to date in our phase 2 clinical trials of PV-10 for metastatic melanoma do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in phase 3 clinical development; even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during clinical trials for our product candidates, including PV-10, that could delay or prevent the commencement and/or completion of our clinical trials, including the following:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- clinical investigators or study subjects fail to comply with clinical study protocols;
- trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling errors;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we commence a phase 3 clinical trial with respect to PV-10 as planned, and undertake additional clinical trials of our other product candidates. Because successful development of our product candidates is

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uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development; however, we believe we have sufficient cash on hand to fund the planned phase 3 clinical trial with respect to PV-10.

Negative or inconclusive results of our future clinical trials of PV-10, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for PV-10, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including PV-10. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including PV-10, may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials for PV-10, include the following:

- inability to raise funding, if necessary, to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;

delays in having subjects complete participation in a trial or return for post-treatment follow-up;

delays caused by subjects dropping out of a trial due to side effects or otherwise;

delays caused by clinical sites dropping out of a trial;

time required to add new clinical sites; and

delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of any of our clinical trials for our product candidates, including PV-10, are delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that

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current or future clinical trials of our prescription drug candidates will take additional years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or the conduct of these trials.

The results of our clinical trials may not support our claims concerning our prescription drug candidates.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims concerning our prescription drug candidates. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

Physicians and patients may not accept and use our prescription drug candidates.

Even if the FDA approves our prescription drug candidates, physicians and patients may not accept and use them. Acceptance and use of our prescription drug products will depend upon a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our prescription drug products;

cost-effectiveness of our prescription drug products relative to competing products;

availability of reimbursement for our prescription drug products from government or other healthcare payers; and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales or licensure of our prescription drug candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing or distribution capabilities for our prescription drug candidates or our OTC products and non-core technologies.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our prescription drug candidates or our OTC

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products and non-core technologies. Our future success depends, in part, on our ability to enter into and maintain such collaborative relationships, the collaborator s strategic interest in the products under development and such collaborator s ability to successfully market and sell any such products. We intend to proceed as rapidly as possible with licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in process of being further developed. We have determined that the most efficient use of our capital in further developing our OTC products is to license the products. There can be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

We cannot be sure that our OTC products or non-core technologies will be licensed or sold in the marketplace.

In order for our OTC products to become commercially successful and our non-core technologies to be further developed, we must license or sell those products and technologies. We have been discussing this strategy with interested groups, though we cannot be sure that we will be successful in licensing or selling such products or technologies.

Competition in the prescription pharmaceutical and biotechnology industries is intense, and we may be unable to succeed if our competitors have more funding or better marketing.

The pharmaceutical and biotechnology industries are intensely competitive. Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of dermatological conditions or cancers of the skin, liver and breast, which could lead to the development of products or therapies that could compete directly with the prescription drug and other product candidates, and OTC products that we are seeking to develop and market.

Many companies are also developing alternative therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have significantly greater financial resources and expertise than we do in:

- research and development;
- manufacturing;
- preclinical and clinical testing;
- obtaining regulatory approvals; and
- marketing.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Academic institutions, government agencies, and other public and private research organizations may also conduct research, seek patent protection, and establish collaborative arrangements for research, clinical development, and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

In addition to the above factors, we expect to face competition in the following areas:

product efficacy and safety;

the timing and scope of regulatory consents;

availability of resources;

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reimbursement coverage;

price; and

patent position, including potentially dominant patent positions of others.

Since our prescription candidates PV-10 and PH-10 have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these products might face when they are finally introduced, if at all. We cannot assure you that these products will not face significant competition for other prescription drugs and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our products and technologies we develop or license. In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our anticipated sales. While some of our products have proprietary patent protection, a challenge to these patents can subject us to expensive litigation. Litigation concerning patents, other forms of intellectual property, and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing their duties.

We also rely upon trade secrets, unpatented proprietary know-how, and continuing technological innovation to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets, or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the intellectual property of others, our business could be harmed.

We could be sued for infringing patents or other intellectual property that purportedly cover products and/or methods of using such products held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our products, any of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by rapid technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, to discover new technologies as a result of that research, to develop products based on our technologies, and to commercialize those products. While we believe that our current technology is adequate for our present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors are using substantial resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different

technologies by one or more of our current or future competitors.

The resignation of our Chief Executive Officer and Chairman of the Board of Directors, the appointment of our Interim Chief Executive Officer and our search for, and appointment of, a long-term Chief Executive Officer creates uncertainties and could have a material adverse impact on our business.

Effective February 27, 2016, Dr. Dees resigned as Chief Executive Officer and Chairman of the Board of Directors. Mr. Culpepper, who was then serving as our Chief Financial Officer and Chief Operating Officer, was

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appointed to serve as our Interim Chief Executive Officer until our Board of Directors completes its search process for a successor Chief Executive Officer to replace Dr. Dees. We face significant competition for executives with the qualifications and experience we are seeking. There can be no assurances concerning the timing or outcome of the Company s search for a new permanent Chief Executive Officer. The Company s ability to execute its business strategies may be adversely affected by the uncertainty associated with this transition.

Executive leadership transitions can be inherently difficult to manage and may cause disruption to our business. As a result of the recent changes in our management team, our existing management team has taken on substantially more responsibility, which has resulted in greater workload demands and could divert their attention away from certain key areas of our business. In addition, management transition inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution, and our results of operations and financial condition could suffer as a result. The loss of services of one or more other members of senior management, or the inability to attract a qualified permanent Chief Executive Officer, could have a material adverse effect on our business.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by three key employees and an independent contractor:

Peter R. Culpepper, CPA, MBA, our Interim Chief Executive Officer and Chief Operating Officer;

Timothy C. Scott, Ph.D., our President;

Eric A. Wachter, Ph.D. our Chief Technology Officer; and

John R. Glass, our Interim Chief Financial Officer, who is an independent contractor.

In addition to their responsibilities for management of our overall business strategy, Drs. Scott and Wachter are our chief researchers in the fields in which we are developing and planning to develop our prescription drug and other product candidates, and our OTC products. The loss of any of these key employees could have a material adverse effect on our operations, and our ability to execute our business plan might be negatively impacted. Any of these key employees or Mr. Glass may leave their employment with us if they choose to do so, and we cannot assure you that we would be able to hire similarly qualified employees if any of our key employees or Mr. Glass should choose to leave.

Because we have only three employees and an independent contractor in total, our management may be unable to successfully manage our business.

In order to successfully execute our business plan, our management must succeed in all of the following critical areas:

Researching diseases and possible therapies in the areas of dermatology and skin care, oncology, and biotechnology;

Developing our prescription drug and other product candidates, and OTC products based on our research;

Marketing and selling developed products;

Obtaining additional capital to finance research, development, production, and marketing of our products; and

Managing our business as it grows.

As discussed above, we currently have only three employees, all of whom are full-time employees and an independent contractor, John R. Glass, our Interim Chief Financial Officer. The greatest burden of succeeding in

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the above areas, therefore, falls on Drs. Scott and Wachter, and Messrs. Culpepper and Glass. Focusing on any one of these areas may divert their attention from our other areas of concern and could affect our ability to manage other aspects of our business. We cannot assure you that our management will be able to succeed in all of these areas or, even if we do so succeed, that our business will be successful as a result. We have added a total of sixty (60) human resources on a full-time equivalent basis, including our employees. While we have not historically had difficulty in attracting employees, our small size and limited operating history may make it difficult for us to attract and retain employees in the future, which could further divert management s attention from the operation of our business.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Among other things, these provisions will:

- permit our board of directors to issue up to 25,000,000 shares of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of the common stock;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder s notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by

our then-current Board of Directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

NYSE MKT has taken actions toward delisting our common stock, including suspending trading in our common stock.

Pursuant to Section 1003(f)(v) of the NYSE MKT Company Guide, on October 13, 2016, the NYSE MKT immediately suspended trading in shares of our common stock and class of warrants listed on the NYSE MKT and commenced delisting procedures as a result of the abnormally low trading price of our common stock. We are appealing the NYSE MKT decision to commence delisting procedures. On October 20, 2016, we submitted a request for a review of such delisting determination, and on November 10, 2016, we submitted to the Listing Qualifications Panel our written submission in connection with our appeal. In the event our appeal is unsuccessful and our common stock is delisted from the NYSE MKT, we may need to make filings and obtain

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approval from certain state regulators for the issuance of the securities being offered pursuant to the Rights Offering, which could delay and increase the costs of the Rights Offering, and possibly make the Rights Offering unavailable in certain states.

Our stock price is below $5.00 per share and is treated as a penny stock , which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as penny stock under the Exchange Act and its rules. The SEC has adopted regulations that define penny stock to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

broker-dealers must deliver, prior to the transaction, a disclosure schedule prepared by the SEC relating to the penny stock market;

broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;

broker-dealers must disclose current quotations for the securities; and

a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer s account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser s written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder s ability to sell their shares.

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following any prospective offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable.

It is our general policy to retain any earnings for use in our operation.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common stock in the foreseeable future, although we intend to issue shares of common stock in satisfaction of the dividend payments due on our Preferred Stock.

Risks Related to the Rights Offering

We will incur substantial expenses in connection with the Rights Offering, which may not return adequate value if the Rights Offering is ultimately not consummated or successful.

The estimated expenses for the Rights Offering are approximately $, excluding fees and expenses of the dealer-manager that we have engaged to assist us with the Rights Offering. If the registration statement of which this prospectus is a part is not declared effective, the Rights Offering is not commenced or the Rights Offering is not ultimately consummated or successful, we will incur these expenses nonetheless. We will provide to the dealer-manager upon completion of the Rights Offering a non-accountable expense allowance equal to $100,000 for expenses incurred in connection with the Rights Offering. We advanced $30,000 against such non-accountable expense allowance to Maxim Group LLC upon its engagement as a dealer-manager; provided that Maxim Group LLC will promptly reimburse to us any portion of the advance not used for actual out-of-pocket expenses if the Rights Offering is not completed. See Plan of Distribution.

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Your ownership in our company may be diluted as a result of this Rights Offering.

Stockholders who do not fully exercise their Subscription Rights should expect that they will, at the completion of the Rights Offering, own a smaller proportional interest in our company than would otherwise be the case had they fully exercised their Basic Subscription Right and Over-Subscription Privilege. Further, the shares of common stock issuable upon the exercise of the Warrants to be issued pursuant to the Rights Offering will dilute the ownership interest of stockholders not participating in this Rights Offering or holders of Warrants issued pursuant to this Rights Offering who have not exercised them.

Further, because the price per Unit being offered may be substantially higher than the net tangible book value per share of our common stock, you may suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. If you purchase Units in this offering at the Subscription Price, you may suffer immediate and substantial dilution in the net tangible book value of the common stock. See Dilution in this prospectus for a more detailed discussion of the dilution which may incur in connection with this Rights Offering.

Price protection provisions attached to the Preferred Stock and August 2016 Warrants may reduce the amount of capital we may receive upon conversion of such Preferred Stock and exercise of such August 2016 Warrants and may also result in dilution to our stockholders.

The conversion price of the Preferred Stock is subject to anti-dilution price protection upon the issuance of equity or equity-linked securities between August 30, 2016, the date of issuance of the Preferred Stock and August 2016 Warrants, and November 23, 2016, which we refer to as the Price Reset Date, at an effective common stock purchase price of less than the conversion price then in effect, subject to certain exceptions as provided in the Certificate of Designation. In addition, if the conversion price in effect on the Price Reset Date exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on August 30, 2016 and ending on the Price Reset Date (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Conversion Price, then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive additional shares of common stock equal to the number of shares of common stock that would have been issued assuming for such purposes the Adjusted Conversion Price were in effect at such time less the shares issued at the then Conversion Price (subject to being held in abeyance based on beneficial ownership limitations); provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

The exercise price of the August 2016 Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, if the exercise price in effect on the Price Reset Date exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on August 30, 2016 and ending on the Price Reset Date (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Exercise Price, then (i) the exercise price shall be reset to the Adjusted Exercise Price (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the August 2016 Warrants, and (ii) the number of shares of common stock issuable upon exercise of the August 2016 Warrants will be reset to equal the number of shares of common stock issuable upon conversion of Preferred Stock after giving effect to the

Adjusted Conversion Price or Adjusted Exercise Price, as applicable. If a holder of August 2016 Warrants exercises its August 2016 Warrants prior to such repricing, then such holder will receive shares of common stock equal to the difference between the exercise price and the Adjusted Exercise Price; provided, however, that only the initial purchaser of Preferred Stock and

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August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

Because these price protection provisions may have the effect of lowering the price at which shares of our common stock are issued upon conversion of the Preferred Stock and exercise of the August 2016 Warrants, if such August 2016 Warrants are exercised for cash, we will receive reduced proceeds. Any such reduction in proceeds may have an adverse effect on our future working capital requirements. In addition, if the price protection provisions are triggered on the Price Reset Date, our stockholders could experience dilution as a result of the additional shares of common stock that the Company will need to issue to holders of Preferred Stock who converted their shares of Preferred Stock prior to the Price Reset Date and holders of August 2016 Warrants who exercised their Warrants prior to the Price Reset Date.

Completion of the Rights Offering is not subject to us raising a minimum offering amount, and if the Rights Offering is not fully subscribed, we will need additional funding to carry out our proposed operating activities, including our clinical trials, after the Rights Offering.

Completion of the Rights Offering is not subject to us raising a minimum offering amount and therefore the net proceeds from the Rights Offering may be insufficient to meet our objectives, thereby increasing the risk to investors in this Rights Offering, including investing in a company that continues to require capital. If we do not sell all of the Units subject to the Rights Offering, we will need to obtain additional financing in the future in order to fully fund our clinical trials of PV-10 and PH-10 through the regulatory approval process. If we sell all of the Units subject to the Rights Offering, we will have sufficient cash on hand to fund all of our research and development and other capital needs through 2017.

This Rights Offering may cause the trading price of our common stock to decrease.

The Subscription Price, together with the number of shares of common stock we propose to issue and ultimately will issue if this Rights Offering is completed, may result in an immediate decrease in the market price of our common stock. This decrease may continue after the completion of this Rights Offering. If that occurs, you may have committed to buy shares of common stock in the Rights Offering at a price greater than the prevailing market price. We cannot predict the effect, if any, that the availability of shares for future sale represented by the Warrants issued in connection with the Rights Offering, or the ability to trade the Warrants themselves, will have on the market price of our common stock from time to time. In addition, a decrease in the market price of our common stock may trigger the price protection provisions of the Preferred Stock and August 2016 Warrants such that the conversion price of the Preferred Stock would be reduced, the exercise price of the August 2016 Warrants would be reduced, and we would be required to issue additional shares of common stock to holders of Preferred Stock who converted their shares of Preferred Stock prior to the Price Reset Date and to holders of August 2016 Warrants who exercised such August 2016 Warrants prior to the Price Reset Date. See Risks Related to the Rights Offering Price protection provisions attached to the Preferred Stock and August 2016 Warrants may reduce the amount of capital we may receive upon conversion of such Preferred Stock and exercise of such August 2016 Warrants and may also result in dilution to our stockholders above. Further, if a substantial number of Subscription Rights are exercised and the holders of the shares received upon exercise of those Subscription Rights or the related Warrants choose to sell some or all of the shares underlying the Subscription Rights or the related Warrants, the resulting sales could depress the market price of our common stock. Following the exercise of your Subscription Rights you may not be able to sell your common stock at a price equal to or greater than the Subscription Price.

If we terminate this Rights Offering for any reason, we will have no obligation other than to return subscription monies as soon as practicable.

We may decide, in our sole discretion and for any reason, to cancel or terminate the Rights Offering at any time prior to the expiration date. If this offering is cancelled or terminated, we will have no obligation with

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respect to Subscription Rights that have been exercised except to return as soon as practicable, without interest or deduction, all subscription payments deposited with the Subscription Agent. If we terminate this Rights Offering and you have not exercised any Subscription Rights, such Subscription Rights will expire and be worthless.

Our common stock price may be even more volatile as a result of this Rights Offering.

The trading price of our common stock may fluctuate substantially. The price of the common stock that will prevail in the market after this Rights Offering may be higher or lower than the Subscription Price depending on many factors, some of which are beyond our control and may not be directly related to our operating performance. Our common stock has traded as low as $0.03 per share and as high as $0.99 per share during the period beginning on January 1, 2015 and ending on November 18, 2016. We believe that our common stock is subject to wide price fluctuations because of several factors, including:

- absence of meaningful earnings and ongoing need for external financing;
- a relatively thin trading market for our common stock, which causes trades of small blocks of stock to have a significant impact on our stock price;
- general volatility of the stock market and the market prices of other publicly-traded companies; and
- investor sentiment regarding equity markets generally, including public perception of corporate ethics and governance and the accuracy and transparency of financial reporting.

Financings that may be available to us under current market conditions frequently involve sales at prices below the prices at which our common stock currently trades on the OTCQB, as well as the issuance of warrants or convertible equity that require exercise or conversion prices that are calculated in the future at a discount to the then market price of our common stock.

Any agreement to sell, or convert equity securities into, our common stock at a future date and at a price based on the then current market price will provide an incentive to the investor or third parties to sell our common stock short to decrease the price and increase the number of shares they may receive in a future purchase, whether directly from us or in the market.

We cannot assure you that the trading price of our common stock will not decline after you elect to exercise your Subscription Rights. If that occurs, you may have committed to buy shares of common stock in the Rights Offering at a price greater than the prevailing market price and could have an immediate unrealized loss. Moreover, we cannot assure you that, following the exercise of your Subscription Rights, you will be able to sell your common stock at a price equal to or greater than the Subscription Price, and you may lose all or part of your investment in our common stock. Until shares of common stock are delivered upon expiration of the Rights Offering, you will not be able to sell the shares of our common stock that you purchase in the Rights Offering. Shares of our common stock purchased will be issued as soon as practicable after the Rights Offering has expired, payment for the shares of common stock and attached Warrants subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms

of the Rights Offering have been effected. We will not pay you interest on funds delivered to the Subscription Agent pursuant to your exercise of Subscription Rights.

Because we do not have any formal commitments from any of our stockholders to participate in the Rights Offering, the net proceeds we receive from the Rights Offering may be lower than we currently anticipate.

We do not have any formal commitments from any of our stockholders to participate in the Rights Offering, and we cannot assure you that any of our stockholders will exercise all or any part of their Basic Subscription Rights or their Over-Subscription Privilege. If our stockholders subscribe for fewer shares of our common stock than we currently anticipate, the net proceeds we receive from the Rights Offering could be significantly lower than we currently expect.

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The Subscription Price determined for this Rights Offering is not an indication of the fair value of our common stock.

In determining the Subscription Price, the pricing committee of our board of directors considered a number of factors, including, but not limited to, the likely cost of capital from other sources, the price at which our stockholders might be willing to participate in the Rights Offering, historical and current trading prices for our common stock, our need for liquidity and capital and the desire to provide an opportunity to our stockholders to participate in the Rights Offering on a pro rata basis. In conjunction with its review of these factors, the pricing committee also reviewed a range of discounts to market value represented by the subscription prices in various prior Rights Offerings of public companies. The Subscription Price is not intended to bear any relationship to the book value of our assets or our past operations, cash flows, losses, financial condition, net worth, or any other established criteria used to value securities. You should not consider the Subscription Price to be an indication of the fair value of our common stock offered in the Rights Offering. After the date of this prospectus, our common stock may trade at prices above or below the Subscription Price.

If you do not act on a timely basis and follow subscription instructions, your exercise of Subscription Rights may be rejected.

Holders of Subscription Rights who desire to purchase shares of our common stock and Warrants in this Rights Offering must act on a timely basis to ensure that all required forms and payments are actually received by the Subscription Agent prior to 5:00 p.m. Eastern Time, on the expiration date, unless extended. If you are a beneficial owner of shares of common stock and you wish to exercise your Subscription Rights, you must act promptly to ensure that your broker, dealer, custodian bank, trustee or other nominee acts for you and that all required forms and payments are actually received by your broker, dealer, custodian bank, trustee or other nominee in sufficient time to deliver such forms and payments to the Subscription Agent to exercise the Subscription Rights granted in this Rights Offering that you beneficially own prior to 5:00 p.m. Eastern Time on the expiration date, as may be extended. We will not be responsible if your broker, dealer, custodian bank, trustee or other nominee fails to ensure that all required forms and payments are actually received by the Subscription Agent prior to 5:00 p.m. Eastern Time, on the expiration date.

If you fail to complete and sign the required subscription forms, send an incorrect payment amount, or otherwise fail to follow the subscription procedures that apply to your exercise in this Rights Offering, the Subscription Agent may, depending on the circumstances, reject your subscription or accept it only to the extent of the payment received. Neither we nor the Subscription Agent undertakes to contact you concerning an incomplete or incorrect subscription form or payment, nor are we under any obligation to correct such forms or payment. We have the sole discretion to determine whether a subscription exercise properly follows the subscription procedures.

You may not receive all of the Units for which you over-subscribe.

Holders who fully exercise their Basic Subscription Rights will be entitled to subscribe for an additional number of Units. Over-Subscription Privileges will be allocated pro rata among Subscription Rights holders who over-subscribed, based on the number of over-subscription Units to which they have subscribed. We cannot guarantee that you will receive any or the entire amount of Units for which you over-subscribed. If the prorated amount of Units allocated to you in connection with your Over-Subscription Privilege is less than your Over-Subscription request, then the excess funds held by the Subscription Agent on your behalf will be returned to you, without interest, as soon as practicable after the Rights Offering has expired and all prorating calculations and reductions contemplated by the

terms of the Rights Offering have been effected, and we will have no further obligations to you.

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If you make payment of the Subscription Price by personal check, your check may not clear in sufficient time to enable you to purchase shares in this Rights Offering.

Any personal check used to pay for shares of common stock and Warrants to be issued in this Rights Offering must clear prior to the expiration date of this Rights Offering, and the clearing process may require five or more business days. If you choose to exercise your Subscription Rights, in whole or in part, and to pay for shares and Warrants by personal check and your check has not cleared prior to the expiration date of this Rights Offering, you will not have satisfied the conditions to exercise your Subscription Rights and will not receive the shares of common stock and Warrants you wish to purchase.

The receipt of Subscription Rights may be treated as a taxable distribution to you.

We believe the distribution of the Subscription Rights in this Rights Offering should be a non-taxable distribution to holders of shares of common stock under Section 305(a) of the Internal Revenue Code of 1986, as amended, or the Code. Please see the discussion on the Material U.S. Federal Income Tax Considerations below. This position is not binding on the IRS, or the courts, however. If this Rights Offering is deemed to be part of a disproportionate distribution under Section 305 of the Code, your receipt of Subscription Rights in this offering may be treated as the receipt of a taxable distribution to you equal to the fair market value of the Subscription Rights. Any such distribution would be treated as dividend income to the extent of our current and accumulated earnings and profits, if any, with any excess being treated as a return of capital to the extent thereof and then as capital gain. Each holder of shares of common stock is urged to consult his, her or its own tax advisor with respect to the particular tax consequences of this Rights Offering.

The Subscription Rights are not transferable, and there is no market for the Subscription Rights.

You may not sell, transfer, assign or give away your Subscription Rights. Because the Subscription Rights are non-transferable, there is no market or other means for you to directly realize any value associated with the Subscription Rights. You must exercise the Subscription Rights to realize any potential value from your Subscription Rights.

Absence of a public trading market for the Warrants may limit your ability to resell the Warrants.

There is no established trading market for the Warrants to be issued pursuant to this offering, and the Warrants may not be widely distributed. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. Even if a market for the Warrants does develop, the price of the Warrants may fluctuate and liquidity may be limited. If the Warrants are not accepted for listing on the NYSE MKT or if a market for the Warrants does not develop, then purchasers of the Warrants may be unable to resell the Warrants or sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the Warrants will depend on many factors, including:

- our operating performance and financial condition;

our ability to continue the effectiveness of the registration statement, of which this prospectus is a part, covering the Warrants and the common stock issuable upon exercise of the Warrants;

the interest of securities dealers in making a market; and

the market for similar securities.

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A continued low trading price or other factors could prevent us from being able to list the Warrants on the NYSE MKT and adversely affect the liquidity of the Warrants.

We intend to apply to list the Warrants included as part of the Units with the NYSE MKT. The NYSE MKT has advised us that NYSE MKT has a minimum price requirement of $0.20 to admit a new warrant for trading on the NYSE MKT. If we are able to effect a reverse stock split, we believe that the price of our common stock will increase to an amount such that our warrants also will be priced in excess of the $0.20 minimum price required by the NYSE MKT for listing the Warrants. There can be no assurance, however, that we will be able to effect a reverse stock split or that the price of the Warrants (as a result of a reverse stock split or otherwise) will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of subscription rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. In addition, if the Warrants are not accepted for listing on the NYSE MKT, we may need to make filings and obtain approval from certain state regulators for the issuance of the Warrants, which could delay and increase the costs of the Rights Offering, and possibly make the Rights Offering unavailable in certain states.

There is no market for the Pre-Funded Warrants.

There is no established trading market for the Pre-Funded Warrants to be issued pursuant to this Rights Offering, if any, and the Pre-Funded Warrants will not be listed for trading on any stock exchange or market.

The Warrants issued in this Rights Offering and our outstanding warrants may have an adverse effect on the market price of our common stock and make it more difficult to effect a business combination.

To the extent we issue shares of common stock to effect a future business combination, the potential for the issuance of a substantial number of additional shares upon exercise of the Warrants issued in this Rights Offering and our outstanding warrants could make us a less attractive acquisition vehicle in the eyes of a target business. Such securities, when exercised, will increase the number of issued and outstanding shares of common stock and reduce the value of the shares issued to complete the business combination. Accordingly, our outstanding warrants, including the Warrants issued in this Rights Offering, may make it more difficult to effectuate a business combination or increase the cost of acquiring a target business. Additionally, the sale, or even the possibility of sale, of the shares of common stock underlying the Warrants and our outstanding warrants could have an adverse effect on the market price for our securities or on our ability to obtain future financing. If and to the extent these outstanding warrants are exercised, you may experience dilution to your holdings.

The market price of our common stock may never exceed the exercise price of the Warrants issued in connection with this Rights Offering.

The Warrants being issued in connection with this Rights Offering become exercisable upon issuance and will expire five years after issuance. We cannot provide you any assurance that the market price of our common stock will ever exceed the exercise price of the Warrants prior to their date of expiration. Any Warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.

The Warrants may be redeemed on short notice. This term may have an adverse impact on the price of the Warrants.

After the one-year anniversary of issuance, we may redeem the Warrants for $0.001 per Warrant once the closing price of our common stock has equaled or exceeded $ per share, 250% of the exercise price, subject to adjustment, for 10 consecutive trading days. If we give notice of redemption, you will be forced to sell or exercise your Warrants or accept the redemption price. The notice of redemption could come at a time when it is not advisable or possible for you to exercise the Warrants. As a result, you would be unable to benefit from owning the Warrants being redeemed.

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The dealer-manager is not underwriting, nor acting as placement agent of, the Subscription Rights or the securities underlying the Subscription Rights.

Maxim Group LLC is acting as dealer-manager for this Rights Offering. Under the terms and subject to the conditions contained in the dealer-manager agreement, the dealer-manager will provide marketing assistance in connection with this Rights Offering. The dealer-manager is not underwriting or placing any of the Subscription Rights or the Units, shares of common stock, Warrants or Pre-Funded Warrants being issued in this Rights Offering, and does not make any recommendation with respect to such Subscription Rights (including with respect to the exercise or expiration of such Subscription Rights), Units, shares of common stock, Warrants or Pre-Funded Warrants. The dealer-manager will not be subject to any liability to us in rendering the services contemplated by the dealer-manager agreement except for any act of bad faith or gross negligence by the dealer-manager. The services of the dealer-manager to us in connection with this offering cannot be construed as any assurance that this offering will be successful.

Since the Warrants and Pre-Funded Warrants are executory contracts, they may have no value in a bankruptcy or reorganization proceeding.

In the event a bankruptcy or reorganization proceeding is commenced by or against us, a bankruptcy court may hold that any unexercised Warrants and Pre-Funded Warrants are executory contracts that are subject to rejection by us with the approval of the bankruptcy court. As a result, holders of the Warrants and Pre-Funded Warrants may, even if we have sufficient funds, not be entitled to receive any consideration for their Warrants and Pre-Funded Warrants or may receive an amount less than they would be entitled to if they had exercised their Warrants and Pre-Funded Warrants prior to the commencement of any such bankruptcy or reorganization proceeding.

Our management team may invest or spend the proceeds of the Rights Offering in ways with which you may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from the Rights Offering. The net proceeds from the Rights Offering will be used for clinical development, including our ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma, working capital and general corporate purposes. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock.

As a result of the Rights Offering, we may be in breach of certain registration rights obligations.

As of September 30, 2016, we have outstanding obligations to register approximately 500,000 warrants to purchase shares of our common stock and 650,000 shares of our common stock issuable upon the exercise of these outstanding warrants under the Securities Act of 1933, as amended, or the Securities Act, which were granted to certain of our consultants. We may be in breach of all of our obligations to register these securities as a result of this Rights Offering. There are no liquidated damages stipulated for our failure to register such securities; however, the holders of these securities may still elect to pursue remedies against us for our failure to meet these registration obligations and, as a result, our business operations, or our ability to raise additional capital in the future, may be adversely affected.

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USE OF PROCEEDS

Assuming that all Units are sold in the Rights Offering and no elections to receive Pre-Funded Warrants are made, we estimate that the net proceeds from the Rights Offering will be approximately $ million, based on a Subscription Price of $ per Unit, after deducting fees and expenses payable to the dealer-manager, and after deducting other expenses payable by us and excluding any proceeds received upon exercise of any Warrants issued in the Rights Offering.

We intend to use approximately $15 million of the net proceeds from this Rights Offering for clinical development, including approximately $5 million to complete our ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma, approximately $5 million to complete our phase 1b/2 combination study of PV-10 and Merck s KEYTRUDA in late stage melanoma and approximately $5 million to complete our phase 1b/2 study of PV-10 in liver cancer, and we intend to use the remaining net proceeds for working capital and general corporate purposes. If we sell all of the Units subject to the Rights Offering, we will have sufficient cash on hand to fund all of our research and development and other capital needs through 2017.

Our management will have broad discretion in the application of the net proceeds from this Rights Offering, and investors will be relying on the judgment of our management with regard to the use of these net proceeds. Until we use the net proceeds of this Rights Offering, we intend to invest the funds in short-term, investment grade, interest-bearing securities and short-term U.S. Treasury bills.

MARKET PRICE OF OUR COMMON STOCK AND DIVIDEND POLICY

On May 16, 2014, our common stock ceased to be traded on the OTCQB Marketplace operated by OTC Markets Group and began trading on the NYSE MKT. On October 13, 2016, NYSE MKT suspended trading of our common stock, due to the abnormally low trading prices of our common stock, and on October 17, 2016 our common stock began trading on the OTCQB. Our trading symbol remains PVCT. The following table sets forth the range of high and low sale prices of our common stock for the periods indicated since January 1, 2014:

	High	Low
2014		
First Quarter (January 1 to March 31)	$ 6.03	$ 1.16
Second Quarter (April 1 to June 30)	$ 3.75	$ 0.30
Third Quarter (July 1 to September 30)	$ 1.20	$ 0.81
Fourth Quarter (October 1 to December 31)	$ 1.10	$ 0.75
2015		
First Quarter (January 1 to March 31)	$ 0.93	$ 0.76
Second Quarter (April 1 to June 30)	$ 0.99	$ 0.49
Third Quarter (July 1 to September 30)	$ 0.70	$ 0.32
Fourth Quarter (October 1 to December 31)	$ 0.60	$ 0.36
2016		
First Quarter (January 1 to March 31)	$ 0.52	$ 0.35
Second Quarter (April 1 to June 30)	$ 0.53	$ 0.31
Third Quarter (July 1 to September 30)	$ 0.38	$ 0.09

Fourth Quarter (through November 18)	$ 0.10	$ 0.03

The closing price for our common stock on November 18, 2016 was $0.04. As of November 15, 2016, we had 975 stockholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently plan to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. We may incur indebtedness in the future which may prohibit or effectively restrict the payment of dividends, although we have no current plans to do so. Any future determination to pay cash dividends will be at the discretion of our board of directors.

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The holders of our outstanding Preferred Stock are entitled to receive cumulative dividends at the rate per share of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Preferred Stock. The dividends become payable, at our option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Preferred Stock, (ii) on each such other date as our board of directors may determine, subject to written consent of the holders of Preferred Stock holding a majority of the then issued and outstanding Preferred Stock, (iii) upon our liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, including any merger or consolidation, sale of all or substantially all of our assets, exchange or conversion of all of our common stock by tender offer, exchange offer or reclassification; provided, however, that if Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Preferred Stock before the date of conversion. Make-whole payments are payable at our option in either cash, out of any funds legally available for such purpose, or in shares of common stock. With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Preferred Stock will be an amount equal to the quotient of (i) the amount of the dividend payable to such holder divided by (ii) the conversion price then in effect.

DILUTION

Purchasers of our common stock in the Rights Offering (and upon exercise of the Warrants issued pursuant to this Rights Offering) will experience an immediate dilution of the net tangible book value per share of our common stock. Our net tangible book value as of September 30, 2016 was approximately $2,873,464, or approximately $0.01 per share of common stock. Net tangible book value per share is determined by dividing our net tangible book value, which consists of our total tangible assets less total liabilities, by the number of shares of our common stock outstanding on that date. Dilution per share equals the difference between the amount per share paid by purchasers of shares of common stock in the Rights Offering and the net tangible book value per share of our common stock immediately after the Rights Offering.

Based on the sale by us in this Rights Offering of a maximum of Units (consisting of shares of our common stock (assuming no Pre-Funded Warrants) and Warrants to purchase an aggregate of shares of common stock upon exercise), at the Subscription Price of $ per Unit, and after deducting estimated offering expenses and dealer-manager fees and expenses payable by us of $ million, and the application of the estimated $ million of net proceeds from the Rights Offering, assuming equity accounting for the Warrants, our pro forma net tangible book value as of September 30, 2016 would have been approximately $ million, or $ per share. This represents an immediate increase in net tangible book value to existing shareholders of $ per share and an immediate dilution to purchasers in the Rights Offering of $ per share.

The following table illustrates this per-share dilution on a pro forma basis, assuming a fully subscribed for Rights Offering of Units at the Subscription Price of $ per Unit (assuming no Pre-Funded Warrants and excluding any issuance of shares of common stock upon exercise of Warrants):

Subscription Price	$

Net tangible book value per share as of September 30, 2016, before giving effect to the Rights Offering	$ 0.01
Net increase in tangible book value per share attributable to the Rights Offering	$
Pro forma net tangible book value per share after giving effect to the Rights Offering	$
Dilution in pro forma net tangible book value per share to purchasers in the Rights Offering	$

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This discussion of dilution, and the table set forth above, is based on 243,895,352 shares of our Common Stock issued and outstanding as of September 30, 2016 before giving effect to the Rights Offering and shares of Common Stock issued and outstanding as of September 30, 2016 after giving effect to the Rights Offering. The foregoing discussion and table assume that none of the following securities have been exercised or converted for or into shares of our Common Stock as of September 30, 2016:

shares of our common stock issuable upon exercise of Warrants issued in the Rights Offering;

24,000,000 shares of our common stock issuable upon exercise of warrants issued in the Preferred Stock Offering on August 30, 2016;

5,000,000 shares of our common stock issuable upon exercise of stock options outstanding as of September 30, 2016; and

101,821,186 shares of our common stock issuable upon exercise of warrants to purchase our common stock outstanding as of September 30, 2016.

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THE RIGHTS OFFERING

The Subscription Rights

We are distributing to the record holders of our common stock, at no charge, non-transferable Subscription Rights to purchase one Unit at a subscription price per Unit of $. See Subscription Price below. Each Basic Subscription Right will entitle you to purchase shares of our common stock and Warrants for the purchase of one additional share of our common stock at an exercise price of $ per share, from the date of issuance through its expiration on , 2021. Each record holder will receive one Subscription Right to purchase one Unit for every shares of our common stock owned by such record holder as of 5:00 p.m. Eastern Time on the Record Date. Each Subscription Right entitles the record holder to a Basic Subscription Right and an Over-Subscription Privilege.

Basic Subscription Rights

For every shares you owned as of the Record Date, you will receive one Basic Subscription Right, which gives you the opportunity to purchase one Unit, consisting of shares of common stock and Warrants to purchase one share of common stock for a price of $ per Unit. For example, if you owned 100 shares of common stock as of the Record Date, you will receive Subscription Rights and will have the right to purchase shares of our common stock and Warrants to purchase shares of our common stock for $ per Unit (or a total payment of $). You may exercise all or a portion of your Basic Subscription Rights, or you may choose not to exercise any of your Basic Subscription Rights. If you do not exercise your Basic Subscription Rights in full, you will not be entitled to exercise your Over-Subscription Privilege.

Over-Subscription Privilege

If you exercise your Basic Subscription Rights in full, you may also choose to exercise your Over-Subscription Privilege. Subject to proration, if applicable, we will seek to honor the Over-Subscription Privilege requests in full. If Over-Subscription Privilege requests exceed the number of Units available, however, we will allocate the available Units pro rata among the record holders exercising the Over-Subscription Privilege in proportion to the number of shares of our common stock each of those record holders owned on the Record Date, relative to the number of shares owned on the Record Date by all record holders exercising the Over-Subscription Privilege. If this pro rata allocation results in any record holder receiving a greater number of Units than the record holder subscribed for pursuant to the exercise of the Over-Subscription Privilege, then such record holder will be allocated only that number of Units for which the record holder oversubscribed, and the remaining Units will be allocated among all other record holders exercising the Over-Subscription Privilege on the same pro rata basis described above. The proration process will be repeated until all Units have been allocated.

If the Rights Offering is oversubscribed (after taking into account all Over-Subscription requests), we may increase the size of the Rights Offering, in our sole discretion, by up to 20%, and we will allocate such increased amount pro rata among our stockholders who exercise both their Basic Subscription Right and their Over-Subscription Privilege in the same manner as described above.

Broadridge Corporate Issuer Solutions, Inc., our Subscription Agent for the Rights Offering, will determine the Over-Subscription allocation based on the formula described above.

To the extent the aggregate subscription payment of the actual number of unsubscribed Units available to you pursuant to the Over-Subscription Privilege is less than the amount you actually paid in connection with the exercise of the Over-Subscription Privilege, you will be allocated only the number of unsubscribed Units available to you, and any excess subscription payments will be returned to you, without interest or penalty, as soon as practicable after expiration of the Rights Offering.

We can provide no assurances that you will actually be entitled to purchase the number of Units issuable upon the exercise of your Over-Subscription Privilege in full at the expiration of the Rights Offering. We will not

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be able to satisfy any requests for Units pursuant to the Over-Subscription Privilege if all of our stockholders exercise their Basic Subscription Rights in full, and we will only honor an Over-Subscription Privilege to the extent sufficient Units are available following the exercise of Basic Subscription Rights.

Pre-Funded Warrants

If your subscription for Units in the Rights Offering may result in the your beneficial ownership of more than 4.99% of our outstanding common stock following the consummation of the Rights Offering, and you do not wish to exceed that ownership threshold, you may elect to receive a Pre-Funded Warrant to purchase one share of common stock in lieu of any share of common stock underlying the Units for which you have subscribed in excess of such threshold.

You may make an election to receive Pre-Funded Warrants in lieu of common stock, to the extent that your beneficial ownership would otherwise be above the ownership threshold. If you intend to do so, in addition to making your election on your Subscription Rights Certificate, we ask that you contact the dealer-manager for the Rights Offering as follows:

Maxim Group LLC

405 Lexington Avenue

New York, New York 10174

Attention Syndicate Department

Email: syndicate@maximgrp.com

Telephone: (212) 895-3745

If you make an election to receive Pre-Funded Warrants but fail to timely provide the required holder information for the issuance of any Pre-Funded Warrants, you may receive the shares of common stock underlying all of your subscribed Units.

Limitation on the Purchase of Units

You may only purchase the number of whole Units purchasable upon exercise of the number of Basic Subscription Rights distributed to you in the Rights Offering, plus the Over-Subscription Privilege, if any. Accordingly, the number of Units that you may purchase in the Rights Offering is limited by the number of shares of our common stock you held on the Record Date and by the extent to which other stockholders exercise their Basic Subscription Rights and Over-Subscription Privileges, which we cannot determine prior to completion of the Rights Offering.

Subscription Price

The Subscription Price per Unit is $. The Subscription Price does not necessarily bear any relationship to our past or expected future results of operations, cash flows, current financial condition, or any other established criteria for value.

We may, in our sole discretion, reduce the Subscription Price by up to 20%, and if we elect to reduce the Subscription Price per Unit, you may elect to receive (i) proportionally more Units based on the payment amount we received from you in connection with the exercise of your Subscription Rights or (ii) an amount in cash equal to the difference between your total payment amount at the original Subscription Price and the payment amount that would have been due for the number of Units for which you subscribed at the reduced Subscription Price. You may make this election on the enclosed Subscription Rights Certificate (if you are a stockholder of record) or on the enclosed Beneficial Owner Election Form (if you are a beneficial owner of shares of our common stock that are registered in the name of a broker, dealer, custodian bank, or other nominee) at the time you exercise your Subscription Rights. See Methods for Exercising

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Subscription Rights below. If you elect to receive cash in lieu of additional Units, the Company will remit such payment within 10 business days after the expiration date of the Rights Offering, without interest or deduction.

In the event that we determine to reduce the subscription price, we will file with the Commission and mail to stockholders of record as of the record date for the Rights Offering a prospectus supplement disclosing the reduced subscription price. The expiration date of the Rights Offering will be no less than seven calendar days after the date of such prospectus supplement disclosing a reduction in subscription price.

Determination of Subscription Price

In the determining the Subscription Price, the pricing committee is expected to consider a variety of factors including those listed below:

- the likely cost of capital from other sources;
- a price that would increase the likelihood of participation in the Rights Offering;
- historical and current trading prices for our common stock;
- our need to raise capital in the near term to continue our operations;
- comparable precedent transactions, including terms of the subscription rights being offered, the subscription price and the discount that the subscription price represents to the immediately prevailing closing prices for these offerings;
- the value of the Warrant being issued as a component of the Unit; and
- the desire to provide an opportunity to our stockholders to participate in the Rights Offering on a pro rata basis.

The Subscription Price does not necessarily bear any relationship to any established criteria for value. No valuation consultant or investment banker has opined upon the fairness or adequacy of the Subscription Price. You should not consider the Subscription Price as an indication of actual value of our company or our common stock. You should not assume or expect that, after the Rights Offering, our shares of common stock will trade at or above the Subscription Price in any given time period. The market price of our common stock may decline during or after the Rights Offering. We cannot assure you that you will be able to sell the shares of our common stock purchased during the Rights Offering at a price equal to or greater than the Subscription Price. You should obtain a current price quote for our common stock before exercising your Subscription Rights and make your own assessment of our business and financial condition, our prospects for the future, and the terms of this Rights Offering.

No Recombination

The common stock and Warrants comprising the Units will separate upon the effectiveness of the exercise of the Subscription Rights and will be issued as separate securities, and the Units will not trade as a separate security. Holders may not recombine shares of common stock and Warrants to receive a Unit.

Non-Transferability of Subscription Rights

The Subscription Rights are non-transferable (other than by operation of law) and, therefore, you may not sell, transfer, assign or give away your Subscription Rights to anyone. The Subscription Rights will not be listed for trading on any stock exchange or market.

Expiration Date; Extension

The subscription period, during which you may exercise your Subscription Rights, expires at 5:00 p.m. Eastern Time, on , 2016, which is the expiration of the Rights Offering. If you do not exercise your Subscription Rights before that time, your Subscription Rights will expire and will no longer be exercisable. We will not be required to issue shares to you if the Subscription Agent receives your Subscription Rights Certificate or your subscription payment after that time. We have the option to extend the Rights Offering in our sole discretion; provided, however, that we may not extend the expiration date of the Rights Offering by more than

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30 days past the original expiration date. We do not presently intend to extend the expiration date of the Rights Offering. We may extend the Rights Offering by giving oral or written notice to the Subscription Agent before the Rights Offering expires. If we elect to extend the Rights Offering, we will issue a press release announcing the extension no later than 9:00 a.m. Eastern Time, on the next business day after the most recently announced expiration date of the Rights Offering.

If you hold your shares of common stock in the name of a broker, dealer, custodian bank or other nominee, the nominee will exercise the Subscription Rights on your behalf in accordance with your instructions. Please note that the nominee may establish a deadline that may be before 5:00 p.m. Eastern Time, on , 2016, which is the expiration date that we have established for the Rights Offering.

Termination

We may terminate the Rights Offering at any time and for any reason prior to the completion of the Rights Offering. If we terminate the Rights Offering, we will issue a press release notifying stockholders and the public of the termination.

Return of Funds upon Completion or Termination

The Subscription Agent will hold funds received in payment for shares in a segregated account pending completion of the Rights Offering. The Subscription Agent will hold this money until the Rights Offering is completed or is terminated. To the extent you properly exercise your Over-Subscription Privilege for an amount of Units that exceeds the number of unsubscribed Units available to you, any excess subscription payments will be returned to you as soon as practicable after the expiration of the Rights Offering, without interest or penalty. If the Rights Offering is terminated for any reason, all subscription payments received by the Subscription Agent will be returned as soon as practicable, without interest or penalty.

Shares of Our Common Stock Outstanding After the Rights Offering

On , 2016, shares of our common stock were outstanding. Based on the foregoing, and assuming no other transactions by us involving our common stock prior to the expiration of the Rights Offering, and that no Pre-Funded Warrants are issued in lieu of common stock, if the Rights Offering is fully subscribed, approximately shares of our common stock will be issued and outstanding and Warrants to purchase approximately additional shares of our common stock will be outstanding (excluding the currently outstanding warrants). The exact number of shares of common stock, Warrants and Pre-Funded Warrants that we will issue in this Rights Offering will depend on the number of Units that are subscribed for in the Rights Offering and the elections of eligible investors to receive Pre-Funded Warrants.

Methods for Exercising Subscription Rights

You may exercise your Subscription Rights as follows:

Subscription by Record Holders

If you are a stockholder of record, the number of Units you may purchase pursuant to your Subscription Rights in indicated on the enclosed Subscription Rights Certificate. You may exercise your Subscription Rights by properly

completing and executing the Subscription Rights Certificate and forwarding it, together with your full payment, to the Subscription Agent at the address given below under Subscription Agent, to be received before 5:00 p.m. Eastern Time, on , 2016.

Subscription by Beneficial Owners

If you are a beneficial owner of shares of our common stock that are registered in the name of a broker, dealer, custodian bank, or other nominee, you will not receive a Subscription Rights Certificate. Instead, we will issue one Subscription Right to such nominee record holder for all shares of our common stock held by such

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nominee at the Record Date. If you are not contacted by your nominee, you should promptly contact your nominee in order to subscribe for shares in the Rights Offering and follow the instructions provided by your nominee.

To properly exercise your Over-Subscription Privilege, you must deliver the subscription payment related to your Over-Subscription Privilege before the Rights Offering expires. Because we will not know the total number of unsubscribed Units before the Rights Offering expires, if you wish to maximize the number of shares you purchase pursuant to your Over-Subscription Privilege, you will need to deliver payment in an amount equal to the aggregate subscription payment for the maximum number of Units that you wish to purchase.

Payment Method

Payments must be made in full in U.S. currency by personal check, certified check or by wire transfer, and payable to Broadridge Corporate Issuer Solutions, Inc., as Subscription Agent for Provectus Biopharmaceuticals, Inc. You must timely pay the full subscription payment, including payment for the Over-Subscription Privilege, for the full number of Units of our common stock and Warrants you wish to acquire pursuant to the exercise of Subscription Rights by delivering a:

- personal check, drawn on a U.S. bank payable to Broadridge Corporate Issuer Solutions, Inc., as Subscription Agent for Provectus Biopharmaceuticals, Inc. ;
- certified check, drawn on a U.S. bank payable to Broadridge Corporate Issuer Solutions, Inc., as Subscription Agent for Provectus Biopharmaceuticals, Inc. ; or
- wire transfer of immediately available funds directly to the account maintained by Broadridge Corporate Issuer Solutions, Inc., as Subscription Agent, for purposes of accepting subscriptions in this Rights Offering at:

US Bank

ABA/Routing number: 123000848

International/Swift code: USBKUS44IMT

Bank: U.S. Bank

800 Nicollet Mall

City/State/Country: Minneapolis, MN 55402 United States

Beneficiary Account Name: Broadridge

Account Number: 153910728465

FFC: Broadridge FBO Provectus

FFC: a/c 153911230024

You should read the instruction letter accompanying the Subscription Rights Certificate carefully and strictly follow it. **DO NOT SEND SUBSCRIPTION RIGHTS CERTIFICATES OR PAYMENTS DIRECTLY TO US**. We will not consider your subscription received until the Subscription Agent has received delivery of a properly completed and duly executed Subscription Rights Certificate and payment of the full subscription payment.

The method of delivery of Subscription Rights Certificates and payment of the subscription payment to the Subscription Agent will be at the risk of the holders of Subscription Rights. If sent by mail, we recommend that you send those statements and payments by registered mail, properly insured, with return receipt requested, or by overnight courier, and that you allow a sufficient number of days to ensure delivery to the Subscription Agent before the Rights Offering expires.

Missing or Incomplete Subscription Forms or Payment

If you fail to complete and sign the Subscription Rights Certificate or otherwise fail to follow the subscription procedures that apply to the exercise of your Subscription Rights before the Rights Offering expires, the Subscription Agent will reject your subscription or accept it to the extent of the payment received. Neither we

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nor our Subscription Agent undertakes any responsibility or action to contact you concerning an incomplete or incorrect subscription form, nor are we under any obligation to correct such forms. We have the sole discretion to determine whether a subscription exercise properly complies with the subscription procedures.

If you send a payment that is insufficient to purchase the number of shares you requested, or if the number of shares you requested is not specified in the forms, the payment received will be applied to exercise your Subscription Rights to the fullest extent possible based on the amount of the payment received. Any excess subscription payments received by the Subscription Agent will be returned, without interest or penalty, as soon as practicable following the expiration of the Rights Offering.

Issuance of Common Stock and Warrants

The shares of common stock and Warrants that are purchased in the Rights Offering as part of the Units will be issued in book-entry, or uncertificated, form meaning that you will receive a direct registration (DRS) account statement from our transfer agent reflecting ownership of these securities if you are a holder of record of shares of our common stock. If you hold your shares of common stock in the name of a custodian bank, broker, dealer, or other nominee, DTC will credit your account with your nominee with the securities you purchased in the Rights Offering.

Any Pre-Funded Warrants that are purchased in the Rights Offering will be issued in physical form.

Subscription Agent

The Subscription Agent for the Rights Offering is Broadridge Corporate Issuer Solutions, Inc. The address to which Subscription Rights Certificates and payments should be mailed or delivered by overnight courier is provided below. If sent by mail, we recommend that you send documents and payments by registered mail, properly insured, with return receipt requested, and that you allow a sufficient number of days to ensure delivery to the Subscription Agent before the Rights Offering expires. Do not send or deliver these materials to us.

By Mail:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS Re-Organization Dept.

P.O. Box 1317

Brentwood, NY 11717

By Hand Delivery or Overnight Courier Excluding USPS:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS IWS

51 Mercedes Way

Edgewood, NY 11717

If you deliver the Subscription Rights Certificate in a manner different than that described in this prospectus, we may not honor the exercise of your Subscription Rights.

Dealer-Manager

You should direct any questions or requests for assistance concerning the method of subscribing for the shares of our common stock or for additional copies of this prospectus to the dealer-manager for the Rights Offering as follows:

Maxim Group LLC

405 Lexington Avenue

New York, New York 10174

Attention Syndicate Department

Email: syndicate@maximgrp.com

Telephone: (212) 895-3745

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No Fractional Shares

We will not issue fractional shares of common stock in the Rights Offering. Rights holders will only be entitled to purchase a number of Units representing a whole number of shares of common stock, rounded down to the nearest whole number of Units a holder would otherwise be entitled to purchase. Any excess subscription payments received by the Subscription Agent will be returned as soon as practicable after expiration of the Rights Offering, without interest or penalty. Similarly, no fractional shares of common stock will be issued in connection with the exercise of a Warrant or Pre-Funded Warrant. If, upon exercise of a Warrant, the holder thereof would be entitled to receive a fractional share of common stock, upon exercise, the holder will only be entitled to receive a whole number of shares of common stock, rounded down to the nearest whole number.

Notice to Brokers and Nominees

If you are a broker, dealer, bank, or other nominee holder that holds shares of our common stock for the account of others on the Record Date, you should notify the beneficial owners of the shares for whom you are the nominee of the Rights Offering as soon as possible to learn their intentions with respect to exercising their Subscription Rights. If a beneficial owner of our common stock so instructs, you should complete the Subscription Rights Certificate and submit it to the Subscription Agent with the proper subscription payment by the expiration date. You may exercise the number of Subscription Rights to which all beneficial owners in the aggregate otherwise would have been entitled had they been direct holders of our common stock on the Record Date, provided that you, as a nominee record holder, make a proper showing to the Subscription Agent by submitting the form entitled Nominee Holder Certification, which is provided with your Rights Offering materials. If you did not receive this form, you should contact our Subscription Agent to request a copy.

Validity of Subscriptions

We will resolve all questions regarding the validity and form of the exercise of your Subscription Rights, including time of receipt and eligibility to participate in the Rights Offering. Our determination will be final and binding. We will not accept any alternative, conditional, or contingent subscriptions. We reserve the absolute right to reject any subscriptions not properly submitted or the acceptance of which would be unlawful. You must resolve any irregularities in connection with your subscriptions before the expiration date of the Rights Offering, unless we waive them in our sole discretion. Neither we nor the Subscription Agent is under any duty to notify you or your representative of defects in your subscriptions. A subscription will be considered accepted, subject to our right to withdraw or terminate the Rights Offering, only when the Subscription Agent receives a properly completed and duly executed Subscription Rights Certificate and any other required documents and the full subscription payment. Our interpretations of the terms and conditions of the Rights Offering will be final and binding.

Stockholder Rights

You will have no rights as a holder of the shares of our common stock you purchase in the Rights Offering until shares are issued in book-entry form or your account at your broker, dealer, bank, or other nominee is credited with the shares of our common stock purchased in the Rights Offering. Holders of Warrants issued in connection with the Rights Offering will not have rights as holders of our common stock until such Warrants are exercised and the shares of common stock underlying the Warrants are issued to the holder.

Foreign Stockholders

We will not mail this prospectus or Subscription Rights Certificates to stockholders with addresses that are outside the United States or that have an army post office or foreign post office address. The Subscription Agent will hold these Subscription Rights Certificates for their account. To exercise Subscription Rights, our foreign stockholders must notify the Subscription Agent prior 5:00 p.m. Eastern Time, on , 2016, the third

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business day prior to the expiration date, of your exercise of Subscription Rights and provide evidence satisfactory to us, such as a legal opinion from local counsel, that the exercise of such Subscription Rights does not violate the laws of the jurisdiction in which such stockholder resides and payment by a U.S. bank in U.S. dollars before the expiration of the Rights Offering. If no notice is received by such time or the evidence presented is not satisfactory to us, the Subscription Rights represented thereby will expire.

Revocation Rights

Exercises of Subscription Rights may be revoked at any time prior to the expiration date of the Rights Offering. If the expiration date of the Rights Offering is extended, you may revoke your exercise of Subscription Rights at any time until the final expiration date of the Rights Offering, as so extended. After the expiration date of the Rights Offering, such exercises are irrevocable.

To be effective, a written notice of revocation must be received by the Subscription Agent at its address identified in this prospectus prior to the expiration date of the Rights Offering, as may be extended. Any notice of revocation must specify the name of the person who exercised the Subscription Rights for which such exercises are to be revoked and the number of Subscription Rights to be revoked. Any funds received by the Subscription Agent will be promptly returned to such holder following a revocation. Revocations of Subscription Rights may not be cancelled; however, you may exercise your Subscription Rights again by following one of the procedures described above in the section entitled The Rights Offering Methods for Exercising Subscription Rights at any time prior to the expiration of the Rights Offering.

All questions as to the form and validity (including time of receipt) of any notice of revocation will be determined by us, in our sole discretion, which determination shall be final and binding, subject to the judgments of any courts with jurisdiction over us that might provide otherwise. Neither we nor any other person will be under any duty to give notification of any defect or irregularity in any notice of revocation or incur any liability for failure to give any such notification, subject to the judgment of any court with jurisdiction over us.

U.S. Federal Income Tax Treatment of Rights Distribution

For U.S. federal income tax purposes, we do not believe holders of shares of our common stock or warrants should recognize income or loss upon receipt or exercise of a Subscription Right. See Material U.S. Federal Income Tax Consequences.

No Recommendation by Our Board to Rights Holders

Our board of directors is not making a recommendation regarding your exercise of the Subscription Rights. Stockholders who exercise Subscription Rights risk total investment loss on money invested. We cannot assure you that the market price of our common stock will reach or exceed the Subscription Price, and even if it does so, that it will not decline during or after the Rights Offering. We also cannot assure you that you will be able to sell shares of our common stock or Warrants purchased in the Rights Offering at a price equal to or greater than the Subscription Price. You should make your investment decision based on your assessment of our business and financial condition, our prospects for the future and the terms of this Rights Offering. Please see Risk Factors for a discussion of some of the risks involved in investing in our common stock.

Fees and Expenses

We will pay all fees charged by the Subscription Agent and Information Agent and by the dealer-manager. You are responsible for paying any other commissions, fees, taxes or other expenses incurred in connection with the exercise of your Subscription Rights.

Listing

The Subscription Rights may not be sold, transferred, assigned or given away to anyone, and will not be listed for trading on any stock exchange or market. We intend to apply to list the Warrants on the NYSE MKT following their issuance under the symbol although there is no assurance that the price of the Warrants

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will meet the minimum listing price of $0.20 to be accepted for listing on the NYSE MKT or that a sufficient number of Subscription Rights will be exercised so that the Warrants will meet the minimum listing criteria to be accepted for listing on the NYSE MKT. The shares of our common stock, including the shares to be issued in the Rights Offering and the shares underlying the Warrants and any Pre-Funded Warrants to be issued in the Rights Offering, are traded on the NYSE MKT under the symbol PVCT. The Pre-Funded Warrants will not be listed for trading on any stock exchange or market.

Important

Do not send Subscription Rights Certificates directly to us. You are responsible for choosing the payment and delivery method for your Subscription Rights Certificate, and you bear the risks associated with such delivery. If you choose to deliver your Subscription Rights Certificate and payment by mail, we recommend that you use registered mail, properly insured, with return receipt requested. We also recommend that you allow a sufficient number of days to ensure delivery to the Subscription Agent prior to the expiration time.

Distribution Arrangements

Maxim Group LLC is the dealer-manager for the Rights Offering. The dealer-manager will provide marketing assistance and advice to us in connection with the Rights Offering and will use its best efforts to solicit the exercise of Subscription Rights and participation in the Over-Subscription Privilege. The dealer-manager is not underwriting or placing any of the Subscription Rights or the Units, shares of common stock or Warrants to be issued in the Rights Offering, and does not make any recommendation with respect to such Subscription Rights (including with respect to the exercise or expiration of such Subscription Rights), Units, shares of common stock or Warrants. We have agreed to pay the dealer-manager certain fees and to reimburse the dealer-manager for certain out-of-pocket expenses incurred in connection with this Rights Offering. See Plan of Distribution for a discussion of the fees and expenses to be paid to the dealer-manager in connection with this Rights Offering.

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DESCRIPTION OF SECURITIES

The following description of our capital, certificate of incorporation and bylaws are only summaries, and we encourage you to review complete copies of these documents, which are incorporated by reference as exhibits to the registration statement of which this prospectus forms a part. You can obtain copies of these documents by following the directions outlined in Where You Can Find More Information elsewhere in this prospectus.

Common Stock

Subject to the preferences that may be applicable to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that may be declared by our board of directors out of funds legally available for that purpose. Holders of our common stock are entitled to one vote for each share on all matters voted on by stockholders, including the election of directors. Holders of our common stock do not have any conversion, redemption, sinking fund or preemptive rights. In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate liquidation preference of any preferred stock then outstanding. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. All outstanding shares of our common stock are, and any shares of common stock that we may issue in the future will be, fully paid and non-assessable. As of September 30, 2016, 243,895,352 shares of common stock were issued and outstanding.

Delaware Anti-Takeover Law and Provisions in Our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/3\%$ of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

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the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any person that is:

the owner of 15% or more of the outstanding voting stock of the corporation;

an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or

the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation s certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and bylaws do not exclude us from the restrictions of Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our board of directors since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws will:

permit our board of directors to issue up to 25,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder s notice;

not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

Preferred Stock

Under our certificate of incorporation, as amended, we are authorized to issue up to 25,000,000 shares of preferred stock, par value $.001 per share, from time to time in one or more series, in any manner permitted by

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law, as determined from time to time by our board of directors, and stated in the resolution or resolutions providing for the issuance of such shares adopted by our board of directors. Without limiting the generality of the foregoing, shares in such series shall have voting powers, full or limited, or no voting powers, and shall have such designations, preferences and relative, participating, optional, or other special rights, and qualifications, limitations, or restrictions thereof, permitted by law, as shall be stated in the resolution or resolutions providing for the issuance of such shares adopted by our board of directors. The number of shares of any such series so set forth in the resolution or resolutions may be increased (but not above the total number of authorized shares of preferred stock) or decreased (but not below the number of shares thereof then outstanding) by further resolution or resolutions adopted by the board of directors. As of September 30, 2016, 18,100 shares of Preferred Stock were issued and outstanding.

Series B Convertible Preferred Stock

The following summary of certain terms and provisions of the Preferred Stock is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in our certificate of designation of preferences, rights and limitations of the Preferred Stock, which is incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part (the certificate of designation).

Our Preferred Stock is convertible into shares of our common stock (subject to the beneficial ownership limitations as provided in the related certificate of designation), at a conversion price equal to $0.25 per share of common stock, subject to adjustment as provided in the certificate of designation, at any time at the option of the holder prior to the fifth anniversary of the date of issuance, at which time all shares of outstanding Preferred Stock shall automatically and without any further action by the holder be converted into shares of our common stock at the then effective conversion price, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

The holders of Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Preferred Stock. The dividends become payable, at our option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Preferred Stock, (ii) on each such other date as our board of directors may determine, subject to written consent of the holders of Preferred Stock holding a majority of the then issued and outstanding Preferred Stock, (iii) upon our liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, including any merger or consolidation, sale of all or substantially all of our assets, exchange or conversion of all of our common stock by tender offer, exchange offer or reclassification; provided, however, that if Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Preferred Stock before the date of conversion. Make-whole payments are payable at our option in either cash, out of any funds legally available for such purpose, or in shares of common stock.

With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Preferred Stock will be an amount equal to the quotient of (i) the

amount of the dividend payable to such holder divided by (ii) the conversion price then in effect. The Preferred Stock is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities within 60 trading days after the date of issuance of the Preferred Stock at an effective common stock purchase price of less than the conversion price then in effect, subject to adjustment as provided in the certificate of designation. In addition, if the conversion price in effect on the 60th trading day following the

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date of issuance of the Preferred Stock exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the Preferred Stock and ending on the 60th trading day following the date of issuance of the Preferred Stock (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Conversion Price , then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the certificate of designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive shares of common stock equal to the difference between the conversion price and the Adjusted Conversion Price; provided, however, that only the initial purchaser of Preferred Stock and Warrants in this offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

The holders of the Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Preferred Stock requires the approval of the holders of a majority of the shares of Preferred Stock then outstanding.

Warrants

Warrants Included in Units Issuable in the Rights Offering

The following is a brief summary of the material terms of the Warrants and is subject in all respects to the provisions contained in the Warrants. The following description does not purport to be complete and is subject to, and qualified in its entirety by, the forms of Warrant and Warrant Agreement being filed as exhibits to the registration statement of which this prospectus forms a part, and reference is made thereto for a complete description of the Warrants.

Exercise. Each whole Warrant entitles the holder to purchase one share of common stock at an exercise price of $ per share from the date of issuance through its expiration five years from the date of issuance. No public market currently exists for our Warrants. We intend to list the Warrants on the NYSE MKT following the closing of the Rights Offering. There can be no assurance, however, that our application will be accepted.

The Warrants are exercisable, at the option of each warrant holder, upon delivery of an executed election to purchase and payment of the exercise price. If at the time of exercise, a registration statement relating to the shares of our common stock underlying the Warrants is not effective, or if the related prospectus is not available for use, then a Warrant holder may elect to exercise its Warrants using a net exercise (i.e. cashless exercise) mechanism.

Anti-Dilution. The exercise price of the Warrants will be adjusted in the event of a stock split, stock dividend, recapitalization, reorganization, scheme, arrangement and the like. In the event that the Warrants exercise price is adjusted due to stock splits, stock dividends, recapitalizations, reorganizations, schemes, arrangements and the like, then the number of shares of common stock issuable upon exercise also will be adjusted, such that the aggregate

exercise price payable for the adjusted number of underlying shares of common stock shall be the same as the aggregate exercise price in effect immediately prior to the adjustment.

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Adjustments for Distributions. If the Company fixes a record date for a dividend or distribution of assets or other securities, other than the distributions referred to under Anti-Dilution above, then the exercise price of the Warrants will be adjusted upon such record date by a percentage equal to (x) the fair market value of the dividend or distribution per share of common stock divided by (y) the price of the common stock as of such record date. In no event will the holders of Warrants be entitled to participate in such dividend or distribution, upon the exercise of Warrants following such record date.

Fundamental Transactions. In the event of a fundamental transaction (generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock), then the holders of the Warrants will not have the option to require the Company to purchase their Warrants for cash at their Black-Scholes value, but such holders will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that they would have received had they exercised the Warrants immediately prior to such fundamental transaction.

Ownership Limitation. The Warrants are not exercisable by their holder to the extent (but only to the extent) that such holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock upon exercise of the Warrants.

Cashless Exercise. If, at the time a holder exercises its Warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the Warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrant.

Redemption. After the one-year anniversary of the date of issuance, we may redeem the Warrants for $0.001 per Warrant if the volume weighted average price of our common stock is above $ per share, 250% of the exercise price, for each of 10 consecutive trading days.

General. The Warrants may be offered for sale, sold, transferred or assigned without our consent. If the Warrants are to be transferred, the holder may surrender the Warrants to us, whereupon we will forthwith issue and deliver upon the order of the holder a new Warrant, registered as the holder may request, representing the right to purchase the number of shares of our common stock being transferred by the holder and, if less than the total number of shares of our common stock then underlying the Warrants is being transferred, a new Warrant to the holder representing the right to purchase the number of shares of our common stock not being transferred.

Except as set forth specifically in the Warrants and described above, the holder of Warrants, solely in its capacity as such, is not entitled to vote or receive dividends or deemed to be the holder of share capital of us for any purpose.

Pre-Funded Warrants Issuable in the Rights Offering

Any Pre-Funded Warrants issued as a part of this Rights Offering will be separately transferable following their issuance and through their expiration five years from the date of issuance. The Pre-Funded Warrants entitle the holder to purchase one share of common stock at an exercise price of $0.01 per share, and the subscription price per Unit for any such electing investors will be reduced to $ (which equals the Subscription Price for the other Units sold

in the Rights Offering, less the $0.01 exercise price for each Pre-Funded Warrant). Each Pre-Funded Warrant will be exercisable from the date of issuance through its expiration on , 2021. The Pre-Funded Warrants will not be listed for trading on any stock exchange or market.

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Any Pre-Funded Warrants that are purchased in the Rights Offering as part of the Units will be issued in physical form. We will arrange for the issuance of the Pre-Funded Warrants as soon as practicable after the expiration of the Rights Offering, payment for the Units subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms of the Rights Offering have been effected.

The Pre-Funded Warrants will be exercisable by paying the exercise price in cash or on a cashless basis. The exercise price of the Pre-Funded Warrants and the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants are subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock.

A holder may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would beneficially own more than 4.99% of our outstanding common stock after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder s Pre-Funded Warrant up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrant.

Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned without our consent.

The Pre-Funded Warrants do not confer upon the holder any voting or any other rights of a shareholder of the Company.

Other Currently Outstanding Warrants

As of September 30, 2016, we have outstanding (i) NYSE MKT-listed warrants to purchase an aggregate of 28,482,344 shares of common stock at an exercise price of $0.85 per share of common stock, (ii) warrants issued in connection with our Preferred Stock offering initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of $0.275 per share of common stock, and (iii) other outstanding warrants (excluding the Warrants and the Pre-Funded Warrants issuable in the Rights Offering) to purchase 49,338,841 shares of common stock at a weighted average exercise price of approximately $1.08 per share of common stock.

Options

As of September 30, 2016, we have reserved for issuance 5,000,000 shares of common stock for issuance upon the exercise of outstanding stock options granted pursuant to our equity incentive plans. The options have a weighted average exercise price of approximately $0.92 per share as of September 30, 2016.

Transfer Agent and Registrar

We have retained Broadridge Corporate Issuer Solutions, Inc., P.O. Box 1342, Brentwood, NY 11717, as the transfer agent for our common stock. Broadridge s telephone number is (877) 830-4936.

Quotation

Beginning October 17, 2016, our common stock trades on the OTCQB under the symbol PVCT. On October 13, 2016, NYSE MKT suspended trading of our common stock due to the abnormally low trading price of our common stock. On October 20, 2016, we submitted a request for a review of NYSE MKT s delisting determination, and we intend to appeal NYSE MKT s decision to commence delisting procedures. There can be no assurance, however, that such appeal will be successful or that our common stock will remain listed on the NYSE MKT.

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MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following discussion is a summary of material U.S. federal income tax consequences relating to the receipt and exercise (or expiration) of the Subscription Rights acquired through the Rights Offering and the ownership and disposition of shares of our common stock and Warrants received upon exercise of the Subscription Rights or Warrants.

This summary deals only with Subscription Rights acquired through the Rights Offering, shares of our common stock and Warrants acquired upon exercise of Subscription Rights and shares of our common stock acquired upon exercise of the Warrants, in each case, that are held as capital assets by a beneficial owner. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to such beneficial owners in light of their personal circumstances. This discussion also does not address tax consequences to holders that may be subject to special tax rules, including, without limitation, insurance companies, real estate investment trusts, regulated investment companies, grantor trusts, tax-exempt organizations, employee stock purchase plans, partnerships and other pass-through entities, persons holding Subscription Rights, shares of our common stock, warrants or Warrants as part of a hedging, integrated, conversion or constructive sale transaction or a straddle, financial institutions, brokers, dealers in securities or currencies, traders that elect to mark-to-market their securities, persons that acquired Subscription Rights, shares of our common stock, warrants or Warrants in connection with employment or other performance of services, U.S. Holders (as defined below) that have a functional currency other than the U.S. dollar, U.S. expatriates, and certain former citizens or residents of the United States. In addition, the discussion does not describe any tax consequences arising out of the tax laws of any state, local or foreign jurisdiction, or any U.S. federal tax considerations other than income taxation (such as Medicare contribution taxation or estate, generation skipping or gift taxation).

The discussion below is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, and regulations, rulings and judicial decisions thereunder, as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively. We have not sought, and will not seek, any rulings from the Internal Revenue Service, or the IRS, regarding the matters discussed below. There can be no assurance that the IRS or a court will not take positions concerning the tax consequences of the receipt of Subscription Rights acquired through the Rights Offering by persons holding shares of our common stock or warrants, the exercise (or expiration) of the Subscription Rights, the acquisition, ownership and disposition of shares of our common stock and the acquisition, ownership and disposition (or expiration) of Warrants acquired upon exercise of the Subscription Rights that are different from those discussed below.

As used herein, a U.S. Holder means a beneficial owner of shares of our common stock, warrants, Subscription Rights, shares of our common stock and Warrants acquired upon exercise of Subscription Rights or shares of our common stock acquired upon exercise of Warrants, as the case may be, that is for U.S. federal income tax purposes: (1) an individual who is a citizen or resident of the United States; (2) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof or the District of Columbia; (3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (4) a trust (a) the administration of which is subject to the primary supervision of a court within the United States and one or more United States persons as described in Section 7701(a)(30) of the Code have authority to control all substantial decisions of the trust, or (b) that has a valid election in effect to be treated as a United States person. A Non-U.S. Holder is such a beneficial owner (other than an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) that is not a U.S. Holder.

If any entity or arrangement that is treated as a partnership for U.S. federal income tax purposes is such a beneficial owner, the U.S. federal income tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Holders that are partnerships (and partners in such partnerships) are urged to consult their own tax advisors.

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HOLDERS OF SHARES OF OUR COMMON STOCK AND SERIES R WARRANTS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES UNDER FEDERAL ESTATE AND GIFT TAX LAWS, FOREIGN, STATE, AND LOCAL LAWS AND TAX TREATIES OF THE RECEIPT, OWNERSHIP AND EXERCISE OF SUBSCRIPTION RIGHTS AND THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF SHARES OF OUR COMMON STOCK AND WARRANTS ACQUIRED UPON EXERCISE OF SUBSCRIPTION RIGHTS AND SHARES OF OUR COMMON STOCK ACQUIRED UPON EXERCISE OF WARRANTS.

Tax Consequences to U.S. Holders

Taxation of Subscription Rights

Receipt of Subscription Rights

Although the authorities governing transactions such as this Rights Offering are complex and do not speak directly to the consequences of certain aspects of this Rights Offering, including the inclusion of the right to purchase Warrants in the Subscription Rights (rather than the right to purchase only shares of our common stock) and the effects of the Over-Subscription Privilege, we do not believe your receipt of Subscription Rights pursuant to the Rights Offering should be treated as a taxable distribution with respect to your existing shares of common stock or warrants for U.S. federal income tax purposes. Section 305(a) of the Code states that a stockholder s taxable income does not include in-kind stock dividends; however, the general non-recognition rule in Section 305(a) is subject to exceptions in Section 305(b), which include disproportionate distributions. A disproportionate distribution is a distribution or a series of distributions, including deemed distributions, that has the effect of the receipt of cash or other property by some stockholders or holders of debt instruments convertible into stock and an increase in the proportionate interest of other stockholders in a corporation s assets or earnings and profits.

Our position regarding the tax-free treatment of the Subscription Right distribution is not binding on the IRS, or the courts. If this position is finally determined by the IRS or a court to be incorrect, whether on the basis that the issuance of the Subscription Rights is a disproportionate distribution or otherwise, the fair market value of the Subscription Rights would be taxable to holders of our common stock as a dividend to the extent of the holder s pro rata share of our current and accumulated earnings and profits, if any, with any excess being treated as a return of capital to the extent thereof and then as capital gain. Although no assurance can be given, it is anticipated that we will not have current and accumulated earnings and profits through the end of 2016. Further, if our position is incorrect, the treatment of holders of warrants in that case is not clear, and it may differ from the treatment of the Subscription Right distribution to the holders of our common stock.

The following discussion is based upon the treatment of the Subscription Right issuance as a non-taxable distribution with respect to your existing shares of common stock or warrants for U.S. federal income tax purposes.

Tax Basis in the Subscription Rights

If the fair market value of the Subscription Rights you receive is less than 15% of the fair market value of your existing shares of common stock or warrants (with respect to which the Subscription Rights are distributed) on the date you receive the Subscription Rights, the Subscription Rights will be allocated a zero basis for U.S. federal income tax purposes, unless you elect to allocate your basis in your existing shares of common stock or warrants between

your existing shares of common stock or warrants and the Subscription Rights in proportion to the relative fair market values of the existing shares of common stock or warrants and the Subscription Rights determined on the date of receipt of the Subscription Rights. If you choose to allocate basis between your existing common shares or warrants and the Subscription Rights, you must make this election on a statement included with your timely filed tax return (including extensions) for the taxable year in which you receive the Subscription Rights. Such an election is irrevocable.

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However, if the fair market value of the Subscription Rights you receive is 15% or more of the fair market value of your existing shares of common stock or warrants on the date you receive the Subscription Rights, then you must allocate your basis in your existing shares of common stock or warrants between those shares or warrants and the Subscription Rights you receive in proportion to their fair market values determined on the date you receive the Subscription Rights.

The fair market value of the Subscription Rights on the date that the Subscription Rights are distributed is uncertain, and we have not obtained, and do not intend to obtain, an appraisal of the fair market value of the Subscription Rights on that date. In determining the fair market value of the Subscription Rights, you should consider all relevant facts and circumstances, including any difference between the Subscription Price of the Subscription Rights and the trading price of our shares of common stock on the date that the Subscription Rights are distributed, the exercise price of the warrants, the length of the period during which the Subscription Rights may be exercised and the fact that the Subscription Rights are non-transferable.

Exercise of Subscription Rights

Generally, you will not recognize gain or loss upon the exercise of a Subscription Right in the Rights Offering. Your adjusted tax basis, if any, in the Subscription Right plus the Subscription Price should be allocated between the new common share and Warrant acquired upon exercise of the Subscription Right in proportion to their relative fair market values on the exercise date. This allocation will establish your initial tax basis for U.S. federal income tax purposes in your new common shares and Warrants. The holding period of a share of common stock or Warrant acquired upon exercise of a Subscription Right in the Rights Offering will begin on the date of exercise.

If you exercise a Subscription Right received in the Rights Offering after disposing of the shares of our common stock or warrants with respect to which such Subscription Right is received, then certain aspects of the tax treatment of the exercise of the Subscription Right are unclear, including (1) the allocation of the tax basis between the shares of common stock or warrants previously sold and the Subscription Right, (2) the impact of such allocation on the amount and timing of gain or loss recognized with respect to the shares of our common stock or warrants previously sold, and (3) the impact of such allocation on the tax basis of the shares of our common stock and warrants acquired upon exercise of the Subscription Right. If you exercise a Subscription Right received in the Rights Offering after disposing of shares of our common stock or warrants with respect to which the Subscription Right is received, you should consult with your tax advisor.

Expiration of Subscription Rights

If you allow Subscription Rights received in the Rights Offering to expire, you should not recognize any gain or loss for U.S. federal income tax purposes, and you should re-allocate any portion of the tax basis in your existing common shares or warrants previously allocated to the Subscription Rights that have expired to the existing common shares or warrants.

Taxation of Warrants

Sale or other Taxable Disposition of Warrants

Upon the sale, exchange or other taxable disposition of a Warrant, in general, you will recognize taxable gain or loss measured by the difference, if any, between (i) the amount of cash and the fair market value of any property received

upon such taxable disposition, and (ii) your adjusted tax basis in the Warrant as allocated pursuant to the rules discussed above. Your gain or loss generally will be capital gain or loss and generally will be long-term capital gain or loss if, at the time of the sale or other disposition, your holding period for the Warrant is more than one year. The deductibility of capital losses is subject to limitations.

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Exercise of Warrants

Upon the exercise of a Warrant for cash, in general, you will not recognize gain or loss for U.S. federal income tax purposes, except to the extent you receive a cash payment for any such fractional share that would otherwise have been issuable upon exercise of the Warrant. Your initial tax basis in common stock received will equal your adjusted tax basis in the Warrant exercised, increased by the amount of cash paid to exercise the Warrant and decreased by the adjusted tax basis allocable to any fractional share that would otherwise have been issuable upon exercise of the Warrant. Your holding period for the shares of our common stock received on exercise generally will commence on the day of exercise.

In certain circumstances, the Warrants will be exercisable on a cashless basis. The tax consequences of a cashless exercise are not clear and could differ from the consequences described above, including the possibility that a cashless exercise could be a taxable event. You should consult your tax advisor regarding the tax consequences of a cashless exercise of a Warrant.

Expiration of Warrants

If you allow a Warrant to expire, you will generally recognize a loss for U.S. federal income tax purposes equal to the adjusted tax basis of the Warrant. In general, such a loss will be a capital loss, and will be a short-term or long-term capital loss depending on your holding period for the Warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of Warrant shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to you if, and to the extent that, such adjustment has the effect of increasing your proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our stockholders). Adjustments to the exercise price of Warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading Taxation of Common Shares Distributions below.

Taxation of Shares of Common Stock

Distributions

Distributions with respect to shares of our common stock acquired upon exercise of Subscription Rights or upon exercise of Warrants will be taxable as dividend income when actually or constructively received to the extent of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. To the extent that the amount of a distribution exceeds our current and accumulated earnings and profits, such distribution will be treated first as a tax-free return of capital to the extent of your adjusted tax basis in such shares of our common stock and thereafter as capital gain.

Dividend income received by certain non-corporate U.S. Holders with respect to shares of our common stock generally will be qualified dividends subject to preferential rates of U.S. federal income tax, provided that the U.S. Holder meets applicable holding period and other requirements. Subject to similar exceptions for short-term and hedged positions, dividend income on our shares of common stock paid to U.S. Holders that are domestic corporations generally will qualify for the dividends-received deduction.

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Dispositions

If you sell or otherwise dispose of shares of common stock acquired upon exercise of Subscription Rights or upon exercise of Warrants in a taxable transaction, you will generally recognize capital gain or loss equal to the difference between the amount realized and your adjusted tax basis in the shares. Such capital gain or loss will be long-term capital gain or loss if your holding period for such shares is more than one year at the time of disposition. Long-term capital gain of a non-corporate U.S. Holder is generally taxed at preferential rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

Information Reporting and Backup Withholding

You may be subject to information reporting and/or backup withholding with respect to the gross proceeds from the disposition of Warrants, shares of our common stock acquired through the exercise of Subscription Rights or through the exercise of Warrants, or dividend payments. Backup withholding (currently at the rate of 28%) may apply under certain circumstances if you (1) fail to furnish your social security or other taxpayer identification number, or TIN, (2) furnish an incorrect TIN, (3) fail to report interest or dividends properly, or (4) fail to provide a certified statement, signed under penalty of perjury, that the TIN provided is correct, that you are not subject to backup withholding and that you are a U.S. person on IRS Form W-9 or Substitute Form W-9. Any amount withheld from a payment under the backup withholding rules is allowable as a credit against (and may entitle you to a refund with respect to) your U.S. federal income tax liability, provided that the required information is timely furnished to the IRS. Certain persons are exempt from information reporting and backup withholding, including corporations and financial institutions, provided that they demonstrate this fact, if requested. You are urged to consult your own tax advisor as to your qualification for exemption from backup withholding and the procedure for obtaining such exemption.

Tax Consequences to Non-U.S. Holders

Overriding Effect of Tax Treaties

The United States has entered into tax treaties with a variety of countries. The terms of those treaties typically override generally applicable rules of the Code and may override the treatment described below. If you are a Non-U.S. Holder and resident of a country with a tax treaty with the United States, you are urged to consult your own tax advisor as to the effect of such treaty on the Subscription Rights and transactions related to them.

Taxation of the Subscription Rights

Receipt, Exercise and Expiration of the Subscription Rights

The discussion assumes that the receipt of Subscription Rights will be treated as a nontaxable distribution. See Tax Consequences to U.S. Holders Taxation of Subscription Rights Receipt of Subscription Rights above. You should not be subject to U.S. federal income tax (or any withholding thereof) on the receipt, exercise or expiration of the Subscription Rights.

Exercise and Expiration of Warrants and Certain Adjustments to Warrants

Exercise of Warrants

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a Warrant, except to the extent the Non-U.S. Holder receives a cash payment for any such fractional share that would otherwise have been issuable upon exercise of the Warrant, which will be treated as a sale subject to the rules described under Sale or Other Disposition of Our Common Stock or Warrants below.

Expiration of Warrants

In general, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Warrant against the Non-U.S. Holder s U.S. federal income tax liability unless the loss is effectively connected with the

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Non-U.S. Holder s conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to the Warrants

Under Section 305 of the Code, an adjustment to the number of Warrant shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a Non-U.S. Holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such Non-U.S. Holder s proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our stockholders). Adjustments to the exercise price of Warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading - Taxation of Distributions on Common Shares below.

Taxation of Distributions on Common Shares

Any distributions of cash or property made with respect to our common stock generally will be subject to withholding tax to the extent paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes, if any, at a rate of 30% (or a lower rate prescribed in an applicable income tax treaty). In order to obtain a reduced withholding tax rate, if applicable, you will be required to provide an IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, certifying your entitlement to benefits under a treaty. In addition, you will not be subject to withholding tax if you provide an IRS Form W-8ECI certifying that the distributions are effectively connected with your conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment within the United States); instead, you generally will be subject to U.S. federal income tax, net of certain deductions, with respect to such income at the same rates applicable to U.S. persons, and if you are a corporation, a branch profits tax of 30% (or a lower rate prescribed in an applicable income tax treaty) also may apply to such effectively connected income.

Non-U.S. Holders may be required to periodically update their IRS Forms W-8.

Sale or Other Disposition of Our Common Stock or Warrants

In general, you will not be subject to U.S. federal income tax on any gain realized on a sale of shares of our common stock, or Warrants unless:

- the gain is effectively connected with your conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment in the United States);
- you are an individual, you hold your Subscription Rights, shares of common stock or Warrants as capital assets, you are present in the United States for 183 days or more in the taxable year of disposition and certain

other conditions are met; or

we are or have been a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes unless an exception for 5% or less stockholders applies.

Gain that is effectively connected with your conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment within the United States) generally will be subject to U.S. federal income tax, net of certain deductions, at the same rates applicable to U.S. persons. If you are a corporation, a branch profits tax of 30% (or a lower rate prescribed in an applicable income tax treaty) also may apply to such effectively connected gain.

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A domestic corporation is treated as a USRPHC if the fair market value of its United States real property interests equals or exceeds 50% of the sum of (1) the fair market value of its United States real property interests, (2) the fair market value of its non-United States real property interests and (3) the fair market value of any other of its assets which are used or held for use in a trade or business. We believe that we are not currently, and have not been within the relevant testing period, a USRPHC. However, no assurance can be given that we will not become a USRPHC in the future. If we are a USRPHC or become a USRPHC in the future, a Non-U.S. Holder may still not be subject to U.S. federal income tax on a sale or other disposition if an exception for 5% or less stockholders applies. You are urged to consult your own tax advisor regarding the U.S. federal income tax considerations that could result if we are, or become, a USRPHC and with respect to the exception for 5% or less stockholders.

Information Reporting and Backup Withholding

Distributions on our common stock and the amount of tax withheld, if any, with respect to such distributions will generally be subject to information reporting. If you comply with certification procedures to establish that you are not a United States person, additional information reporting and backup withholding should not apply to distributions on our common stock and information reporting and backup withholding should not apply to the proceeds from a sale or other disposition of Warrants or shares of our common stock. The amount of any backup withholding will generally be allowed as a refund or credit against your U.S. federal income tax liability, provided that the required information is timely furnished to the IRS.

FATCA

Legislation enacted in 2010 and commonly referred to as FATCA may impose withholding taxes on certain types of payments made to foreign financial institutions and certain other non-U.S. entities. The legislation imposes a 30% withholding tax on dividends on shares of our common stock and on or after January 1, 2017, the gross proceeds from the sale or other disposition of our shares of common stock or Warrants received by a foreign financial institution unless the foreign financial institution enters into an agreement with the U.S. Treasury to among other things, undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. In addition, the legislation imposes a 30% withholding tax on the same types of payments to a non-financial foreign entity unless the entity certifies that it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Depending on your circumstances, you may be entitled to a refund or credit in respect of some or all of this withholding. However, even if you are entitled to have any such withholding refunded, the required procedures could be cumbersome and significantly delay your receipt of any withheld amounts. Prospective investors should consult their tax advisors regarding this legislation.

THE PRECEDING DISCUSSION OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES IS NOT TAX ADVICE. HOLDERS OF SHARES OF OUR COMMON STOCK AND SERIES R WARRANTS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES UNDER FEDERAL ESTATE AND GIFT TAX LAWS, FOREIGN, STATE, AND LOCAL LAWS AND TAX TREATIES OF THE RECEIPT, OWNERSHIP AND EXERCISE OF SUBSCRIPTION RIGHTS AND THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF SHARES OF OUR COMMON STOCK AND WARRANTS ACQUIRED UPON EXERCISE OF SUBSCRIPTION RIGHTS AND SHARES OF OUR COMMON STOCK ACQUIRED

UPON EXERCISE OF WARRANTS.

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PLAN OF DISTRIBUTION

On or about , 2016, we will distribute the Subscription Rights, Rights Certificates and copies of this prospectus to the holders of our common stock on the Record Date. Subscription Rights holders who wish to exercise their Subscription Rights and purchase Units must complete the Subscription Rights Certificate and return it with payment for the shares to the Subscription Agent at the following address:

By Mail:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS Re-Organization Dept.

P.O. Box 1317

Brentwood, NY 11717

By Hand Delivery or Overnight Courier Excluding USPS:

Broadridge Corporate Issuer Solutions, Inc.

Attn: BCIS IWS

51 Mercedes Way

Edgewood, NY 11717

See Questions and Answers Relating to the Rights Offering To whom should I send my forms and payment? and The Rights Offering.

If you have other questions or need assistance, please contact the dealer-manager or the Information Agent for the Rights Offering:

Maxim Group LLC

405 Lexington Avenue

New York, New York 10174

Attention Syndicate Department

Email: syndicate@maximgrp.com

Telephone: (212) 895-3745

Broadridge Corporate

Issuer Solutions, Inc.

(844) 695-1509

(720) 414-6879 (toll number)

Other than as described in this prospectus, we do not know of any existing agreements between any stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the underlying common stock.

Maxim Group LLC is the dealer-manager of this Rights Offering. We and Maxim may introduce one or more co-dealer-managers and one or more financial advisors to assist in the Rights Offering. In any such event, Maxim Group LLC will be the lead dealer-manager. In such capacity, the dealer-manager will provide marketing assistance and advice to us in connection with this offering and will solicit the exercise of Subscription Rights and participation in the Over-Subscription Privilege. The dealer-manager is not underwriting or placing any of the Subscription Rights or the Units, shares of common stock, Warrants or Pre-Funded Warrants being issued in this offering, and does not make any recommendation with respect to such Subscription Rights (including with respect to the exercise or expiration of such Subscription Rights), Units, shares of common stock, Warrants or Pre-Funded Warrants.

In connection with this Rights Offering, we have agreed to pay to the dealer-manager a cash fee equal to 8% of the dollar amount of the Units sold to holders of Subscription Rights. We will provide to the dealer-manager upon completion of the Rights Offering a non-accountable expense allowance equal to $100,000 for expenses incurred in connection with the Rights Offering. We advanced $30,000 against such non-accountable expense allowance to Maxim Group LLC upon its engagement as a dealer-manager; provided that Maxim Group LLC

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will promptly reimburse to us any portion of the advance not used for actual out-of-pocket expenses if the Rights Offering is not completed. See Plan of Distribution for more information.

At the closing of the Rights Offering, we will grant to the dealer-managers (or their designated affiliates) warrants to purchase shares of common stock, which we refer to as the Dealer-Manager Warrants, equal to 6.0% of the total number of shares of common stock included in the Units sold in the Rights Offering (excluding the shares of common stock underlying the Warrants). The Dealer-Manager Warrants will be non-exercisable for six months after the date of the closing of the Rights Offering and will expire five years from such date. The Dealer-Manager Warrants will be exercisable at the same per share exercise price as the Warrants included in the Units. The Dealer-Manager Warrants will not be redeemable and may not be transferred, assigned or hypothecated for a period of six months following the closing of the Rights Offering, except they may be assigned to any officer, manager or member of the dealer managers. The Dealer-Manager Warrants may be exercised as to all or a lesser number of shares of common stock and will provide for cashless exercise.

We have also agreed to indemnify the dealer-manager and its respective affiliates against certain liabilities arising under the Securities Act. The dealer-manager s participation in this offering is subject to customary conditions contained in the dealer-manager agreement, including the receipt by the dealer-manager of an opinion of our counsel. The dealer-manager and its affiliates may provide to us from time to time in the future in the ordinary course of their business certain financial advisory, investment banking and other services for which they will be entitled to receive fees.

In November 2008, we entered into an agreement with Maxim Group LLC, under which Maxim Group LLC provides valuation, strategic advisory and other similar services to use and receives $7,500 a month. The agreement is a month-to-month arrangement and may be terminated by us at any time upon 30 days notice. From time to time in the ordinary course of their respective business, the placement agent and its affiliates have and may in the future engage in commercial banking or investment banking transactions with us and our affiliates. We have no present arrangements with the placement agent for any such transactions.

Maxim Group LLC is a broker-dealer and member of the Financial Industry Regulatory Authority, Inc. The principal business address of Maxim Group LLC is 405 Lexington Avenue, New York, New York 10174.

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SELECTED FINANCIAL DATA

The following table sets forth our selected consolidated financial data and has been derived from our audited and unaudited consolidated financial statements. The selected consolidated financial data as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013 have been derived from, and qualified by reference to, our audited financial statements included elsewhere in this prospectus and should be read in conjunction with those consolidated financial statements and notes thereto. The selected consolidated financial data as of December 31, 2013, 2012 and 2011 and for the years ended December 31, 2012 and 2011 has been derived from our audited financial statements not included in this prospectus. The summary unaudited consolidated financial data as of and for the nine months ended September 30, 2016 and for the nine months ended September 30, 2015 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The following selected consolidated financial data should be read in conjunction with, and are qualified by reference to, Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and notes thereto included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Nine months ended September 30 (Unaudited)		Years ended December 31				
	2016	2015	2015	2014	2013	2012	2011
	(all amounts in thousands except per share data)						
Consolidated Statement of Operations Data:							
Gain on settlement net of discount	$	$	$	$ 4,178	$	$	$
Operating expenses							
Research and development	6,874	7,537	11,380	5,809	4,267	5,677	9,479
General and administrative	12,455	7,453	13,274	11,002	8,761	8,661	11,962
Total operating loss	(19,329)	(14,991)	(24,654)	(12,633)	(13,028)	(14,338)	(21,441)
Other income, net	(98)	141	152	2,390	(14,670)	1,769	2,006
Net loss	(19,427)	(14,850)	(24,502)	(10,243)	(27,698)	(12,569)	(19,435)
Dividend paid in-kind to preferred shareholders	(2,257)						
Deemed dividend	(727)						
Dividends on preferred stock					(1,188)	(183)	(247)
Net loss applicable to common stockholders	$ (22,411)	$ (14,850)	$ (24,502)	$ (10,243)	$ (28,886)	$ (12,752)	$ (19,682)
Basic and diluted loss per common share	$ (0.10)	$ (0.08)	$ (0.13)	$ (0.06)	$ (0.22)	$ (0.11)	$ (0.19)
	213,723	192,604	195,662	175,828	132,001	112,987	105,725

Weighted average number of common shares outstanding basic and diluted	

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	As of September 30 (Unaudited) 2016	2015	As of December 31 2014	2013	2012	2011
			(all amounts in thousands)			
Consolidated Balance Sheet Data:						
Cash, cash equivalents and marketable securities	$ 5,178	$ 14,179	$ 17,392	$ 15,696	$ 1,222	$ 7,705
Patents, net	2,409	2,913	3,584	4,255	4,926	5,598
Other assets	3,098	3,348	5,208	57	56	47
Total assets	10,686	20,440	26,184	20,008	6,204	13,350
Current liabilities	5,376	4,123	848	513	511	263
Long-term liability			147	12,866	1,300	3,067
Preferred stock					2	4
Common stock	244	205	185	160	118	110
Additional paid-in capital	205,289	196,908	181,299	152,520	122,626	115,690
Accumulated deficit	(200,223)	(180,796)	(156,294)	(146,051)	(118,353)	(105,784)
Total stockholders equity	5,310	16,317	25,190	6,629	4,393	10,020

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this prospectus. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

Critical Accounting Policies

Long-Lived Assets

We review the carrying values of our long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment.

Patent Costs

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over their remaining lives, which range from 1-6 years. Annual amortization of the patents is expected to approximate $671,000 for 2016, $659,000 in 2017 and 2018, $547,000 in 2019, and $330,000 in 2020, and $47,000 thereafter.

Stock-Based Compensation

The compensation cost relating to share-based payment transactions is measured based on the fair value of the equity or liability instruments issued and is expensed on a straight-line basis. For purposes of estimating the fair value of each stock option, on the date of grant, we utilize the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the company s common stock (as determined by reviewing its historical public market closing prices).

Warrants to non-employees are generally vested and nonforfeitable upon the date of the grant. Accordingly, fair value is determined on the grant date.

Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, legal, insurance, rent and utilities, and depreciation.

Derivative Instruments

The warrants issued in conjunction with convertible preferred stock in March and April 2010 private placements include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of $1.00. Effective January 1, 2009, the reset provision of these warrants preclude equity accounting treatment under ASC 815. Accordingly, the Company is required to

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record the warrants as liabilities at their fair value upon issuance and remeasure the fair value at each period end with the change in fair value recorded in the statement of operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. At December 31, 2015 there are no remaining 2010 warrants and, therefore, no associated liability. Significant assumptions used at December 31, 2014 include a weighted average term of 0.2 years, a 5% probability that the warrant exercise price would be reset, a volatility of 63.7% and a risk free interest rate that ranges between 0.03% and 0.04%.

Additionally, the Series A and Series C Warrants issued in conjunction with the January 2011 registered direct public offering include a reset provision if the Company issues additional warrants, in certain circumstances as defined in the agreement, below the exercise price of $1.12. During 2012, the warrant exercise price was reset to $0.675. Significant assumptions used at December 31, 2015 include a weighted average term of 0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 40.4% and a risk free interest rate of 0.13%. Significant assumptions used at December 31, 2014 include a weighted average term of 1.0 years, a 5% probability that the warrant exercise price would be further reset, a volatility of 159.2% and a risk free interest rate of 0.25%.

On February 22, 2013, the Company entered into a Securities Purchase Agreement with certain accredited investors for the issuance and sale in a private placement of an aggregate of $2,550,000 of Units at a purchase price of $0.75 per Unit. Each Unit consists of one share of Series A 8% Convertible Preferred Stock, par value $.001 per share, and a warrant to purchase one and one-quarter shares of the Company s common stock, par value $.001 per share (subject to adjustment) at an exercise price of $1.00 per whole share (subject to adjustment). The total Series A 8% Convertible Preferred Stock issued was 3,400,001 shares, and the total warrants were 4,250,000. The Company used the net proceeds of the private placement for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

The Company determined that warrants issued in February 2013 with the Series A 8% Convertible Preferred Stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability. At June 30, 2014 there were no remaining 2013 warrants and therefore no associated warrant liability.

We are currently evaluating the accounting treatment of our issuance of the Preferred Stock and August 2016 Warrants.

Fair Value of Financial Instruments

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, short-term receivable, and accounts payable approximate their fair value because of the short-term nature of these items. Cash equivalents are measured on a recurring basis within the fair value hierarchy using Level 1 inputs.

The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. Certain derivatives with limited market activity are valued using Level 3 inputs with externally developed models that consider unobservable market parameters.

Plan of Operation

We have implemented our integrated business plan, including execution of the current and next phases in clinical development of our pharmaceutical products and continued execution of research programs for new research initiatives.

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Peter R. Culpepper has agreed to serve as our Interim Chief Executive Officer until our Board of Directors completes its search process for a successor Chief Executive Officer to replace H. Craig Dees, our former Chief Executive Officer (the Former CEO), who resigned effective February 27, 2016 as our Chief Executive Officer and Chairman of the Board of Directors. Our Board of Directors has also recently retained John R. Glass as our Interim Chief Financial Officer. We also plan to continue operating with our four primary consultants and various vendor relationships totaling sixty (60) full-time equivalents, and anticipate adding additional personnel or contract research organizations if necessary in the next 12 months. Our current plans also include minimal purchases of new property, plant and equipment, and increased research and development for additional clinical trials.

We believe that our investigational drugs PV-10 and PH-10 provide us with two products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin, and important immunologic data has been corroborated and characterized by institutions such as Moffitt Cancer Center in Tampa, Florida, M.D. Anderson in Houston, Texas, and the University of Illinois at Chicago. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will continue to be shown based on data in previous studies, and which result in one or more license transactions with pharmaceutical and or biotech companies. Together with our non-core technologies, which we intend to sell or license in the future, we believe this combination represents the foundation for maximizing shareholder value this year and beyond.

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2016 and September 30, 2015

Revenues

We had no revenue during the three and six months ended September 30, 2016 and 2015.

Research and Development

Research and development costs of $2,461,407 for the three months ended September 30, 2016 included amortization of patents of $167,780, payroll of $206,563, consulting and contract labor of $1,866,360, legal of $109,828, insurance of $65,772, lab supplies and pharmaceutical preparations of $23,975, rent and utilities of $18,195, and depreciation expense of $2,934. Research and development costs of $2,864,331 for the three months ended September 30, 2015 included amortization of patents of $167,780, payroll of $542,851, consulting and contract labor of $1,538,362, legal of $11,664, insurance of $60,598, lab supplies and pharmaceutical preparations of $517,529, rent and utilities of $22,256, and depreciation expense of $3,291. The overall decrease in research and development costs is due primarily to a decrease of approximately $500,000 in lab supplies and pharmaceutical preparations due to lower investigational drug costs for the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizumab which commenced in the quarter ended September 30, 2015, and is also due to approximately $300,000 in decreased payroll expense due to the departure of the Former CEO. This decrease is offset partially by approximately $300,000 in increased consulting and contract labor due to the ongoing PV-10 related clinical studies.

Research and development costs of $6,874,353 for the nine months ended September 30, 2016 included amortization of patents of $503,340, payroll of $737,704, consulting and contract labor of $5,054,234, legal of $256,238, insurance of $177,567, lab supplies and pharmaceutical preparations of $63,718, rent and utilities of $71,626, and depreciation

expense of $9,926. Research and development costs of $7,537,440 for the nine months ended September 30, 2015 included amortization of patents of $503,340, payroll of $1,372,200, consulting and contract labor of $4,142,207, legal of $222,623, insurance of $127,432, lab supplies and pharmaceutical preparations of $1,096,333, rent and utilities of $63,636, and depreciation expense of $9,669. The overall decrease in research and development costs is due primarily to a decrease of approximately $1,000,000 in lab

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supplies and pharmaceutical preparations due to lower investigational drug costs for the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizumab which commenced in the quarter ended September 30, 2015, and is also due to approximately $600,000 in decreased payroll expense due to the departure of the Former CEO. This decrease is offset partially by approximately $900,000 in increased consulting and contract labor due to the ongoing PV-10 related clinical studies.

General and Administrative

General and administrative expenses increased by $401,180 in the three months ended September 30, 2016 to $3,315,555 from $2,914,375 for the three months ended September 30, 2015. General and administrative expenses were very similar for both periods except for two primary accounts. Approximately $100,000 in increased expense is due to higher total of investor and public relations expense during the three months ended September 30, 2016 versus the three months ended September 30, 2015 due primarily to efforts to maximize the visibility and awareness of the Company in the marketplace. Approximately $300,000 in increased expense is due to legal compliance during the three months ended September 30, 2016 versus the three months ended September 30, 2015 due primarily to increased legal costs associated with the audit committee s investigation into Company procedures, policies and practices, including travel expense advancements and reimbursements received by our Former CEO, offset by savings in payroll and travel related expenses due to the resignation of our Former CEO.

General and administrative expenses increased by $5,001,260 in the nine months ended September 30, 2016 to $12,454,661 from $7,453,401 for the nine months ended September 30, 2015. General and administrative expenses were very similar for both periods except for three primary accounts. Approximately $2.7 million in increased expense is due to the warrant incentive expense during the nine months ended September 30, 2016 versus the nine months ended September 30, 2015, as described in Note 4(c) to the accompanying financial statements. Approximately $1.3 million in increased expense is due to higher total of investor and public relations expense during the nine months ended September 30, 2016 versus the nine months ended September 30, 2015 due primarily to efforts to maximize the warrant exchange transaction described in Note 4(c) to the accompanying financial statements. Approximately $900,000 in increased expense is due to legal compliance during the nine months ended September 30, 2016 versus the nine months ended September 30, 2015 due primarily to increased legal costs associated with the audit committee s investigation into Company procedures, policies and practices, including travel expense advancements and reimbursements received by our Former CEO, offset by savings in payroll and travel related expenses due to the resignation of our Former CEO.

Investment Income

Investment income was insignificant in both the three and nine months ended September 30, 2016 and 2015.

Public offering issuance expense

The Company incurred public offering expenses of $436,248 in the three months ended September 30, 2016 compared to no expense in 2015 since the financing that results in this public offering issuance expense was only incurred in the three months ended September 30, 2016.

The Company incurred public offering expenses of $436,248 in the nine months ended September 30, 2016 compared to no expense in 2015 since the financing that results in this public offering issuance expense was only incurred in the

three months ended September 30, 2016.

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Gain/Loss on change in fair value of warrant liability

The change in fair value of warrant liability increased by $339,256 in the three months ended September 30, 2016 to a gain of $336,649 from a loss of $2,607 for the three months ended September 30, 2015. See Note 4, *August 2016 Public Offering.*

The change in fair value of warrant liability increased by $199,662 in the nine months ended September 30, 2016 to a gain of $336,649 from a gain of $136,987 for the nine months ended September 30, 2015. See Note 4, *August 2016 Public Offering.*

Liquidity and Capital Resources

The Company s cash and cash equivalents were $5,178,076 at September 30, 2016, compared with $14,178,902 at December 31, 2015. The accompanying condensed consolidated financial statements for the nine months ended September 30, 2016 have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of $201 million as of September 30, 2016. These conditions raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to obtain additional financing as may be required to fund current operations. Management s plans include selling its equity securities and obtaining other financing to fund its capital requirement and on-going operations; however, there can be no assurance the Company will be successful in these efforts. The financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern. Significant funds will be needed for the Company to continue and complete its Phase 3 clinical trials.

On August 30, 2016, we closed a public offering of 240,000 shares of our Series B Convertible Preferred Stock, par value $0.001 per share (the Preferred Stock) (which shares are initially convertible into an aggregate of 24,000,000 shares of our common stock), and warrants (the August 2016 Warrants) initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of $0.275 per share of common stock. The Preferred Stock and August 2016 Warrants were sold together at a price of $25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in gross offering proceeds of $6,000,000 to us before the payment of placement agent fees and expenses related to the offering.

In November or December 2016, we intend to distribute to holders of our common stock, par value $0.001 per share, at no charge, non-transferable subscription rights to purchase Units. Each Unit consists of a to be determined number of shares of common stock and a to be determined number of warrants representing the right to purchase one share of our common stock, which we refer to as the Warrants. Each whole Warrant will be exercisable for one share of our common stock. We refer to this offering as the Rights Offering. In the proposed Rights Offering, each stockholder will receive one subscription right for each share of common stock owned at 5:00 p.m., Eastern Time, on the to be determined record date of the Rights Offering, or the Record Date. The common stock and the Warrants comprising the Units will separate upon the closing of the Rights Offering and will be issued separately but may only be purchased as a Unit, and the Units will not trade as a separate security. The subscription rights will not be tradable. There can be no assurance, however, that the registration statement with respect to the Rights Offering will be declared effective, that the Rights Offering will be successful or that the Company will issue any Units, common stock or Warrants pursuant to the Rights Offering

Management believes that the Company has access to capital resources through possible public or private equity offerings, exchange offers, debt financings, corporate collaborations or other means. We expect that the existing and forthcoming clinical and nonclinical mechanism of action data for both PV-10 and PH-10 will

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further aid in both regulatory clarity and transactions with potential partners. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidates, PV-10 and PH-10, through potential co-development and licensing transactions, although there can be no assurance that the Company will be successful with such plans. The Company has historically been able to raise capital through equity offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital through the planned Rights Offering (see Footnote 8 to the financial statements, Subsequent Events), it may be forced to implement significant cost cutting measures as early as the first quarter of 2017.

We continue to provide data on a confidential basis to both potential global and geographic partners for both PV-10 for oncology, and PH-10 for dermatology, via a secure electronic data room. We are encouraged by the number of companies doing due diligence on our technologies. For instance, we are discussing transactions with potential partners in China, India, MENAT, Brazil, Israel and Russia.

We also announced throughout 2015 discussions continuing with Sinopharm-China State Institute of Pharmaceutical Industry (Sinopharm-CSIPI), the leader among all pharmaceutical research institutes in China, and Sinopharm A-THINK Pharmaceutical Co., Ltd. (Sinopharm A-THINK), the only injectable anti-tumor drug research and development, manufacture and distribution integrated platform within Sinopharm Group. The discussions are based on the frame of reference established in the original Memorandum of Understanding (MOU) signed in 2014 and extended since the passing of the original deadline. The original MOU was signed in August 2014, and, since then, the parties have sought to enter into a definitive licensing agreement, subject to additional negotiation, due diligence, and any required regulatory and corporate approvals.

Also, we announced in July 2015 signing a Letter of Intent (the LOI) with Boehringer Ingelheim (China) Investment Co. Ltd. (Boehringer). The purpose of the LOI is to lay a foundation for the two parties to collaborate in bringing PV-10 to market in mainland China, Hong Kong and Taiwan. Maxim Group LLC acted as strategic advisor to Provectus in structuring and negotiating the LOI. Under the terms of the LOI, Boehringer will provide certain commercially reasonable support in the aspects of product registration with the China Food and Drug Administration (CFDA), communication preparation, market intelligence and other assistance to the Company in China to the extent that is within Boehringer s approved business scope and permissible by Chinese laws.

In return, we will grant Boehringer the first priority to be the exclusive collaborator of the Company in China for PV-10 in the event that PV-10 is successfully registered and approved by the CFDA. The exclusive collaboration may take the form of exclusive distribution and promotion, exclusive licensing or other agreement, subject to both parties mutual agreement. At the appropriate time, the Company and Boehringer may enter into a definitive agreement, including a non-compete provision, for PV-10 to be exclusively developed, distributed and promoted through the collaboration within China, although there can be no assurance that the parties will enter into a definitive agreement.

In the LOI signed July 2, 2015, at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2015 in Barcelona, the two parties have agreed to meet regularly and maintain effective communication in order to move forward with the registration and commercialization of the product and assess the potential cooperation between them in China, which may be adopted in a form of exclusive commercial supply, distribution and promotion, partnership or any other forms suitable to both parties interests.

Comparison of the Years Ended December 31, 2015 and 2014

Gain on Settlement

The gain on settlement, net of discount, of $4,178,345 occurred in 2014 as a result from accounting for the settlement of the Shareholder Derivative Lawsuit described in Note 9 to the financial statements.

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Research and development

Research and development costs totaling $10,708,569 for 2015 included payroll of $2,292,710, consulting and contract labor of $6,652,406, lab supplies and pharmaceutical preparations of $1,115,140, legal of $358,582, insurance of $189,358, rent and utilities of $87,208, and depreciation expense of $13,165. Research and development costs totaling $5,137,927 for 2014 included payroll of $1,395,321, consulting and contract labor of $2,355,780, lab supplies and pharmaceutical preparations of $790,653, legal of $384,061, insurance of $115,957, rent and utilities of $87,623, and depreciation expense of $8,532.

The increase in consulting and contract labor of approximately $4.3 million in 2015 over 2014 is primarily the result of the preparation, and commencement of phase 3 PV-10 for locally advanced cutaneous melanoma, phase 1b/2 for PV-10 in combination with pembrolizumab, and further development in other PV-10 and PH-10 programs. The increase in lab supplies and pharmaceutical preparations of approximately $300,000 in 2015 over 2014 is primarily the result of the preparation of additional phase 3 PV-10 drug supply, as well as for other PV-10 programs, along with phase 2 PH-10 mechanism of action drug supply. The increase in payroll of approximately $900,000 in 2015 over 2014 is the result of increased payroll expense and stock option expense. The increase in consulting and contract labor, lab supplies and pharmaceutical preparations, and payroll expense represents virtually all of the increase in research and development expenses in 2015 versus 2014.

General and administrative

General and administrative expenses increased by $2,271,746 for 2015 to $13,274,072 from $11,002,326 in 2014. General and administrative expenses were very similar for both periods; however, the increase is due to approximately $1.85 million of accrued settlement expense to settle the existing class action lawsuit and $1.1 million of reserve for uncollectible receivable from Dr. Dees related to the settlement receivable (see Note 9 to the financial statements) and partially offset by the lower stock price of our common stock during 2015 versus 2014, which resulted in lower noncash expenses charged to operations for the value of both common stock and warrants issued for services.

Investment income

Investment income is immaterial for all periods presented.

Change in fair value of warrant liability

Change in fair value of warrant liability decreased by $2,237,833 to a gain of $146,560 in 2015 from a gain of $2,384,393 in 2014. This activity results from accounting for the warrant liability described in Notes 3(c), 3(d), 3(e) and 8 to the financial statements.

Cash Flow

Our cash and cash equivalents were $14,178,902 at December 31, 2015, compared with $17,391,601 at December 31, 2014. The decrease of approximately $3.2 million was due primarily to a decrease of the total sales of common stock and warrants and exercises of warrants and stock options, and an increase of approximately $3.5 million more cash that was used in operating activities. Additionally, thus far in 2016, the Company received approximately $100,000 from the repayment of bonuses and costs associated with the settlement of the Shareholder Derivative Lawsuit. At our current cash expenditure rate, our cash and cash equivalents will be sufficient to meet our current and planned needs

until into 2017 without additional cash inflows from the exercise of existing warrants, stock options, or sales of equity securities.

Comparison of the Years Ended December 31, 2014 and 2013

Gain on Settlement

The gain on settlement, net of discount, of $4,178,345 occurred in 2014 as a result from accounting for the settlement of the Shareholder Derivative Lawsuit described in Note 9 to the financial statements.

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Research and development

Research and development costs totaling $5,137,927 for 2014 included payroll of $1,395,321, consulting and contract labor of $2,355,780, lab supplies and pharmaceutical preparations of $790,653, legal of $384,061, insurance of $115,957, rent and utilities of $87,623, and depreciation expense of $8,532. Research and development costs totaling $3,595,555 for 2013 included payroll of $1,459,057, consulting and contract labor of $1,317,472, lab supplies and pharmaceutical preparations of $310,160, legal of $262,720, insurance of $161,268, rent and utilities of $78,512, and depreciation expense of $6,366.

The increase in consulting and contract labor of approximately $1.0 million in 2014 over 2013 is primarily the result of the preparation of phase 3 PV-10 for locally advanced cutaneous melanoma and further development in other PV-10 and PH-10 programs. The increase in lab supplies and pharmaceutical preparations of approximately $0.5 million in 2014 over 2013 is primarily the result of the preparation of additional phase 3 PV-10 drug supply, as well as for other PV-10 programs, along with phase 2 PH-10 mechanism of action drug supply. The increase in both consulting and contract labor, and lab supplies and pharmaceutical preparations represents virtually all of the increase in research and development expenses in 2014 versus 2013.

General and administrative

General and administrative expenses increased by $2,241,062 for 2014 to $11,002,326 from $8,761,264 in 2013. General and administrative expenses were very similar for both periods; however, almost $600,000 in increased expense is due to the higher stock price of our common stock during the three months ended March 31, 2014 versus the three months ended March 31, 2013, which resulted in higher noncash expenses charged to operations for the value of both common stock and warrants issued for services. Additionally, legal expense increased by about $500,000 primarily due to our NYSE MKT listing and the Controlled Equity Offering^{SM} Sales Agreement with Cantor and investor relations and related travel expenses increased approximately $1,100,000 in 2014 over 2013.

Investment income

Investment income is immaterial for all periods presented.

Change in fair value of warrant liability

Change in fair value of warrant liability increased by $17,055,523 to a gain of $2,384,393 in 2014 from a loss of $14,671,130 in 2013. This activity results from accounting for the warrant liability described in Notes 3(c), 3(d), 3(e) and 8 to the financial statements.

Cash Flow

Our cash and cash equivalents were $17,391,601 at December 31, 2014, compared with $15,696,243 at December 31, 2013. The increase of approximately $1.7 million was due primarily to sales of common stock and warrants as well as exercises of warrants and stock options offset partially by approximately $4 million more cash that was used in operating activities in 2014 versus 2013.

Liquidity and Capital Resources

The Company s cash and cash equivalents were $5,178,076 at September 30, 2016, compared with $14,178,902 at December 31, 2015. The accompanying financial statements for the nine months ended September 30, 2016 have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of $201 million as of September 30, 2016. These conditions raise substantial doubt about our ability to continue as a going concern. Our financial

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statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to obtain additional financing as may be required to fund current operations. Management s plans include selling its equity securities and obtaining other financing to fund its capital requirement and on-going operations; however, there can be no assurance the Company will be successful in these efforts. The financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern. Significant funds will be needed for the Company to continue and complete its Phase 3 clinical trials.

On August 30, 2016, we closed a public offering of 240,000 shares of our Series B Convertible Preferred Stock, par value $0.001 per share, which we refer to as the Preferred Stock (which shares are initially convertible into an aggregate of 24,000,000 shares of the our common stock), and warrants, which we refer to as the August 2016 Warrants, initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of $0.275 per share of common stock. The Preferred Stock and August 2016 Warrants were sold together at a price of $25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in gross offering proceeds of $6,000,000 to us before the payment of placement agent fees and expenses related to the offering.

Management believes that the Company has access to capital resources through possible public or private equity offerings, including this Rights Offering, exchange offers, debt financings, corporate collaborations or other means. We expect that the existing and forthcoming clinical and nonclinical mechanism of action data for both PV-10 and PH-10 will further aid in both regulatory clarity and transactions with potential partners. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidate, PV-10, through potential licensing transactions, although there can be no assurance provided that the Company will be successful with such plans. The Company has historically been able to raise capital through equity offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital, it may be forced to implement significant cost cutting measures as early as the fourth quarter of 2016.

We continue to provide data on a confidential basis to both potential global and geographic partners for both PV-10 for oncology, and PH-10 for dermatology, via a secure electronic data room. We are encouraged by the number of companies doing due diligence on our technologies. For instance, we are discussing transactions with potential partners in China, India, Brazil and Russia.

We also announced throughout 2015 discussions continuing with Sinopharm-China State Institute of Pharmaceutical Industry (Sinopharm-CSIPI), the leader among all pharmaceutical research institutes in China, and Sinopharm A-THINK Pharmaceutical Co., Ltd. (Sinopharm A-THINK), the only injectable anti-tumor drug research and development, manufacture and distribution integrated platform within Sinopharm Group. The discussions are based on the frame of reference established in the original Memorandum of Understanding (MOU) signed in 2014 and extended since the passing of the original deadline. The original MOU was signed in August 2014, and, since then, the parties have sought to enter into a definitive licensing agreement, subject to additional negotiation, due diligence, and any required regulatory and corporate approvals.

Also we announced in July 2015 signing a Letter of Intent (the LOI) with Boehringer Ingelheim (China) Investment Co. Ltd. (Boehringer). The purpose of the LOI is to lay a foundation for the two parties to collaborate in bringing PV-10 to market in mainland China, Hong Kong and Taiwan. Maxim Group LLC acted as strategic advisor to Provectus in structuring and negotiating the LOI. Under the terms of the LOI, Boehringer will provide certain commercially reasonable support in the aspects of product registration with the China Food and Drug Administration

(CFDA), communication preparation, market intelligence and other assistance to the Company in China to the extent that is within Boehringer s approved business scope and permissible by Chinese laws.

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In return, we will grant Boehringer the first priority to be the exclusive collaborator of the Company in China for PV-10 in the event that PV-10 is successfully registered and approved by the CFDA. The exclusive collaboration may take the form of exclusive distribution and promotion, exclusive licensing or other agreement, subject to both parties mutual agreement. At the appropriate time, the Company and Boehringer may enter into a definitive agreement, including a non-compete provision, for PV-10 to be exclusively developed, distributed and promoted through the collaboration within China, although there can be no assurance that the parties will enter into a definitive agreement.

In the LOI signed July 2, 2015, at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2015 in Barcelona, the two parties have agreed to meet regularly and maintain effective communication in order to move forward with the registration and commercialization of the product and assess the potential cooperation between them in China, which may be adopted in a form of exclusive commercial supply, distribution and promotion, partnership or any other forms suitable to both parties interests.

We also have considered co-development transactions since 2015 with one or more pharmaceutical or biotech companies to combine PV-10 with immunology agents such as those referred to as systemic immunomodulatory agents, immune checkpoint inhibitors or systemic immunotherapies. Our announced joint patent issuance in 2015 co-owned with Pfizer supports these efforts from an intellectual property protection perspective. And our initiated phase 1b/2 study in September 2015 combining PV-10 and Merck s KEYTRUDA, a systemic immunotherapy also known as pembrolizumab, potentially demonstrates the relevance of PV-10 synergy with agents such as KEYTRUDA.

If and when we obtain an MOU, definitive agreement or similar indication of interest from a potential partner, we will issue a press release and file a Current Report on Form 8-K with the SEC to notify the market. Furthermore, the strategy of our company for the benefit of stockholders is a series of partnerships followed by an acquisition of our company along the lines of Celgene-Abraxis, although there can be no assurance that such partnerships or acquisition will occur. An interim transaction could be a co-development deal like Roche-NewLink, Bristol-Celldex or AstraZeneca-Incyte. We are not in discussions regarding the sale of our business, and there can be no assurance that we will be able to monetize PV-10 or PH-10 in the manner described herein.

We have signed multiple advisory agreements with accomplished individuals and organizations to help identify partners, including collaborators, distribution and joint venture partners, and licensees for PV-10 in China, Brazil and Latin America in general, India and the Indian Subcontinent, MENAT, Russia, European Union (EU), Japan and North America. These agreements are intended to enhance our reach into key markets and will bolster our efforts in developing partnering opportunities in various countries in Asia including China, India, Russia and Japan, where we have held numerous detailed discussions with pharmaceutical companies over the last year, and now also in Brazil, Europe and elsewhere. We are already seeing the results of efforts to enter into partnerships from the activity in our electronic data room. We are not in discussions regarding the sale of our business, and there can be no assurance that we will be able to monetize PV-10 or PH-10 in the manner described herein.

The primary financial objective of our company is to strategically monetize the core value of PV-10 and PH-10 through the various transactions discussed elsewhere in this prospectus. Ultimately, we want to leverage value creation through the sale of the business or a merger that may include upfront cash, acquirer stock, and/or a contingency value right (CVR) as part of the total consideration. A CVR represents the right for its holder to receive certain defined payments upon the achievement of a specified milestone and would be designed to facilitate potential upside for our stockholders on a post-transaction basis. A CVR could trade on an exchange. We are not in discussions regarding the sale of our business and there can be no assurance that we will be able to monetize PV-10 or PH-10 in

the manner described herein.

However, we cannot assure you that we will be successful in licensing either PV-10 or PH-10, entering into any equity transaction, or selling a majority stake of the OTC and other non-core assets via a spin-out transaction and licensing our existing non-core products. Moreover, even if we are successful in improving our current cash

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flow position, we nonetheless plan to seek additional funds to meet our long-term requirements in 2017 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placements, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities, including this Rights Offering. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, Leases (ASU 2016-02), which amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective beginning in the first quarter of 2019. Early adoption of ASU 2016-02 is permitted. The new standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We are currently evaluating the impact of adopting ASU 2016-02 on our condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. This ASU amends the principal versus agent guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was issued in May 2014 (ASU 2014-09). Further, in April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*. This ASU also amends ASU 2014-09 and is related to the identification of performance obligations and accounting for licenses. The effective date and transition requirements for both of these amendments to ASU 2014-09 are the same as those of ASU 2014-09, which was deferred for one year by ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*. That is, the guidance under these standards is to be applied using a full retrospective method or a modified retrospective method, as outlined in the guidance, and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted only for annual periods, and interim period within those annual periods, beginning after December 15, 2016. We are currently evaluating the provisions of each of these standards and assessing their impact on our condensed consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This ASU makes targeted amendments to the accounting for employee share-based payments. This guidance is to be applied using various transition methods such as full retrospective, modified retrospective, and prospective based on the criteria for the specific amendments as outlined in the guidance. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted, as long as all of the amendments are adopted in the same period. We are currently evaluating the provisions of this guidance and assessing its impact on our condensed consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-03, *Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments*, which clarifies the requirements for assessing whether contingent call or put options that can accelerate the repayment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. We are currently evaluating the provisions of

this guidance and assessing its impact on our condensed consolidated financial statements and disclosures.

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Quantitative and Qualitative Disclosures About Market Risk

We had no holdings of financial or commodity instruments as of September 30, 2016, other than cash and cash equivalents, short-term deposits, money market funds, and interest bearing investments in U.S. governmental debt securities. We have accounted for certain warrants issued in March and April 2010, January 2011 and February 2013 as liabilities at their fair value upon issuance, which were remeasured at each period end with the change in fair value recorded in the statement of operations. All such warrants were valued at $0 as of December 31, 2015.

All of our business is transacted in U.S. dollars and, accordingly, foreign exchange rate fluctuations have not had a significant impact on us, and they are not expected to have a significant impact on us in the foreseeable future. The formation of our Australian subsidiary is initially for the purpose of enabling lower clinical developments costs in Australia and will not impact our financial statements.

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BUSINESS

General

Provectus Biopharmaceuticals, Inc., a Delaware corporation formed in 2002, together with its six wholly owned subsidiaries and one majority owned subsidiary managed on a consolidated basis, is a development-stage biopharmaceutical company that is primarily engaged in developing ethical pharmaceuticals for oncology and dermatology indications. Our goal is to develop alternative treatments that are safer, more effective, less invasive and more economical than conventional therapies. We develop and intend to license or market and sell our two prescription drug candidates, PV-10 and PH-10. We also hold patents and other intellectual property which we believe may be used in over-the-counter products, which we refer to as OTC products, and various other non-core technologies. We have transferred all our intellectual property related to OTC products and non-core technologies to our subsidiaries and have designated such subsidiaries as non-core to our primary business of developing our oncology and dermatology prescription drug candidates.

Prescription Drugs

We focus on developing our prescription drug candidates PV-10 and PH-10. We are developing PV-10 for treatment of several life threatening cancers including metastatic melanoma, liver cancer, and breast cancer. We are developing PH-10 to provide minimally invasive treatment of chronic severe skin afflictions such as psoriasis and atopic dermatitis, a type of eczema. We believe that our prescription drug candidates will be safer and more specific than currently existing products. All of our prescription drug candidates are in either the pre-clinical or clinical trial stage.

The table below sets forth our two prescription drug candidates and our progress in developing those candidates for the indications shown:

Product Pipeline

Melanoma*

PV-10

Phase 3 study in progress: Opened recruitment in April 2015

Phase 1 and 2 studies completed, full reports submitted

Orphan drug status obtained in January 2007

Melanoma

PV-10 +

Pembrolizumab

Phase 1b/2 study initiated September 2015

Melanoma

(Method of Action)

PV-10

Phase 1 study to detect immune cell infiltration into melanomas treated with PV-10 has now finished recruiting

Data published in peer-reviewed journal May 2016

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Cancers of the Liver

PV-10

Orphan drug status obtained in April 2011

Phase 1 patient accrual and treatment completed

Phase 1 protocol expansion (September 2012 into 2017)

Data communicated in 2015

Phase 1b/2 commencement expected late 2016 / early 2017

Breast Cancer

PV-10

Phase 1 study completed

Further clinical development is being planned

Psoriasis

PH-10

Phase 2c randomized study completed and full report submitted to FDA

Toxicity study R&D for advanced studies 2012 to 2016

Psoriasis

(Mechanism of Action)

PH-10

Phase 2 mechanism of action study initiated in January 2015 by leading research facility

Phase 2 study recruitment began in Q1 2015

Phase 2 study recruitment completed in Q3 2015

Phase 2 study data being compiled for FDA end of Phase 2 meeting

Atopic Dermatitis

PH-10

Phase 2 study completed and full report submitted to FDA

Toxicity study R&D for advanced studies 2012 to 2016

* In addition to clinical trials, patients enrolled in the Compassionate Use Program for PV-10 are also receiving PV-10 treatments.

Oncology (PV-10)

Reported by Global Cancer Facts & Figures, 3rd Edition, according to estimates from the International Agency for Research on Cancer (IARC), there were 14.1 million new cancer cases in 2012 worldwide, of which

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8 million occurred in economically developing countries, which contain about 82% of the world s population. These estimates do not include non-melanoma skin cancers, which are not tracked in cancer registries. The corresponding estimates for total cancer deaths in 2012 were 8.2 million (about 22,000 cancer deaths a day) 2.9 million in economically developed countries, and 5.3 million in economically developing countries. By 2030, the global burden is expected to grow to 21.7 million new cancer cases and 13 million cancer deaths simply due to the growth and aging of the population. However, the estimated future cancer burden will probably be considerably larger due to the adoption of lifestyles that are known to increase cancer risk, such as smoking, poor diet, physical inactivity, and fewer pregnancies, in economically developing countries. Cancers related to these factors, such as lung, breast, and colorectal cancers, are already on the rise in economically transitioning countries. In economically developed countries, the three most commonly diagnosed cancers were prostate, lung, and colorectal among males, and breast, colorectal, and lung among females. In economically developing countries, the three most commonly diagnosed cancers were lung, liver, and stomach in males, and breast, cervix uteri, and lung in females. In both economically developed and developing countries, the three most common cancer sites were also the three leading causes of cancer death. Rates of cancers common in Western countries will continue to rise in developing countries if preventive measures are not widely applied. The most common types of cancer also vary by geographic area. For example, among women breast cancer was the most common cancer in 19 out of the 21 world areas, while cervical cancer was the most common in the remaining two areas. Further variations are observed by examining individual countries. In 2012, the most common cancer site among males in most economically developed countries was prostate, with the exception of certain countries of Southern and Eastern Europe (lung cancer), Slovakia (colorectal cancer), and Japan (stomach cancer). Lung and stomach cancer were the top cancer sites in Asia. The greatest variation among males was in Africa, where the most common cancer was prostate, liver, Kaposi sarcoma, lung, non-Hodgkin lymphoma, colorectal, leukemia, esophagus, or stomach. Among females, the most common cancer sites were either breast or cervical cancer, with the exceptions of China and North Korea (lung), South Korea (thyroid), and Mongolia and Laos (liver).

We believe our prescription drug candidate PV-10, a novel investigational drug, may afford competitive advantage compared to currently available options for the treatment of certain types of cancer; particularly solid tumors. Additional geographic variations exist as well. In short, we believe PV-10 is appropriate to treat any solid tumor anywhere. We are developing PV-10, a sterile injectable form of rose bengal disodium (Rose Bengal), for direct injection into tumors. It is an ablative immunotherapy or immuno-chemoablative agent that when injected intralesionally is tantamount to an in situ vaccination following acute and durable necrosis of diseased tissue. Because PV-10 is retained in diseased or damaged tissue but quickly dissipates from healthy tissue, we believe we can develop therapies that confine treatment to cancerous tissue and reduce collateral impact on healthy tissue. We have conducted phase 1 and phase 2 studies of PV-10 for the treatment of recurrent and metastatic melanoma, and phase 1 studies of PV-10 for the treatment of liver and breast cancers, each of which are described in more detail below. Furthermore, in 2015, we commenced a phase 3 study of PV-10 to treat locally advanced cutaneous melanoma as well as a phase 1b/2 study that combines PV-10 and pembrolizumab, both of which are described in more detail below.

Recurrent or Locally Advanced Cutaneous Melanoma and Widely Metastatic [Melanoma] Disease

According to Global Cancer Facts & Figures, 3rd Edition, estimated new cases for men in developed countries totaled 99,400 in 2012, and 91,700 for women. Estimated deaths continue to increase as well. PV-10 is potentially applicable for treating all stage III and IV patients, either as a neoadjuvant therapy, monotherapy, or in combination with a systemic agent for late stage patients in particular.

Our Phase 3 clinical trial of intralesional PV-10 as a melanoma treatment is progressing as we expected. We are actively recruiting and treating patients in centers in the U.S. Other sites are now also listed on clinicaltrials.gov and more will be added. We expect to have other sites for the U.S., Australia and elsewhere joining the study soon. We are seeking 225 patients for this study. The primary outcome measure is progression-free survival, PFS, to be assessed every 12 weeks up to 18 months. The secondary outcome measures include complete response rate, CRR, and its duration to be set every 12 weeks up to 18 months and overall survival to

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be assessed every 12 weeks up to 18 months. Unlike our Phase 2 study, which was a single arm study, the Phase 3 is a randomized trial. And we hope to further demonstrate conclusively that PV-10 is both safe and effective and is statistically superior to the control systemic chemotherapy.

Our estimated primary completion date is September 2017, and an estimated study completion date of October 2017. When 50 percent of the events required for the primary endpoint have occurred, the Independent Data Monitoring Committee will report an interim assessment of efficacy and safety. So, meaningful clinical data could come as early as the middle of this year, which is halfway through the study, as documented on clinicaltrials.gov.

This phase 3 randomized controlled trial of PV-10 in patients with unresectable locally advanced cutaneous melanoma will assess response to PV-10 versus that of systemic chemotherapy in patients who have disease limited to cutaneous and subcutaneous sites and who have failed or are ineligible for systemic immunotherapy. Progression-free survival and complete response rate will be assessed using standard criteria (RECIST 1.1). Overall survival and exploratory assessment of patient reported outcomes related to lesion pain and other melanoma symptoms will also be assessed.

We are not alone in advocating for an intralesional approach in the treatment of cancer. For melanoma patients with recurrent or in-transit disease confined to their skin this approach has been used to treat patients for many years, as evidenced by guidelines published by the National Comprehensive Cancer Network (NCCN Guidelines®) defining the standard of care for cancer treatment in the United States. Intralesional injection with BCG and certain immunomodulatory agents, local ablation, topical therapy for superficial lesions and regional radiotherapy are consensus interventions for these patients, while systemic therapy remains an option and participation in a clinical trial is the preferred option. We believe that, in this context, PV-10 is well positioned to show superiority in phase 3 testing as a single agent.

For those patients who do not have all disease accessible to injection, medical oncologists have stated that using an agent like PV-10 to prime the immune system could be synergistic in combination with a systemic agent. Our patent application on this strategy was published in 2012 and we have been vigorously pursuing this approach. We believe the nonclinical research we first presented at the Society for Immunotherapy of Cancer (SITC) annual meeting that year, together with ongoing translational clinical research on PV-10 s mechanism of action we are sponsoring at Moffitt and our own phase 2 data, provide a rationale for combination testing of PV-10. This development track, separate from the phase 3 study, using PV-10 in combination with checkpoint protein inhibitors could present a path forward for patients with significant disease burden not amenable to intralesional injection.

While we believe the rapid ablative effect immediately evident in patients treated with PV-10 highlights our path to initial approval, the bystander effect, or secondary immunomodulatory benefit of PV-10 as a result of direct ablation, continues to be of scientific interest and studies to quantify systemic tumor-specific immune response in cancer patients are ongoing. This is why we term the overall function of PV-10 as ablative immunotherapy. This emerging understanding of the secondary effect of tumor ablation with PV-10 is an important foundation for future studies to assess the long-term impact of PV-10 on distant metastasis and possible combination strategies for use of PV-10 in the treatment of cancer patients with more advanced disease. PV-10 is therefore becoming known as an ablative immunotherapy, and we believe it is therefore a next generation ablative immunological treatment.

As mentioned before, we are also engaged in studying the use of PV-10 as part of a combination therapy for melanoma for Stage 4 patients. Scientifically, combination therapy in cancer treatment is a rapidly maturing area, where a rational combination of agents is replacing the empirical approaches of the past. In this specific instance, we have completed development of the protocol for Phase 1b-2 testing of PV-10 in combination with Merck s Keytruda in

patients with Stage 4 melanoma. And we are actively recruiting and treating patients. Keytruda is an immune checkpoint inhibitor approved for treatment of patients with advanced or unresectable melanoma. The

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PV-10 mechanism of action study s preliminary clinical findings reported initially and then further updated by Moffitt Cancer Center showed that the immunologic effect of tumor ablation with PV-10 may be complementary to immune checkpoint inhibition. Companion preclinical testing of PV-10 in murine models of melanoma also reported that the therapeutic effects of PV-10 in immune checkpoint inhibition are increased when the two are used in combination. Put simply, they may work better together, especially for late stage patients. And this Phase 1b-2 study will help us prepare for potential marketing of PV-10 as part of a combination therapy with Keytruda. When we announced the joint patent co-owned with Pfizer in August 2015, it specifically covered the use of PV-10 to treat melanoma and liver cancers in combination with systemic inhibitors of immune system down regulation, such as anti-CTLA-4, PD-1 and PD-L1 antibodies, along with enhancers of immune system up regulation, such as IL-2 and interferon-gamma. In other words, the Keytruda work we have begun is patent protected.

PV-10 represents both a unique opportunity and an incredible responsibility because the type of agent has the potential to change the way cancer is treated around the world. PV-10 is a small molecule designed to be injected directly into tumors, thereby focusing its effect on disease tissue, while limiting exposure in healthy tissue. We believe that this focused effective tumors has the potential to educate the immune system to find other cancer cells with the same characteristics, thereby potentially having an effect on metastases elsewhere in the body. The work previously reported by our collaborators at Moffitt Cancer Center in Tampa and at the University of Illinois in Chicago clearly indicate that this is taking place in laboratory models of multiple tumor types. Additional information on how this translates to patients was reported November 2015 by the Moffitt team at the Society of Immunotherapy of Cancer Annual Meeting in Washington. We expect information as well to be communicated throughout the remainder of 2016.

We also report ongoing progress with our Compassionate Use Program for PV-10 for non-visceral cancers. With well over 140 patients enrolled in eight centers across the U.S. and Australia, the protocol enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the phase 2 trials. Its dosage has been very helpful with planning for the phase 3 melanoma study as well as treating other types of cutaneous and subcutaneous cancers, and we are gratified we can provide PV-10 now for patients that request it who have no other available option.

We are continuing to assess how much additional work we should do by ourselves, and when to partner with a larger company to further co-develop PV-10, as well as potential paths to accelerated and expedited approval in the U.S. and abroad, including in China and India.

We strengthened our position in the Chinese market with our letter of intent with Boehringer Ingelheim (China) Investment Company Limited, signed July 2, 2015. We are benefiting from their 20 plus years of experience in China, and we are building a relationship with them that may help us in commercializing and marketing PV-10 in mainland China, Hong Kong and Taiwan, as we work with the appropriate regulatory bodies. We are committed to being successful in China, in particular, and Asia in general.

Discussions have continued on the basis of a memorandum of understanding signed last year with Sinopharm-China State Institute of Pharmaceutical Industry, CSIPI, the leader among all pharmaceutical research institutes in China and Sinopharm A-Think Pharmaceutical Company Limited, Sinopharm A-Think, the only injectable anti-tumor drug research and development manufacturer and distribution integrated platform within Sinopharm Group. While our working arrangement is more developed with Boehringer, management of Provectus and senior personnel and Sinopharm, CSIPI, and Sinopharm A-Think has held numerous conference calls, have met face-to-face in both China and the U.S., and Chinese scientists on staff at Sinopharm have discussed in person PV-10 and its clinical results with

various lead investigators we work with globally. Some more formal relationship with them remains an option for us in China, and will endeavor to include Boehringer as well in any future developments and potential partnerships.

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Efforts have been more active in Brazil as we work with potential partners there, and Latin America in general, as well as in India, as we continue our focus to enter into geographic license and our collaborations that allow us to generate meaningful clinical data more rapidly than otherwise.

We have signed agreements with two manufacturers to supply us with clinical-quality PV-10, and we now have sufficient quantities of PV-10 available to continue the phase 3 trial and our other PV-10 development activities. To assure smooth execution of the study we have lined up specialty contract research organizations (CROs) and other service providers with expertise in clinical operations and integrated data management. As is standard in our industry, this includes full-service, international CROs who will coordinate the global efforts of this team of specialists.

We have worked to establish an independent Clinical Trial Data Monitoring Committee (DMC). The FDA states A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial. The DMC will ensure that our study provides patients with maximum possible safety while protecting the scientific validity and integrity of the data we gather.

Liver Cancer

According to Global Cancer Facts & Figures, 3rd Edition, liver cancer is the fifth most common cancer in men and the ninth in women. An estimated 782,500 new liver cancer cases occurred in the world during 2012, with China alone accounting for about 50% of the total. Rates are more than twice as high in men as in women. Liver cancer rates are the highest in Central America, West and Central Africa, and East and Southeast Asia (Figure 9). Most primary liver cancers occurring worldwide are hepatocellular carcinoma (HCC), which likely accounts for 70% to 90% of cases. One type of liver cancer (cholangiocarcinoma) that is rare in most parts of the world has high incidence rates in Thailand and other parts of Asia due to the high prevalence of liver fluke infection. Worldwide, liver cancer is the second leading cause of cancer death in men and the sixth leading cause among women, with about 745,500 deaths in 2012.

Early detection is difficult and as a result, most cases reach an advanced metastatic stage and are unresectable. If the cancer cannot be completely removed, the disease is usually deadly within three to six months. Malignant lesions in the liver arising from HCC or metastases from a wide range of cancers represent an ongoing treatment challenge for oncologists. HCC is one of the most common malignancies worldwide, and its incidence is rapidly increasing in the United States. The liver is a common site of metastases from solid tumors, particularly those arising in the gastrointestinal tract. Other tumors, such as lung and breast cancer and melanoma, also readily spread to the liver.

We collaborated with XenoTech, a preclinical CRO and pioneer in collaborative research surrounding in vitro drug metabolism and pharmacokinetics (DMPK) services, in writing an article describing a study to determine the potential of rose bengal disodium to cause drug-drug interactions which has been published by Xenobiotica, a peer-reviewed scientific journal that publishes comprehensive research papers on pharmacokinetics (the study of distribution, metabolism, disposition and excretion of drugs). The published research indicated that the risk of PV-10 causing clinically relevant drug-drug interactions is likely minimal.

The study was undertaken prior to initiation of the now ongoing testing of PV-10 plus sorafenib (cohort 2) in a clinical trial of PV-10 intralesional injection in hepatocellular carcinoma patients taking a stable dose of sorafenib. Sorafenib is a competitive inhibitor of cytochrome P450 (CYP) drug metabolism enzymes and is reliant on the

UDP-glucuronosyltransferase (UGT) pathway for efficient clearance. CYP and UGT enzymes help to biotransform small lipophilic drugs like sorafenib into water-soluble excretable metabolites.

Provectus researchers collaborated with XenoTech s experts to design the appropriate in vitro experiments necessary to assess the risk for potential liability when rose bengal is co-administered with other drugs in

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humans. Rose Bengal, known for inducing singlet oxygen on exposure to light, can cause erroneous results in conventional in vitro test systems. These assay artifacts were shown to be test system dependent in DMPK studies. XenoTech scientists successfully tailored experiments to ascertain CYP and UGT inhibition potential in more appropriate model systems.

We have recently expanded our exploratory phase 1 study of cancers of the liver to three centers (St. Luke s University Health Network, Bethlehem, Pennsylvania, and The Southeastern Center for Digestive Disorders & Pancreatic Cancer, Tampa, Florida, in addition to Sharp Memorial Hospital, San Diego, California), and we are evaluating the addition of several more centers to further advance this initial effort. We are working with our investigators to report results from long-term follow-up of our initial patients in the coming months. We are assessing strategies to accelerate transition to phase 2 testing in a randomized controlled trial, either alone or in combination with systemic therapy. Any combination studies in the liver are likely to follow similar development strategies to those outlined above for melanoma and rely on much of the same foundational science.

The current phase 1 study, initially designed solely to establish safety of percutaneous injection of PV-10 into liver tumors (that is, injection through the skin), is providing valuable data crucial for planning such phase 2 development. This trial is open to patients with hepatocellular carcinoma or other cancers metastatic to the liver who have at least one tumor that has either originated in or spread to the liver and are not candidates for surgery or transplant. All patients enrolled in this open-label study receive the same treatment: an interventional radiologist injects PV-10 percutaneously into a single liver tumor. Patients with multiple injectable tumors may later receive further PV-10 to their other tumors. We have received numerous inquiries about this study from researchers as well as patients and their doctors, and refer these to our investigators through the contact information available on the clinicaltrials.gov website. We plan to commence the phase 1b/2 liver study in late 2016 or early 2017. This study has potential for generating sufficient data to support expedited approval under one or more FDA programs.

In July 2015, data were presented at two conferences that show our progress to date on the treatment of hepatocellular carcinoma and cancers metastatic to the liver. We made a poster presentation at the ESMO 17th World Congress on Gastrointestinal Cancer (ESMO GI) in Barcelona at the beginning of July, and detailed data from our relevant Phase 1 study of PV-10. The main conclusion was that preliminary evidence of efficacy in treatment of cancers of the liver with PV-10 was observed. That same week, Dr. Sanjiv Agarwala presented the data in poster form at the 6th Asia-Pacific Primary Liver Cancer Expert Meeting, APPLE 2015, in Osaka, Japan. Both of these posters can be found on our website pvct.com. What these data show is that PV-10 affects cancers of the liver in much the same way it does melanoma. More work has to be done, but we believe that these results support rapidly development of PV-10 in a randomized Phase 2 study after dosing with standard of care is optimized. This is the Phase 1b/2 study we also refer to above.

Breast Cancer

According to Global Cancer Facts & Figures, 3rd Edition, breast cancer is the most frequently diagnosed cancer in women worldwide with nearly 1.7 million new cases diagnosed in 2012, accounting for 25% of all new cancer cases in women. A little more than half (53%) of these cases occurred in economically developing countries, which represents about 82% of the world population. An estimated 521,900 breast cancer deaths occurred in women in 2012. Breast cancer is the leading cause of cancer death among women in developing countries and the second leading cause of cancer death (following lung cancer) among women in developed countries. Asian countries, which represent 59% of the global population, have the largest burden of breast cancer, with 39% of new cases, 44% of deaths, and 37% of the world s five-year survivors. Although Northern America (US and Canada) represents only 5% of the world

population, it accounts for 15% of new cases, 9% of deaths, and 17% of survivors, reflecting the high incidence and survival rates in the region. In contrast, African countries (15% of world population) represent 8% of the total new cases, but 12% of breast cancer deaths because of poor survival due to late stage at diagnosis and limited treatment.

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In 2005, we began a phase 1 study of PV-10 to assess the safety and tolerability of injections of PV-10 into recurrent breast carcinoma. We completed the phase 1 study in 2008. The primary outcome measure was systemic and locoregional adverse experience. The secondary outcome measures were (i) histopathologic response of PV-10 injected lesions and (ii) wound healing of PV-10 injected lesions.

The goals of the phase 1 clinical trial were to determine the safety of the treatment and the appropriate dosage. We have also wanted to show that PV-10 has multi-indication potential. We continued to demonstrate this objective in 2011 through 2015, and expect to do so in 2016. We are now in a position for a phase 2 study in recurrent breast carcinoma with our lead oncology drug product candidate PV-10. We are evaluating potential for further development of PV-10 to treat recurrent breast cancer based on the published data provided by Moffitt as well as interest to address this important indication.

Colon and Rectum Cancer

According to Global Cancer Facts & Figures, 3rd Edition Colon and Rectum, colorectal cancer is the third most common cancer in men and the second in women. Worldwide, an estimated 1.4 million cases of colorectal cancer occurred in 2012. The highest incidence rates were in Northern America, Australia, New Zealand, Europe, and South Korea. Rates were low in Africa and South Central Asia. About 693,900 deaths from colorectal cancer occurred in 2012 worldwide, accounting for 8% of all cancer deaths. The incidence of colorectal cancer is increasing in certain countries where risk was historically low (e.g., Japan).

The greatest increases are in Asia (Japan, Kuwait, and Israel) and Eastern Europe (Czech Republic, Slovakia, and Slovenia). In fact, incidence rates among males in the Czech Republic, Slovakia, and Japan have exceeded the peak rates observed in longstanding developed countries, such as the United States, Canada, and Australia, and continue to increase. In high-risk/high-income countries, trends over the past 20 years have either gradually increased (Finland and Norway), stabilized (France and Australia), or declined (United States) with time. The decrease in colorectal cancer incidence in the United States among those 50 years of age and older partially reflects the increase in detection and removal of precancerous lesions through screening. In contrast to the stabilizing rates observed in most Western and Northern European countries, relatively large increases have been observed in Spain, which may be related to the increasing prevalence of obesity in recent years in that country. The increase in several Asian and Eastern European countries may also reflect increased prevalence of risk factors for colorectal cancer associated with westernization such as unhealthy diet, obesity, and smoking. In contrast to incidence trends, decreasing colorectal cancer mortality rates have been observed in a large number of countries worldwide and are most likely due to colorectal cancer screening and/or improved treatments. However, increases in mortality rates are still occurring in countries that have more limited resources, including Brazil and Chile in South America and Romania and Russia in Eastern Europe.

On February 2, 2015, data discussing the immunologic effects of PV-10 on colon cancer cells were presented at the 11th Annual Academic Surgical Congress in Jacksonville, Florida. The abstract, titled PV-10 Induces Potent Immunogenic Apoptosis in Colon Cancer Cells, was presented by N. M. Kunda of the University of Illinois at Chicago, Division of Surgical Oncology, Department of Surgery, College of Medicine, Chicago, IL, USA. The research team is led by Dr. A.V. Maker, and co-authors in addition to Drs. Kunda and Maker are: J. Qin, G. Qiao also of UIC, Division of Surgical Oncology, Department of Surgery. The team of authors also includes B. Prabhakar of the University of Illinois at Chicago, Department of Microbiology & Immunology, College of Medicine, Chicago, IL, USA. Dr. Maker belongs to both Departments.

In the presentation, Dr. Kunda noted that in vitro testing of PV-10 on colon cancer (murine CT-26 cells) showed cytotoxicity consistent with immunogenic apoptosis. Further, he stated that the researchers observed cell arrest, apoptosis, autophagy and endoplasmic reticulum (ER) stress. He concluded that these results are consistent with immunologic cell death caused by PV-10.

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The work reported in Dr. Kunda s presentation further expands our understanding of the mechanism of action of PV-10 as an ablative immunotherapy for solid tumors, and parallels immunologic signaling noted upon ablation of melanoma with PV-10.

Other Indications

The compassionate use program for PV-10 is only available for cancer indications that do not involve treatment of visceral organs and are not subject to enrollment in ongoing clinical trials. These indications include certain breast cancers, basal cell carcinoma, squamous cell carcinoma, certain head and neck cancers and melanoma. Compassionate use programs provide patients with access to experimental therapeutics prior to FDA approval.

The protocol for the compassionate use program enables subjects to undergo more frequent and extensive treatments of PV-10 over a longer period of time than was allowed under the protocol used for the phase 2 trial of PV-10. Based on the success of the compassionate use program, its dose regimen served as the blueprint for the phase 3 study for melanoma. The majority of patients enrolled in the program have been treated for melanoma, with other patients for other indications such as recurrent squamous cell carcinoma and refractory scalp sarcoma.

Additionally, we are considering a clinical study of PV-10 for each of multiple other solid tumor indications.

Dermatology (PH-10)

Our prescription drug candidate PH-10 is an aqueous hydrogel formulation of Rose Bengal for topical administration to the skin. It is a novel nonsteroidal anti-inflammatory agent that interacts with ambient and other light sources. We believe PH-10 is appropriate to treat all indications that are described as inflammatory dermatoses. We are developing PH-10 for the treatment of cutaneous skin disorders, specifically psoriasis and atopic dermatitis, and we believe that PH-10 may be successful in treating other skin diseases. We believe that PH-10 offers a superior treatment for psoriasis and atopic dermatitis because it selectively treats diseased tissue with negligible potential for side effects in healthy tissue.

We have been actively discussing licensing transactions with a number of potential out licensing partners for PH-10. We believe that our phase 2c trial of PH-10 for psoriasis will further solidify the commercial viability of PH-10 in these discussions. In August 2011, we completed follow-up of all phase 2c patients and communicated data of the study to both prospective partners as well as the public market in early 2012. In January 2015, we commenced a mechanism of action study of PH-10 to better characterize the unique immunologic signaling aspects along with PH-10 safety and efficacy. This study was completed in January 2016 and data will be reported when available this year.

Psoriasis

Psoriasis is a common chronic disorder of the skin characterized by dry scaling patches, called plaques, for which current treatments are few and those that are available have potentially serious side effects. There is no known cure for the disease at this time. According to the National Institutes of Health, as many as 7.5 million Americans, or approximately 2.2 percent of the U.S. population, have psoriasis. The National Psoriasis Foundation reports that approximately 125 million people worldwide, 2 to 3 percent of the total population, have psoriasis. It also reports that total direct and indirect health care costs of psoriasis for patients exceed $11 billion annually.

According to the National Psoriasis Foundation, the majority of psoriasis sufferers, those with mild to moderate cases, are treated with topical steroids that can have unpleasant side effects. None of the other treatments for moderate cases of psoriasis have proven completely effective. The 25-30% of psoriasis patients

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who suffer from more severe cases generally are treated with more intensive drug therapies or PUVA, a light-based therapy that combines the drug Psoralen with exposure to ultraviolet A light. While PUVA is one of the more effective treatments, it increases a patient s risk of skin cancer.

Our phase 1 study for PH-10 was initiated in April 2001 to evaluate the safety of three different doses of PH-10 in separate patient segment groups. Subjects in the study each received a single dose of PH-10 followed by administration of green light on psoriatic plaques. Subjects were examined post-treatment, with a final follow-up examination at 90 days.

Our phase 2 study of PH-10 for treatment of psoriasis was initiated in 2009 and completed in April 2010. There were 30 subjects treated in the completed phase 2 study, and an additional six subjects were treated in an earlier study that was terminated in favor of an increased dosing frequency. Consistent with the preliminary data that we announced in December 2009, 70% of the 30 subjects enrolled in the phase 2 clinical trial of PH-10 for psoriasis demonstrated improvement in their Psoriasis Severity Index (PSI) scores at the end of four weeks of daily treatment with PH-10. In addition, 86% of subjects reported no or only mild pruritus (itching) by week four of the trial, and no significant safety issues were noted. At the four-week interval substantial improvement was observed across all standard disease assessment scores.

During 2010, we initiated a phase 2c clinical trial of PH-10 for psoriasis. This multicenter, randomized controlled phase 2c study enrolled 99 subjects at four different sites, which began in December 2010. The subjects were randomized sequentially by center to one of four treatment cohorts, and assessed efficacy and safety of topical PH-10 applied once daily to areas of mild to moderate plaque psoriasis. The primary efficacy endpoint was treatment success, a static endpoint assessed at day 29 after initial PH-10 treatment and defined as 0 or 1 on all Psoriasis Severity Index (PSI) components and 0 or 1 on the Plaque Response scale. The primary safety endpoint was incidence of adverse experiences, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality). The secondary outcome measures were (i) Psoriasis Severity Index (PSI) score changes at each visit from day 1 pre-treatment, (ii) Plaque Response score changes at each visit from day 1 pre-treatment, and (iii) Pruritus Self-Assessment score changes at each visit from day 1 pre-treatment.

The phase 2c trial was conducted at four sites in the U.S. including the Mount Sinai School of Medicine in New York City, Wake Research Associates in Raleigh, North Carolina, Dermatology Specialists in Oceanside, California, and International Dermatology Research in Miami, Florida. With over 90 subjects, this trial is the largest dermatological trial that we have conducted to date.

The results of this study helped define the parameters necessary for the design of a pivotal phase 3 trial, and it was an important milestone on the regulatory pathway leading towards commercialization. In addition, we have held discussions with a number of potential out licensing partners, and we believe this phase 2c trial has further solidified the commercial viability of PH-10 in these discussions. We have also continued important toxicity study research and development in 2012 through 2014 and into 2015 to prepare for a phase 3 study and to support a New Drug Approval filing.

On December 23, 2014, we announced that the protocol for our phase 2 study of the mechanism of action of PH-10 in psoriasis is now available on ClinicalTrials.gov, Identifier NCT02322086: [https://www.clinicaltrials.gov/ct2/show/NCT02322086]. The purpose of the trial is to study the safety and efficacy of PH-10, a 0.005% preparation of Rose Bengal, in the treatment of psoriasis.

Officially titled, A Phase 2 Study of Cellular and Immunologic Changes in the Skin of Subjects Receiving PH-10 Aqueous Hydrogel to Plaque Psoriasis, total enrollment is expected to consist of 30 patients. Subjects will apply PH-10 vehicle daily for 28 consecutive days followed by active PH-10 daily for 28 consecutive days to their plaque psoriasis areas on the trunk or extremities (excluding palms, soles, scalp, facial and intertriginous sites). Biopsies of one target plaque will be collected at baseline (at least 7 days prior to first study treatment on Day 1) and at Days 29 and 64, with a 7-day interval between biopsy at Day 29 at the end of vehicle application

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and commencement of application of active PH-10 on Day 36. Study data from each subject will serve as an internal control (i.e., with assessment at baseline and at the end of application of PH-10 vehicle) for evaluation of clinical and cellular response to active investigational agent.

The protocol states that the multicenter study is designed to assess treated psoriatic plaque for changes in immunologic, structural and hyperproliferative state and for any evidence of cellular atypia when treated with PH-10 and to correlate observed changes in the skin with clinical response to treatment. These assessments are expected to advance the understanding of the mechanism of action of PH-10 in psoriasis and other inflammatory dermatoses, such as atopic dermatitis, and further substantiate the safety profile of the agent. Biopsy specimens will be assessed for changes in epidermal hyperplasia (i.e., disordered condition of the skin creating thickening and scaling); infiltration with immune cells; and molecular markers of inflammation. Correlation of clinical response to these cellular and molecular changes will be performed at the plaque level using Psoriasis Severity Index (PSI) assessment data. Safety will be assessed by monitoring the frequency, duration, severity and attribution of clinical adverse events; evaluating changes in laboratory values and vital signs; and by correlation of clinical adverse events with observed histopathologic and immunohistopathologic changes in the skin.

By capturing data at the clinical and cellular level, we expect this study to allow us to establish how PH-10 affects psoriatic plaque and other similar inflammatory diseases of the skin, and to relate the safety profile from earlier studies to such effects. We believe that understanding these effects with this level of detail will allow us to properly position PH-10 within the competitive landscape and should provide crucial safety data to support extended dosing. We expect this effort to provide a comparable level of understanding of the effects of PH-10 in diseased skin to the keen insight we have gained through our clinical and nonclinical mechanism studies of PV-10, our novel investigational cancer drug, in melanoma and other cancers. Because there are no good model systems for psoriasis, we believe this study affords a critical opportunity to link the clinical effects we have observed to changes in well-established immunologic drivers of the disease. The study will be performed at three centers in the United States. On January 29, 2015, we announced that we have opened recruitment for our PH-10 mechanism study. PH-10 has already been testing phase 1 and 2 studies and a total of 226 patients. In this study, we are looking at possible changes in the immunologic, structural and hyperproliferative state of the skin in the target plaque and evidence of cellular atypia following PH-10 application. We will use this data to aid in further development of PH-10 with our objective to co-develop or license PH-10 with dermatological partner as we continue to prepare to advance PH-10 for approval as topical anti-inflammatory non-steroidal agent for treating psoriasis and other inflammatory dermatoses. According to clinicaltrials.gov, the estimated completion date of the study was January 2016 and data is now being compiled for communication to the FDA and the public.

Atopic Dermatitis

Atopic Dermatitis, the most severe and common type of eczema, is a long-term skin disease that causes dry and itchy skin, rashes on the face, inside the elbows, behind the knees, and on the hands and feet. Scratching of the afflicted skin can cause redness, swelling, cracking, weeping clear fluid, crusting, thick skin, and scaling. According to the National Eczema Association, physicians estimate that 65% of eczema patients are diagnosed in the first year of life and 90% of patients experience it before age five. Often the symptoms fade during childhood, though most will have atopic dermatitis for life. The National Eczema Association estimates that atopic dermatitis affects over 30 million Americans.

In 2008, we initiated a phase 2 study of PH-10 for the treatment of atopic dermatitis. This phase 2 study assessed whether topical PH-10 applied once daily to mild, moderate or severe atopic dermatitis may ameliorate inflammation

of the skin when activated by ambient light. The subjects applied PH-10 daily for 28 days to skin areas affected by atopic dermatitis. The subjects were assessed weekly during the treatment period and for four weeks following the treatment period. The primary outcome measures were (i) treatment success, defined as a score of 0 to 1 at day 28, the end of the study treatment period, by the Investigator s Global Assessment (IGA) scoring system for atopic dermatitis status, and (ii) adverse experience, including pain and dermatologic/skin toxicity (incidence, severity, frequency, duration and causality) during the eight weeks following treatment.

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Data from the subjects indicated that a substantial majority of subjects had improvement in the Eczema Area Severity Index (EASI) during four weeks of treatment. The treatments were generally well tolerated with no significant safety issues identified. At the four-week interval substantial improvement was observed across all standard disease assessment scores. We have also continued important toxicity study research and development in 2012 through 2015 and thus far in 2016 to prepare for continued development in this indication and to support a New Drug Approval filing.

Other Indications

We have investigated the use of PH-10 for treatment of actinic keratosis (also called solar keratosis or senile keratosis), which is the most common pre-cancerous skin lesion among fair-skinned people and is estimated to occur in over 50% of elderly fair-skinned persons living in sunny climates. We have previously conducted a phase I clinical trial of PH-10 for actinic keratosis to examine the safety profile of a single treatment using topical PH-10 with green light photoactivation. No significant safety concerns were identified in the study. We have decided to prioritize further clinical development of PH-10 for treatment of psoriasis and atopic dermatitis rather than actinic keratosis at this time since the market is much larger for psoriasis and atopic dermatitis.

We have also conducted pre-clinical studies of PH-10 for use in treating severe acne vulgaris. Moderate to severe forms of the disease have proven responsive to several photodynamic regimens, and we anticipate that PH-10 can be used as an advanced treatment for this disease. Our pre-clinical studies show that the active ingredient in PH-10 readily kills bacteria associated with acne. This finding, coupled with our clinical experience in psoriasis, atopic dermatitis, and actinic keratosis, suggests that therapy with PH-10 will exhibit no significant side effects and will afford improved performance relative to other therapeutic alternatives. If correct, this would be a major advance over currently available products for severe acne.

The active ingredient in PH-10 is photoactive in that it reacts to light of certain wavelengths thereby potentially increasing its therapeutic effects. We believe that photodynamic treatment regimens can deliver a higher therapeutic effect at lower dosages of active ingredient, thus minimizing potential side effects including damage to nearby healthy tissues. PH-10 is especially responsive to green light, which is strongly absorbed by the skin and thus only penetrates the body to a depth of about three to five millimeters. For this reason, in the past we have investigated PH-10 combined with green-light activation, for topical use in surface applications where serious damage could result if medicinal effects were to occur in deeper tissues.

Over-the-Counter Pharmaceuticals

We have designated our subsidiary that holds our OTC products, GloveAid and Pure-ific, Pure-Stick, Pure N Clear as non-core. The potential further development and licensure of our OTC products would likely be facilitated by selling a majority stake of the underlying assets of the non-core subsidiary holding the OTC products. This transaction would likely be accomplished through a non-core spin-out process, which would enable the non-core subsidiary to become a separate publicly held company. The new public entity could then raise funds without diluting the ownership of the then current stockholders of the Company, although there can be no assurance that this process will occur.

GloveAid

Personnel in many occupations and industries now use disposable gloves daily in the performance of their jobs, including airport security personnel, food handling and preparation personnel, health care workers such as hospital

and blood bank personnel, laboratory researchers, police, fire and emergency response personnel, postal and package delivery handlers and sorters, and sanitation workers.

Accompanying the increased use of disposable gloves is a mounting incidence of chronic skin irritation. To address this market, we have developed GloveAid, a hand cream with both antiperspirant and antibacterial properties, to increase the comfort of users hands during and after the wearing of disposable gloves. During 2003, we ran a pilot scale run at the manufacturer of GloveAid.

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Pure-ific

Our Pure-ific line of products includes two quick-drying sprays, Pure-ific and Pure-ific Kids, that immediately kill up to 99.9% of germs on skin and prevent regrowth for six hours. We have determined the effectiveness of Pure-ific based on our internal testing and testing performed by Paratus Laboratories H.B., an independent research lab. Pure-ific products help prevent the spread of germs and thus complement our other OTC products designed to treat irritated skin or skin conditions such as acne, eczema, dandruff and fungal infections. Our Pure-ific sprays have been designed with convenience in mind and are targeted towards mothers, travelers, and anyone concerned about the spread of sickness-causing germs. During 2003 and 2004, we identified and engaged sales and brokerage forces for Pure-ific. We emphasized getting sales in independent pharmacies and mass (chain stores) markets. The supply chain for Pure-ific was established with the ability to support large-scale sales and a starting inventory was manufactured and stored in a contract warehouse/fulfillment center. In addition, a website for Pure-ific was developed with the ability for supporting online sales of the antibacterial hand spray. During 2005 and 2006, most of our sales were generated from customers accessing our website for Pure-ific and making purchases online. We discontinued our proof-of-concept program in November 2006 and have, therefore, ceased selling our OTC products. We now intend to license the Pure-ific product, a strategy we have been discussing with interested groups. Additionally, we also intend to sell a majority stake in the underlying assets via a non-core spin-out transaction, as discussed below.

On December 15, 2011, we sold Units to accredited investors which included shares of common stock in Pure-ific and a warrant to purchase 3/4 of a share of the Company s common stock. A total of 666,666 Units were sold for gross proceeds of $500,000 resulting in the sale of a 33% non-controlling interest in Pure-ific. At the time of the sale and as of December 31, 2011, the carrying value of the net assets in Pure-ific was $0. The sale also resulted in the issuance of warrants to purchase 500,000 shares of the Company s common stock at an exercise price of $1.25 per share with a five-year term. We intend to use the proceeds, after deducting offering expenses of approximately $56,500, to spin-off Pure-ific as a new publicly-traded company, a process we have initiated but have not yet completed. Network 1 Financial Securities, Inc., served as placement agent for the offering.

Acne

Our acne products Pure-Stick and Pure N Clear work by decreasing the production of fats, oils and sweat that create an environment conducive to unchecked growth of bacteria. Secondly, the products also act to reduce the number of bacteria already present. Pure-Stick and Pure N Clear represent new formulations of proven, safe ingredients that achieve both steps required to successfully treat acne. Since Pure-Stick and Pure N Clear are applied topically to affected areas there are no safety concerns with healthy skin. The unique combinations have allowed the Company to secure patent protection for these products.

Medical Devices

We have non-core medical device technologies that we believe may address two major markets:

- cosmetic treatments, such as reduction of wrinkles and elimination of spider veins and other cosmetic blemishes; and

therapeutic uses, including photoactivation of PH-10, other prescription drugs and non-surgical destruction of certain skin cancers.

We expect to further develop our non-core medical devices through partnerships with, or selling our assets to, third-party device manufacturers or, if appropriate opportunities arise, through acquisition of one or more device manufacturers. Additionally, we also intend to sell a majority stake in the underlying assets via a non-core spin-out transaction.

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Photoactivation

Our clinical tests of PH-10 for dermatology have in the past utilized a number of commercially available lasers for activation of the drug. This approach has several advantages, including the leveraging of an extensive base of installed devices present throughout the pool of potential physician-adopters for PH-10. Access to such a base could play an integral role in early market capture. However, since the use of such lasers, which were designed for occasional use in other types of dermatological treatment, is potentially too cumbersome and costly for routine treatment of the large population of patients with psoriasis, we have begun investigating potential use of other types of photoactivation hardware, such as light booths. The use of such booths is consistent with current care standards in the dermatology field, and may provide a cost-effective means for addressing the needs of patients and physicians alike. We anticipate that such photoactivation hardware would be developed, manufactured, and supported in conjunction with one or more third-party device manufacturers.

Laser-Based Treatment of Melanoma

We have conducted extensive research on ocular melanoma at the Massachusetts Eye and Ear Infirmary (a teaching affiliate of Harvard Medical School) using a new laser treatment that may offer significant advantage over current treatment options. A single quick non-invasive treatment of ocular melanoma tumors in a rabbit model resulted in elimination of over 90% of tumors, and may afford significant advantage over invasive alternatives, such as surgical excision, enucleation, or radiotherapy implantation. Ocular melanoma is rare, with approximately 2,000 new cases annually in the U.S. However, we believe that our extremely successful results could be extrapolated to treatment of primary melanomas of the skin, which have an incidence of over 60,000 new cases annually in the U.S. and a 6% five-year survival rate after metastasis of the tumor. We have performed similar laser treatments on large (averaging approximately 3 millimeters thick) cutaneous melanoma tumors implanted in mice, and have been able to eradicate over 90% of these pigmented skin tumors with a single treatment. Moreover, we have shown that this treatment stimulates an anti-tumor immune response that may lead to improved outcome at both the treatment site and at sites of distant metastasis. From these results, we believe that a device for laser treatment of primary melanomas of the skin and eye is nearly ready for human studies. We anticipate partnering with, or selling our assets to, a medical device manufacturer to bring it to market in reliance on a 510(k) notification. For more information about the 510(k) notification process, see Federal Regulation of Therapeutic Products below.

Research and Development

We continue to actively develop projects that are product-directed and are attempting to conserve available capital and achieve full capitalization of our company through equity and convertible debt offerings, generation of product revenues, and other means. All ongoing research and development activities are directed toward maximizing shareholder value and advancing our corporate objectives in conjunction with our OTC product licensure, our current product development and maintaining our intellectual property portfolio.

Research and development costs of $2,461,407 for the three months ended September 30, 2016 included amortization of patents of $167,780, payroll of $206,563, consulting and contract labor of $1,866,360, legal of $109,828, insurance of $65,772, lab supplies and pharmaceutical preparations of $23,975, rent and utilities of $18,195, and depreciation expense of $2,934. Research and development costs of $2,864,331 for the three months ended September 30, 2015 included amortization of patents of $167,780, payroll of $542,851, consulting and contract labor of $1,538,362, legal of $11,664, insurance of $60,598, lab supplies and pharmaceutical preparations of $517,529, rent and utilities of $22,256, and depreciation expense of $3,291. Research and development costs of $6,874,353 for the nine months

ended September 30, 2016 included amortization of patents of $503,340, payroll of $737,704, consulting and contract labor of $5,054,234, legal of $256,238, insurance of $177,567, lab supplies and pharmaceutical preparations of $63,718, rent and utilities of $71,626, and depreciation expense of $9,926. Research and development costs of $7,537,440 for the nine months ended September 30, 2015 included amortization of patents of $503,340, payroll of $1,372,200, consulting and contract

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labor of $4,142,207, legal of $222,623, insurance of $127,432, lab supplies and pharmaceutical preparations of $1,096,333, rent and utilities of $63,636, and depreciation expense of $9,669.

Research and development costs totaling $10,708,569 for 2015 included payroll of $2,292,710, consulting and contract labor of $6,652,406, lab supplies and pharmaceutical preparations of $1,115,140, legal of $358,582, insurance of $189,358, rent and utilities of $87,208, and depreciation expense of $13,165. Research and development costs totaling $5,137,927 for 2014 included payroll of $1,395,321, consulting and contract labor of $2,355,780, lab supplies and pharmaceutical preparations of $790,653, legal of $384,061, insurance of $115,957, rent and utilities of $87,623, and depreciation expense of $8,532. Research and development costs totaling $3,595,555 for 2013 included payroll of $1,459,057, consulting and contract labor of $1,317,472, lab supplies and pharmaceutical preparations of $310,160, legal of $262,720, insurance of $161,268, rent and utilities of $78,512, and depreciation expense of $6,366.

Production

We have determined that the most efficient use of our capital in further developing our OTC products is to license the products. We have been discussing this strategy with interested groups. Additionally, we also intend to sell a majority stake in the underlying assets via a non-core spin-out transaction.

Sales

We have not had any significant sales of any of our OTC products, though we commenced limited sales of Pure-ific, our antibacterial hand spray in 2004 through 2006, in a proof-of-concept program. We discontinued our proof-of-concept program in 2006 and have, therefore, ceased selling our OTC products. We will continue to seek additional markets for our products through existing distributorships that market and distribute medical products, ethical pharmaceuticals, and OTC products for the professional and consumer marketplaces through licensure, partnership and asset sale arrangements, and through potential merger and acquisition candidates.

In addition to developing products ourselves, we are negotiating actively with a number of potential licensees for several of our intellectual properties, including patents and related technologies. To date, we have not yet entered into any licensing agreements; however, we anticipate consummating one or more such licenses in the future.

Intellectual Property

Patents

We hold a number of U.S. patents covering the technologies we have developed and are continuing to develop for the production of prescription drugs, non-core technologies and OTC pharmaceuticals. All patents material to an understanding of the Company are included and a cross reference to a discussion that explains the patent technologies and products is identified for each patent in the following table:

U.S. Patent No	Title and Cross Reference	Issue Date	Expiration Date
5,829,448	Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business	November 3, 1998	October 30, 2016

5,832,931	Method for improved selectivity in photo-activation and detection of diagnostic agents; see discussion under Medical Devices in Description of Business	November 10, 1998	October 30, 2016
5,998,597	Method for improved selectivity in activation of molecular agents; see discussion under Medical Devices in Description of Business	December 7, 1999	October 30, 2016

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6,042,603	Method for improved selectivity in photo-activation of molecular agents; see discussion under Medical Devices in Description of Business	March 28, 2000	October 30, 2016
6,331,286	Methods for high energy phototherapeutics; see discussion under Oncology in Description of Business	December 18, 2001	February 27, 2019
6,451,597	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	September 17, 2002	April 6, 2020
6,468,777	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	October 22, 2002	April 6, 2020
6,493,570	Method for improved imaging and photodynamic therapy; see discussion under Oncology in Description of Business	December 10, 2002	November 2, 2018
6,495,360	Method for enhanced protein stabilization for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	December 17, 2002	April 6, 2020
6,519,076	Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business	February 11, 2003	October 30, 2016
6,525,862	Methods and apparatus for optical imaging; see discussion under Medical Devices in Description of Business	February 25, 2003	October 30, 2016
6,541,223	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	April 1, 2003	April 6, 2020
6,986,740	Ultrasound contrast using halogenated xanthenes; see discussion under Oncology in Description of Business	January 17, 2006	August 3, 2019
6,991,776	Intracorporeal medicaments for high energy phototherapeutic treatment of disease; see discussion under Oncology in Description of Business	January 31, 2006	February 24, 2019
7,036,516	Treatment of pigmented tissues using optical energy; see discussion under Medical Devices in Description of Business	May 2, 2006	October 30, 2016
7,201,914	Combination antiperspirant and antimicrobial compositions; see discussion under Over-the-Counter Pharmaceuticals in Description of Business	April 10, 2007	May 15, 2024
7,338,652	Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business	March 4, 2008	November 2, 2018

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7,346,387	Methods Of Improved Selectivity in Photo-Activation and Detection of Molecular Diagnostic Agents; see discussion under Medical Devices in Description of Business	March 18, 2008	October 30, 2016
7,353,829	Improved Methods and Apparatus For Multi-Photon Photo-Activation of Therapeutic Agents; see discussion under Medical Devices in Description of Business	April 8, 2008	October 30, 2016
7,384,623	A Radiosensitizer Agent comprising Tetrabromoerythrosin; see discussion under Oncology in Description of Business	June 10, 2008	October 30, 2016
7,390,668	Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business	June 24, 2008	October 30, 2016
7,402,299	Intracorporeal photodynamic medicaments for photodynamic treatment containing a halogenated xanthene or derivative; see discussion under Dermatology in Description of Business	July 22, 2008	September 1, 2017
7,427,389	Diagnostic Agents for Positron Emission Imaging; see discussion under Oncology in Description of Business	September 23, 2008	October 30, 2016
7,648,695	Improved Medicaments for chemotherapeutic treatment of disease; see discussion under Oncology in Description of Business	January 19, 2010	October 30, 2016
7,863,047	Improved intracorporeal medicaments for photodynamic treatment of disease; see discussion under Dermatology in Description of Business	January 4, 2011	October 30, 2016
8,470,296	Improved intracorporeal medicaments for high energy photodynamic treatment of disease; see discussion under Dermatology in Description of Business	June 25, 2013	July 28, 2022
8,530,675	Process for the synthesis rose bengal and related xanthenes; see discussion under Oncology in Description of Business	September 10, 2013	April 21, 2031
8,557,298	Chemotherapeutic agents for cancer; see discussion under Oncology in Description of Business	October 15, 2013	October 30, 2016
8,974,363	Topical medicaments for disease; see discussion under Dermatology in Description of Business	March 10, 2015	December 2, 2019
9,107,887	Combination therapy for cancer; see discussion under Oncology in Description of Business	August 15, 2015	March 9, 2032
9,273,022	Process for the synthesis of 4,5,6,7-tetrachloro-3',6'-dihydroxy-2', 4', 5'7'-tetraiodo-3H-spiro[isobenzofuran-1,9'-xanthen]-3-one (Rose Bengal) and related xanthenes	March 1, 2016	September 17, 2030
9,422,260	Process for the synthesis of 4,5,6,7-tetrachloro-3',6'-dihydroxy-2',4',5',7'-tetraiodo-3H-spiro[isoben-zofuran-1,9'-xanthen]-3-one(Rose Bengal) and related xanthenes	August 23, 2016	September 26, 2030

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We continue to pursue patent applications on numerous other developments we believe to be patentable. We consider our issued patents, our pending and patent applications, and any patentable inventions which we may develop to be extremely valuable assets of our business.

Material Transfer Agreement

We have entered into a Material Transfer Agreement dated as of July 31, 2003 with Schering-Plough Animal Health Corporation, which we refer to as SPAH , the animal-health subsidiary of Schering-Plough Corporation, a major international pharmaceutical company which is still in effect. Under the Material Transfer Agreement, we will provide SPAH with access to some of our patented technologies to permit SPAH to evaluate those technologies for use in animal-health applications. If SPAH determines that it can commercialize our technologies, then the Material Transfer Agreement obligates us and SPAH to enter into a license agreement providing for us to license those technologies to SPAH in exchange for progress payments upon the achievement of goals.

The Material Transfer Agreement covers four U.S. patents that cover biological material manufacturing technologies (i.e., biotech related). The Material Transfer Agreement continues indefinitely, unless SPAH terminates it by giving us notice or determines that it does not wish to secure from us a license for our technologies. The Material Transfer Agreement can also be terminated by either of us in the event the other party breaches the agreement and does not cure the breach within 30 days of notice from the other party. We cannot assure you that SPAH will determine that it can commercialize our technologies or that the goals required for us to obtain progress payments from SPAH will be achieved.

We have received no progress payments in relation to our Material Transfer Agreement with SPAH. Progress payments could potentially total $50,000 for the first cell line for which SPAH uses our technology and $25,000 for each use of the same technology thereafter. We do not know how many cell lines SPAH may have and we currently have no indication from SPAH that it intends to use any of our technologies in the foreseeable future.

Additionally, we also intend to sell a majority stake in these underlying assets via a non-core spin-out transaction.

Competition

In general, the pharmaceutical and biotechnology industries are intensely competitive, characterized by rapid advances in products and technology. A number of companies have developed and continue to develop products that address the areas we have targeted. Some of these companies are major pharmaceutical companies and biotechnology companies that are international in scope and very large in size, while others are niche players that may be less familiar but have been successful in one or more areas we are targeting. Existing or future pharmaceutical, device, or other competitors may develop products that accomplish similar functions to our technologies in ways that are less expensive, receive faster regulatory approval, or receive greater market acceptance than our products. Many of our competitors have been in existence for considerably longer than we have, have greater capital resources, broader internal structure for research, development, manufacturing and marketing, and are in many ways further along in their respective product cycles.

While it is possible that eventually we may compete directly with major pharmaceutical companies, we believe it is more likely that we will enter into joint development, marketing, or other licensure arrangements with such competitors. Eventually, we believe that we will be acquired.

We also have a number of market areas in common with traditional skincare cosmetics companies, but in contrast to these companies, our products are based on unique, proprietary formulations and approaches. For example, we are unaware of any products in our targeted OTC skincare markets that are similar to our Pure-ific product. Further, proprietary protection of our products may help limit or prevent market erosion until our patents expire.

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Federal Regulation of Therapeutic Products

All of the prescription drugs we currently contemplate developing will require approval by the FDA prior to sales within the United States and by comparable foreign agencies prior to sales outside the United States. The FDA and comparable regulatory agencies impose substantial requirements on the manufacturing and marketing of pharmaceutical products and medical devices. These agencies and other entities extensively regulate, among other things, research and development activities and the testing, manufacturing, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our proposed products. While we attempt to minimize and avoid significant regulatory bars when formulating our products, some degree of regulation from these regulatory agencies is unavoidable. Some of the things we do to attempt to minimize and avoid significant regulatory bars include the following:

Using chemicals and combinations already allowed by the FDA;

Using drugs that have been previously approved by the FDA and that have a long history of safe use; and

Using chemical compounds with known safety profiles.

The regulatory process required by the FDA, through which our drug or device products must pass successfully before they may be marketed in the U.S., generally involves the following:

Preclinical laboratory and animal testing;

Submission of an application that must become effective before clinical trials may begin;

Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication; and

FDA approval to market a given product for a given indication after the appropriate application has been filed.

For pharmaceutical products, preclinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. Where appropriate (for example, for human disease indications for which there exist inadequate animal models), we will attempt to obtain preliminary data concerning safety and efficacy of proposed products using carefully designed human pilot studies. We will require sponsored work to be conducted in compliance with pertinent local and international regulatory requirements, including those providing for Institutional Review Board approval, national governing agency approval and patient informed consent, using protocols consistent with ethical principles stated in the Declaration of Helsinki and other internationally recognized standards. We expect any pilot studies to be conducted outside the United States; but if any are conducted in the United States, they will comply with applicable FDA

regulations. Data obtained through pilot studies will allow us to make more informed decisions concerning possible expansion into traditional FDA-regulated clinical trials.

If the FDA is satisfied with the results and data from preclinical tests, it will authorize human clinical trials. Human clinical trials typically are conducted in three sequential phases which may overlap. Each of the three phases involves testing and study of specific aspects of the effects of the pharmaceutical on human subjects, including testing for safety, dosage tolerance, side effects, absorption, metabolism, distribution, excretion and clinical efficacy.

Phase 1 clinical trials include the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. While the FDA can cause us to end clinical trials at any phase due to safety concerns, phase 1 clinical trials are primarily concerned with safety issues. We also attempt to obtain sufficient information about

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the drug s pharmacokinetics and pharmacological effects during phase 1 clinical trial to permit the design of well-controlled, scientifically valid, phase 2 studies.

Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in phase 1 studies varies with the drug, but is generally in the range of 20 to 80.

Phase 2 clinical trials include the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving several hundred people.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

Applicable medical devices can be cleared for commercial distribution through a notification to the FDA under Section 510(k) of the applicable statute. The 510(k) notification must demonstrate to the FDA that the device is as safe and effective and substantially equivalent to a legally marketed or classified device that is currently in interstate commerce. Such devices may not require detailed testing. Certain high-risk devices that sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury, are subject to a more comprehensive FDA approval process initiated by filing a premarket approval, also known as a PMA, application (for devices) or accelerated approval (for drugs).

We have established a core clinical development team and have been working with outside FDA consultants to assist us in developing product-specific development and approval strategies, preparing the required submittals, guiding us through the regulatory process, and providing input to the design and site selection of human clinical studies. Historically, obtaining FDA approval for photodynamic therapies has been a challenge. Wherever possible, we intend to utilize lasers or other activating systems that have been previously approved by the FDA to mitigate the risk that our therapies will not be approved by the FDA. The FDA has considerable experience with lasers by virtue of having reviewed and acted upon many 510(k) and premarket approval filings submitted to it for various photodynamic and non-photodynamic therapy laser applications, including a large number of cosmetic laser treatment systems used by dermatologists.

The testing and approval process requires substantial time, effort, and financial resources, and we may not obtain FDA approval on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. The FDA or the research institution sponsoring the trials may suspend clinical trials or may not permit trials to advance from one phase to another at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Once issued, the FDA may withdraw a product approval if we do not comply with pertinent regulatory requirements and standards or if problems occur after the product reaches the market. If the FDA grants approval of a product, the approval may impose limitations, including limits on the indicated uses for which we may market a product. In addition, the FDA may require additional testing

and surveillance programs to monitor the safety and/or effectiveness of approved products that have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Further, later discovery of

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previously unknown problems with a product may result in restrictions on the product, including its withdrawal from the market.

Marketing our products abroad will require similar regulatory approvals by equivalent national authorities and is subject to similar risks. To expedite development, we may pursue some or all of our initial clinical testing and approval activities outside the United States, and in particular in those nations where our products may have substantial medical and commercial relevance. In some such cases, any resulting products may be brought to the U.S. after substantial offshore experience is gained. Accordingly, we intend to pursue any such development in a manner consistent with U.S. standards so that the resultant development data is maximally applicable for potential FDA approval.

OTC products are subject to regulation by the FDA and similar regulatory agencies, but the regulations relating to these products are much less stringent than those relating to prescription drugs and medical devices. The types of OTC products developed and previously sold by us only require that we follow cosmetic rules relating to labeling and the claims that we make about our product. The process for obtaining approval of prescription drugs with the FDA does not apply to the OTC products, which we have sold. The FDA can, however, require us to stop selling our product if we fail to comply with the rules applicable to our OTC products.

Employees

We currently have three employees, all of whom are full-time employees, and an independent contractor, John R. Glass, our Interim Chief Financial Officer. We currently engage four full-time consultants, including a lab technician, a contract research associate, an analytical chemist, and an information technology consultant. We also work with various vendors and disclose on our corporate website that we currently have human resources focused on our activities that equate to sixty (60) full-time equivalents, including our seven full-time employees and consultants.

Equity Issuances and Financing During 2015

During the three months ended March 31, 2015, we issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $64,000. During the three months ended March 31, 2015, we issued 3,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $1,632. During the three months ended March 31, 2015, we completed a private offering of common stock and warrants to accredited investors for gross proceeds of $776,000. We received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.25 per share. The purchase price for each share of common stock together with the warrants is $1.00. We used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, we paid $100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of $1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended June 30, 2015, we issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $63,000. During the three months ended June 30, 2015, we issued 100,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $53,582. During the three months ended June 30, 2015, we completed a private offering of common stock and

warrants to accredited investors for gross proceeds of $1,011,100. We received subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the

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number of shares purchased by the investors in the offering. The warrants have an exercise price of $1.25 per share. The purchase price for each share of common stock together with the warrants is $1.00. We used the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, we paid $131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of $1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended September 30, 2015, we issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $38,439. During the three months ended September 30, 2015, we issued 79,500 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $24,262.

During the three months ended December 31, 2015, we issued 76,750 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $37,375. During the three months ended December 31, 2015, we issued 1,766,202 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were $472,882.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(a)(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

On June 24, 2015, we completed a public offering of common stock and warrants for gross proceeds of $13,151,250 (the Offering). The Offering consisted of 17,500,000 shares of common stock and warrants to purchase 17,500,000 shares of common stock with a public offering price of $0.75 for a fixed combination of one share of common stock and a warrant to purchase one share of common stock. Investors received five year fully vested warrants to purchase up to 100% of the number of shares purchased by the investors in the Offering. The warrants have an exercise price of $0.85 per share. At the closing, the underwriters exercised their over-allotment option with respect to warrants to purchase up to an additional 2,625,000 shares of common stock at $0.01 per warrant. The warrants issued in the Offering began trading on the NYSE MKT on June 22, 2015, under the ticker symbol PVCTWS. As of June 30, 2015, 20,125,000 tradable warrants are outstanding. We used the proceeds of the Offering for clinical development, working capital and general corporate purposes. Maxim Group LLC acted as sole book-running manager for the Offering. In connection with the Offering, we paid $1,052,100 to Maxim Group LLC.

Equity Issuances and Financing During 2016

During the three months ended March 31, 2016, we issued 51,745 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were $20,163. During the three months ended March 31, 2016, 1,048,494 warrants expired.

During the three months ended June 30, 2016, 1,757,253 warrants expired. During the three months ended June 30, 2016, our employees forfeited 3,830,000 stock options due to the expiration of such options.

During the three months ended September 30, 2016, 53,500 warrants were forfeited.

As of December 28, 2015, we had outstanding warrants to purchase an aggregate of 59,861,601 shares of common stock, which were issued between January 6, 2011 and November 1, 2015 in transactions exempt from registration under the Securities Act (the Existing Warrants). Each Existing Warrant has an exercise price of between $1.00 and $3.00 per share, and expires between January 6, 2016 and November 1, 2020. On December 31, 2015, we offered pursuant to an Offer Letter/Prospectus 59,861,601 shares of our common stock for issuance upon exercise of the Existing Warrants. The shares issued upon exercise of the Existing Warrants are unrestricted and freely transferable. The Offer was to temporarily modify the terms of the Existing Warrants so that each holder who tendered Existing Warrants during the Offer Period for early exercise were able to do so at

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a discounted exercise price of $0.50 per share. Each Existing Warrant holder who tendered Existing Warrants for early exercise during the Offer Period received, in addition to the shares of common stock purchased upon exercise, an equal number of new warrants to purchase common stock, with an exercise price of $0.85 per share, expiring June 19, 2020 (the Replacement Warrants). The modification of the exercise price of the Existing Warrants and the Replacement Warrants are treated as an inducement to enter into the exchange offer and were accounted for as of the closing date. The exchange offer expired at 4:00 p.m., Eastern Time, on March 28, 2016. We accepted for purchase approximately 7,798,507 Existing Warrants properly tendered, resulting in the issuance of approximately 7,798,507 shares of common stock upon exercise of Existing Warrants and the issuance of approximately 7,798,507 Replacement Warrants, resulting in gross proceeds of $3,899,254 upon closing of the exchange offer. Maxim Group LLC and Network 1 Financial Securities, Inc. received a total of $264,214 in placement agent fees and 467,910 warrants with a cash exercise price of $0.85 per share which expire on June 19, 2020, unless sooner exercised. In connection with the exchange offer, a warrant incentive expense totaling $2,718,407 was recorded. The value was determined using the Black-Scholes option-pricing model between the Existing Warrants exchanged and the common stock and Replacement Warrants received.

On May 13, 2016, we offered pursuant to an Offer Letter/Prospectus 51,149,594 shares of its common stock for issuance upon exercise of the Existing Warrants. The Offer was to temporarily modify the terms of the Existing Warrants so that each holder who tendered Existing Warrants during the Offer Period for early exercise were able to do so at a discounted exercise price of $0.75 per share. Each Existing Warrant holder who tendered Existing Warrants for early exercise during the Offer Period were to receive, in addition to the shares of common stock purchased upon exercise, an equal number of new warrants to purchase common stock, with an exercise price of $0.85 per share, expiring June 19, 2020 (the Replacement Warrants). The exchange offer expired at 4:00 p.m., Eastern Time, on July 28, 2016 with no warrants tendered.

On August 30, 2016, we closed a public offering of 240,000 shares of our Preferred Stock (which are initially convertible into an aggregate of 24,000,000 shares of the our common stock), and August 2016 Warrants initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of $0.275 per share of common stock. The Preferred Stock and August 2016 Warrants were sold together at a price of $25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in gross offering proceeds of $6,000,000 to us before the payment of placement agent fees and expenses related to the offering.

The conversion feature embedded within the Preferred Stock is subject to anti-dilution price protection upon the issuance of equity or equity-linked securities within 60 trading days from the date of issuance of the Preferred Stock at an effective common stock purchase price of less than the conversion price then in effect, subject to certain exceptions as provided in the Certificate of Designation. In addition, if the conversion price in effect on the 60th trading day following the date of issuance of the Preferred Stock exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the Preferred Stock and ending on the 60th trading day following the date of issuance of the Preferred Stock (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Conversion Price, then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive additional shares of common stock equal to the number of shares of common stock that would have been issued assuming for such purposes the Adjusted Conversion Price were in effect at such time less the shares issued at the then Conversion Price (subject to being held in abeyance based on beneficial

ownership limitations); provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

The August 2016 Warrants expire on August 30, 2021. The exercise price of the August 2016 Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock

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combinations, reclassifications or similar events affecting the common stock. In addition, if the exercise price in effect on the 60th trading day following the date of issuance of the August 2016 Warrants exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the August 2016 Warrants and ending on the 60th trading day following the date of issuance of the August 2016 Warrants (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Exercise Price, then (i) the exercise price shall be reset to the Adjusted Exercise Price (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the August 2016 Warrants, and (ii) the number of shares of common stock issuable upon exercise of the August 2016 Warrants will be reset to equal the number of shares of common stock issuable upon conversion of Preferred Stock after giving effect to the adjusted conversion price or adjusted exercise price, as applicable. If a holder of August 2016 Warrants exercises its August 2016 Warrants prior to such repricing, then such holder will receive shares of common stock equal to the difference between the exercise price and the Adjusted Exercise Price; provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

Properties

We currently lease approximately 6,000 square feet of space outside of Knoxville, Tennessee for our corporate office and operations. Our monthly rental charge for these offices is approximately $5,000 per month, and the lease is on an annual basis, renewable for one year at our option. We have a lease commitment of $15,000 as of September 30, 2016. We believe that these offices generally are adequate for our needs currently and in the immediate future.

Legal Proceedings

Except as described below, we are not involved in any legal proceedings nor are we party to any pending claims that we believe could reasonably be expected to have a material adverse effect on our business, financial condition, or results of operations.

Kleba Shareholder Derivative Lawsuit

On January 2, 2013, Glenn Kleba, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against H. Craig Dees, Timothy C. Scott, Eric A. Wachter, and Peter R. Culpepper (collectively, the Executives), Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, together with the Executives, the Individual Defendants), and against the Company as a nominal defendant (the Shareholder Derivative Lawsuit). The Shareholder Derivative Lawsuit alleged (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on Mr. Kleba s allegations that the defendants authorized and/or accepted stock option awards in violation of the terms of the Company s 2002 Stock Plan (the Plan) by issuing stock options in excess of the amounts authorized under the Plan and delegated to defendant H. Craig Dees, the Former CEO, the sole authority to grant himself and the other Executives cash bonuses that Mr. Kleba alleges to be excessive.

In April 2013, the Company s Board of Directors appointed a special litigation committee to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee conducted its investigation, and proceedings in the case were stayed pending the conclusion of the committee s investigation. At that time, the Company established a reserve of $100,000 for potential

liabilities because such is the amount of the self-insured retention of its insurance policy. On February 21, 2014, an Amended Shareholder Derivative Complaint was filed which added Don B. Dale (Mr. Dale) as a plaintiff.

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On March 6, 2014, the Company filed a Joint Notice of Settlement (the Notice of Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Notice of Settlement are Mr. Kleba, Mr. Dale and the Individual Defendants.

On June 6, 2014, the Company, in its capacity as a nominal defendant, entered into a Stipulated Settlement Agreement and Mutual Release (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company and the Individual Defendants, Plaintiffs Glenn Kleba and Don B. Dale are parties to the Settlement.

By entering into the Settlement, the settling parties resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the settling plaintiffs have not admitted that any claims or allegations lack merit or foundation. Under the terms of the Settlement, (i) the Executives each agreed (A) to re-pay to the Company $2.24 million of the cash bonuses they each received in 2010 and 2011, which amount equals 70% of such bonuses or an estimate of the after-tax net proceeds to each Executive; provided, however, that subject to certain terms and conditions set forth in the Settlement, the Executives are entitled to a 2:1 credit such that total actual repayment may be $1.12 million each; (B) to reimburse the Company for 25% of the actual costs, net of recovery from any other source, incurred by the Company as a result of the Shareholder Derivative Lawsuit; and (C) to grant to the Company a first priority security interest in 1,000,000 shares of the Company s common stock owned by each such Executive to serve as collateral for the amounts due to the Company under the Settlement; (ii) Drs. Dees and Scott and Mr. Culpepper agreed to retain incentive stock options for 100,000 shares but shall forfeit 50% of the nonqualified stock options granted to each such Executive in both 2010 and 2011. The Settlement also requires that each of the Executives enter into new employment agreements with the Company, which were entered into on April 28, 2014, and that the Company adhere to certain corporate governance principles and processes in the future. Under the Settlement, Messrs. Fuchs and Smith and Dr. McMasters have each agreed to pay the Company $25,000 in cash, subject to reduction by such amount that the Company s insurance carrier pays to the Company on behalf of such defendant pursuant to such defendant s directors and officers liability insurance policy. The Settlement also provides for an award to plaintiffs counsel of attorneys fees and reimbursement of expenses in connection with their role in this litigation, subject to Court approval.

On July 24, 2014, the Court approved the terms of the proposed Settlement and awarded $911,000 to plaintiffs counsel for attorneys fees and reimbursement of expenses in connection with their role in the Shareholder Derivative Lawsuit. The payment to plaintiff s counsel was made by the Company during October 2014 and was recorded as other current assets at December 31, 2014, as the Company is seeking reimbursement of the full amount from its insurance carrier. If the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants. The amount was reclassed to long-term receivable at December 31, 2015. A reserve for uncollectibility of $227,750 was established at December 31, 2015 in connection with the resignation of the Former CEO. As of September 30, 2016, the Company has the net amount of the receivable of $683,250 included in long term assets on its condensed balance sheet.

On October 3, 2014, the Settlement was effective and stock options for the Former CEO, Dr. Scott and Mr. Culpepper were rescinded, totaling 2,800,000. $900,000 was repaid by the Executives as of December 31, 2015. The first year payment due has been paid. The remaining cash settlement amounts will continue to be repaid to the Company over a period of four years with the second payment due in total by October 2016 and the final payment is expected to be received by October 3, 2019. $150,000 was repaid by the Executives during the three months ended September 30, 2016, and a total of $450,000 was repaid for the nine months ended September 30, 2016. An additional $19,962 of the settlement discount was amortized as of September 30, 2016, and a total of $63,774 was amortized for the nine months ended September 30, 2016. $167,743 of the settlement discount was amortized as of September 30, 2016. The

remaining balance due the Company as of September 30, 2016 is $2,125,509, including a reserve for uncollectibility of $870,578 in connection with the resignation of the Former CEO, with a present value discount remaining of $133,912. As a result of his resignation, the Former CEO is no longer entitled to the 2:1 credit, such that his total repayment obligation of $2,040,000 (the total $2.24 million owed by the Former CEO pursuant to the Settlement less the $200,000 that he repaid as of December 31, 2015) plus the Former CEO s

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proportionate share of the litigation costs is immediately due and payable. The Company sent the Former CEO a notice of default in March 2016 for the total amount he owes the Company.

Class Action Lawsuits

On May 27, 2014, Cary Farrah and James H. Harrison, Jr., individually and on behalf of all others similarly situated (the Farrah Case), and on May 29, 2014, each of Paul Jason Chaney, individually and on behalf of all others similarly situated (the Chaney Case), and Jayson Dauphinee, individually and on behalf of all others similarly situated (the Dauphinee Case) (the plaintiffs in the Farrah Case, the Chaney Case and the Dauphinee Case collectively referred to as the Plaintiffs), each filed a class action lawsuit in the United States District Court for the Middle District of Tennessee against the Company, the Former CEO, Timothy C. Scott and Peter R. Culpepper (the Defendants) alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and seeking monetary damages. Specifically, the Plaintiffs in each of the Farrah Case, the Chaney Case and the Dauphinee Case allege that the Defendants are liable for making false statements and failing to disclose adverse facts known to them about the Company, in connection with the Company s application to the FDA for Breakthrough Therapy Designation (BTD) of the Company s melanoma drug, PV-10, in the Spring of 2014, and the FDA s subsequent denial of the Company s application for BTD.

On July 9, 2014, the Plaintiffs and the Defendants filed joint motions in the Farrah Case, the Chaney Case and the Dauphinee Case to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered an order consolidating the Farrah Case, the Chaney Case and the Dauphinee Case (collectively and, as consolidated, the Securities Litigation) and transferred the Securities Litigation to the United States District Court for the Eastern District of Tennessee.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint) in the Securities Litigation, alleging that Provectus and the other individual defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTD, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

On June 5, 2015, Provectus filed its Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response). Pursuant to order of the Court, Provectus replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015. On January 28, 2016, a settlement terms sheet (the Terms Sheet) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Securities Litigation.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Securities Litigation, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier agreed to pay the total amount of $3.5 million (the Settlement Funds) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Securities Litigation. The Company has determined that it is probable that the Company will pay $1.85 million of the total, which has been accrued at December 31, 2015 and was paid in March 2016. The

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insurance carrier will pay $1.65 million of the total directly to the plaintiff s trust escrow account and it will not pass through the Company. Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Securities Litigation will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Securities Litigation and the Securities Litigation will be fully concluded. If the court does not give final approval of the settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and includes the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement further provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Securities Litigation.

On April 7, 2016, the court in the Securities Litigation held a hearing on preliminary approval of the settlement, entered an order preliminarily approving the settlement, ordered that the class be notified of the settlement as set forth in the Stipulation of Settlement, and set a hearing on September 26, 2016 to determine whether the proposed settlement is fair, reasonable, and adequate to the class; whether the class should be certified and the plan of allocation of the Settlement Funds approved; whether to grant Lead Plaintiff s request for expenses and Lead Plaintiff s counsel s request for fees and expenses; and whether to enter judgment dismissing the Securities Litigation as provided in the Stipulation of Settlement. On September 16, 2016, the Lead Plaintiff notified the court that approximately 6,300 stockholders did not receive notification of the proposed settlement until late August 2016 because of the delayed receipt of potential Settlement Class Member information from a number of brokers. As a result, on September 22, 2016, the parties filed a joint motion requesting that the court extend the deadlines to file a Proof of Claim, request exclusion from the settlement, or file an objection to the settlement, and that the court schedule a continued settlement hearing. The court granted the motion, cancelling the settlement hearing that had been set for September 26 and re-setting the hearing to take place on December 12, 2016. The court set a new deadline of November 10, 2016 for objections and requests for exclusion, and November 25, 2016 for submitting proofs of claim. If the settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

2014-2015 Derivative Lawsuits

On June 4, 2014, Karla Hurtado, derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee against the Former CEO, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Hurtado Shareholder Derivative Lawsuit). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) abuse of control, both claims based on Ms. Hurtado s allegations that the Individual Defendants (a) recklessly permitted the Company to make false and misleading disclosures and (b) failed to implement adequate controls and procedures to ensure the accuracy of the Company s disclosures. On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the case to the United States District Court for the Eastern District of Tennessee and, in light of the pending Securities Litigation, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee.

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit) against the Former CEO, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants). As a practical matter, the factual allegations and requested relief in the Montiminy Shareholder Derivative Lawsuit are substantively the same as those in the Hurtado Shareholder Derivative Lawsuit. On December 29, 2014, the United States District Court for the Eastern District

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of Tennessee (the Court) entered an order consolidating the Hurtado Shareholder Derivative Lawsuit and the Montiminy Derivative Lawsuit. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits pending a ruling on the Motion to Dismiss filed by the Company in the Securities Litigation.

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Former CEO, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Foley Shareholder Derivative Lawsuit). The Foley Shareholder Derivative Lawsuit was brought by the same attorney as the Montiminy Shareholder Derivative Lawsuit, Paul Kent Bramlett of Bramlett Law Offices. Other than the difference in the named plaintiff, the complaints in the Foley Shareholder Derivative Lawsuit and the Montiminy Shareholder Derivative Lawsuit are identical. On March 6, 2015, the Chancery Court of Knox County, Tennessee entered an Order staying the Foley Derivative Lawsuit until the United States District Court for the Eastern District of Tennessee issues a ruling on the Motion to Dismiss filed by the Company in the Securities Litigation.

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee against the Former CEO, Timothy C. Scott, Jan. E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company s purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. We are not in a position at this time to give you an evaluation of the likelihood of an unfavorable outcome, or an estimate of the amount or range of potential loss to the Company.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

While the parties to the Securities Litigation were negotiating and documenting the Stipulation of Settlement in the Securities Litigation, the parties to the Hurtado, Montiminy, and Foley Shareholder Derivative Lawsuits, through counsel, engaged in settlement negotiations as well. On or about April 11, 2016, the parties entered into a Stipulation of Settlement, which was filed with the United States District Court for the Eastern District of Tennessee on April 29, 2016.

Pursuant to the Stipulation of Settlement, the parties agreed to settle the cases, contingent upon the approval of the court. The Company agreed to implement certain corporate governance changes, including the adoption of a Disclosure Controls and Procedures Policy, and to use its best efforts to replace one of its existing directors with an independent outside director by June 30, 2017. The Company agreed to pay from insurance proceeds the amount of $300,000 to plaintiffs counsel in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits. The insurance carrier will pay directly to the plaintiff s trust escrow account and it will not pass through the Company. Notice of the proposed settlement will be provided to shareholders as set forth in the Stipulation of Settlement. If the court enters final approval of the settlement, the Individual Defendants will be released from any and all claims in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

The United States District Court for the Eastern District of Tennessee preliminarily approved the settlement by order dated June 2, 2016. Pursuant to this court order, the notice to the class was filed with the Securities and Exchange

Commission, published on the Company s website, and posted on plaintiffs counsel s websites by June 13, 2016. On August 26, 2016, the court held a final hearing on the fairness of the settlement and entered an order approving the settlement and dismissing the action with prejudice.

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Collection Lawsuit

On May 5, 2016, the Company filed a lawsuit in the United States District Court for the Eastern District of Tennessee at Knoxville against the Former CEO and his wife, and together with the Former CEO, the Defendants). The Company alleges that between 2013 and the present, the Former CEO received approximately $2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that the Former CEO did not use these funds for legitimate travel and entertainment expenses as he requested and the Company intended. Instead, the Company believes that the Former CEO created false receipts and documentation for the expenses and applied the funds to personal use. The Company and the Former CEO are parties to a Stipulated Settlement Agreement dated October 3, 2014 (the Kleba Settlement Agreement) that was negotiated to resolve certain claims asserted against the Former CEO derivatively. Pursuant to the terms of the Kleba Settlement Agreement, the Former CEO agreed to repay the Company compensation that was paid to him along with legal fees and other expenses incurred by the Company. As of the date of his resignation, the Former CEO still owed the Company $2,267,750 under the Kleba Settlement Agreement. The Former CEO has failed to make such payment, and the Company has notified him that he is in default and demanded payment in full. Therefore, the Company is alleging counts of conversion, fraud, breach of fiduciary duty, breach of contract, breach of Kleba Settlement Agreement, unjust enrichment and punitive damages in this lawsuit. We are seeking that the Defendants be prohibited from disposing of any property that may have been paid for with the misappropriated funds, the Defendants be disgorged of any funds shown to be fraudulently misappropriated and that the Company be awarded compensatory damages in an amount not less than $5 million. Furthermore, we are seeking for the damages to be joint and several as to the Defendants and that punitive damages be awarded against the Former CEO in our favor. We are also seeking foreclosure of our first-priority security interest in the 1,000,000 shares of common stock granted by Dr. Dees to the Company as collateral pursuant to that certain Stock Pledge Agreement dated October 3, 2014, between Dr. Dees and the Company in order to secure Dr. Dees obligations under the Kleba Settlement Agreement. The United States District Court for the Eastern District of Tennessee at Knoxville entered a default judgment against Dr. Dees on July 20, 2016; however, the Company cannot predict when these shares will be recovered by the Company. The Court recently issued a Temporary Restraining Order upon the Company s application for same upon notice that Dr. Dees was attempting to sell his shares of the Company s common stock. The Temporary Restraining Order was converted to a Preliminary Injunction on September 16, 2016, which order will remain in place until the trial of the underlying lawsuit absent further court order.

The Bible Harris Smith Lawsuit

On November 17, 2016, the Company filed a lawsuit in the Circuit Court for Knox County, Tennessee against Bible Harris Smith PC (BHS) for professional negligence, common law negligence and breach of fiduciary duty arising from accounting services provided by BHS to the Company. The Company alleges that between 2013 and the present, the Former CEO received approximately $2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that the Former CEO did not submit back-up documentation in support of substantially all of the advances he received purportedly for future travel and entertainment expenses. The Company further alleges that had BHS provided competent accounting and tax preparation services, it would have discovered the Former CEO s failure to submit back-up documentation supporting the advanced travel funds at the inception of the Former CEO s conduct, and prevented the misuse of these and future funds. The Company has made a claim for damages against BHS in an amount in excess of $3 million. The Complaint against BHS has been filed and served, but no Answer has been received.

Other Regulatory Matters

From time to time the Company receives subpoenas and/or requests for information from governmental agencies with respect to our business. We have received a subpoena from the staff of the Securities and Exchange Commission related to the travel expense advancements and reimbursements received by our Former CEO. At this time, the staff s investigation into this matter remains ongoing. The Company is cooperating with the staff but cannot predict with any certainty what the outcome of the foregoing may be.

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MANAGEMENT

Executive Officers and Directors

Name	Age	Position Held with Provectus
Peter R. Culpepper	56	Interim Chief Executive Officer and Chief Operating Officer
John R. Glass, CPA	72	Interim Chief Financial Officer
Timothy C. Scott, Ph.D.	58	President and Director
Eric A. Wachter, Ph.D.	54	Chief Technology Officer and Director
Jan E. Koe	66	Director
Alfred E. Smith IV	65	Director and Chairman of the Board
Kelly M. McMasters, PhD, MD	55	Director

There are no family relationships among our directors and executive officers. All directors are elected to hold office until the next annual meeting of stockholders following election and until their successors are duly elected and qualified. Executive officers are appointed by the Board of Directors and serve at the discretion of the Board.

Peter R. Culpepper, 56, serves as our Interim Chief Executive Officer (since February 2016) and Chief Operating Officer (since July 2008). Mr. Culpepper previously served as Chief Financial Officer from February 2004 to April 18, 2016. Previously, Mr. Culpepper served as Chief Financial Officer for Felix Culpepper International, Inc. from 2001 to 2004; was a Registered Representative with AXA Advisors, LLC from 2002 to 2003; has served as Chief Accounting Officer and Corporate Controller for Neptec, Inc. from 2000 to 2001; has served in various Senior Director positions with Metromedia Affiliated Companies from 1998 to 2000; has served in various Senior Director and other financial positions with Paging Network, Inc. from 1993 to 1998; and has served in a variety of financial roles in public accounting and industry from 1982 to 1993. Mr. Culpepper is a member of the AICPA and Financial Executives International and serves on the Accounting Council of Gerson Lehrman Group. He earned a Masters in Business Administration in Finance from the University of Maryland College Park in 1992. He earned an AAS in Accounting from the Northern Virginia Community College Annandale, Virginia in 1985. He earned a BA in Philosophy from the College of William and Mary Williamsburg, Virginia in 1982. He is a licensed Certified Public Accountant in both Tennessee and Maryland.

John R. Glass, CPA, 72, serves as our Interim Chief Financial Officer (since April 18, 2016). Mr. Glass is the President of J.R. Glass & Associates, a consulting firm he founded in 1990 to assist clients in the financial, operational and marketing segments of their business. In this role, his responsibilities have included, among others, preparation of periodic reports to be filed with the Securities and Exchange Commission and Sarbanes-Oxley compliance documentation. From January 2007 to May 2014, Mr. Glass served as controller for CytoCore, Inc. (OTCBB: CYOE) (now known as Medite Cancer Diagnostics Inc.), a late development stage bio molecular diagnostics company. His prior chief financial officer experience includes serving as Chief Financial Officer of U. S. RealTel, Inc., a publicly traded company in the telecommunications industry, Vice President and Chief Financial Officer of Health Charge Corporation, a financial services company in the health care industry, and Vice President and Chief Financial Officer of Aluminum Distributors, Inc., a metal processor and distributor. He also previously served as Vice President of Fulton Manufacturing Industries, Inc. and as a Manager at Grant Thornton LLP, a registered public accounting firm. Mr. Glass is chairman of the Plan Commission of Elk Grove Village, a member of the Illinois CPA Society and past chairman and member of the board of directors for the Greater O Hare Service Corporation. He received his B.B.A. in

Accounting from Loyola University.

Timothy C. Scott, Ph.D., 58, has served as our President and as a member of our board of directors since we acquired PPI on April 23, 2002. Prior to joining us, Dr. Scott was a senior member of the Photogen management team from 1997 to 2002, including serving as Photogen s Chief Operating Officer from 1999 to 2002, as a director of Photogen from 1997 to 2000, and as interim CEO for a period in 2000. Before joining Photogen, he served as senior management of Genase LLC, a developer of enzymes for fabric treatment and held senior research and management positions at Oak Ridge National Laboratory. Dr. Scott earned a Ph.D. in Chemical Engineering from the University of Wisconsin Madison in 1985.

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Eric A. Wachter, Ph.D., 54, serves as our Chief Technology Officer since May 14, 2012 and as a member of our board of directors since February 29, 2016. Dr. Wachter previously served as Executive Vice President Pharmaceuticals and as a member of our board of directors since we acquired PPI on April 23, 2002 until May 14, 2012. Prior to joining us, from 1997 to 2002 he was a senior member of the management team of Photogen, including serving as Secretary and a director of Photogen since 1997 and as Vice President and Secretary and a director of Photogen since 1999. Prior to joining Photogen, Dr. Wachter served as a senior research staff member with Oak Ridge National Laboratory. He earned a Ph.D. in Chemistry from the University of Wisconsin Madison in 1988.

Jan E. Koe, 66, has served as a member of our board of directors since May 14, 2012. Mr. Koe has a 30-year track record of success in consulting, asset management, real estate and public company governance, and has represented major insurance firms, national retailers and Fortune 500 companies. He is President of GoStar, which is the manager of Real Solutions Opportunity Fund 2005-I and Real Solutions Fund Management LLC and Real Solutions Investment LLC. He is also Principal of Method K Partners, Inc., a commercial real estate firm, which he founded in 1988. He has served on the Board of Directors of ONE Bio, Corp. where he was Chair of the Compensation Committee and a member of the Financial Audit Committee. He holds a degree in Business Administration and Psychology from Luther College.

Kelly M. McMasters, M.D., Ph.D., 55, has served as a member of our board of directors since June 9, 2008. Additionally, Dr. McMasters serves as chairman of our scientific advisory board. Dr. McMasters received his undergraduate training at Colgate University prior to completing the MD/PhD program at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School and Rutgers University. He then completed the residency program in General Surgery at the University of Louisville, and a fellowship in Surgical Oncology at M.D. Anderson Cancer Center in Houston. He is currently the Sam and Lolita Weakley Professor of Surgical Oncology at the University of Louisville in Kentucky, a position he has held since 1996. Since 2005, he has chaired the Department of Surgery at the University of Louisville and also has been Chief of Surgery at University of Louisville Hospital. Since 2000, he has also been Director of the Multidisciplinary Melanoma Clinic of the James Graham Brown Cancer Center at the University of Louisville. His is an active member of the surgery staff at the University of Louisville Hospital, Norton Hospital and Jewish Hospital in Louisville. He is on the editorial boards of the Annals of Surgical Oncology, Cancer Therapy and the Journal of Clinical Oncology as well as an ad hoc reviewer for 9 other publications. He holds several honors, chief among them is Physician of the Year awarded by the Kentucky Chapter of the American Cancer Society. He is the author and principal investigator (PI) of the Sunbelt Melanoma Trial, a multi-institutional study involving 3500 patients from 79 institutions across North America and one of the largest prospective melanoma studies ever performed. He has been a PI, Co-PI or local PI in over thirty clinical trials ranging from Phase 1 to Phase 3. For the past 12 years he has also directed a basic and translational science laboratory studying adenovirus-mediated cancer gene therapy funded by the American Cancer Society and the National Institutes of Health (NIH).

Alfred E. Smith, IV, 65, also known as Al, IV, is the Founder of AE Smith Associates, LLC and serves as its Chief Executive Officer. Mr. Smith served as a Senior Advisor for Kroll Bond Rating Agency; and K2 Global Consulting, N.A., LLC from 2008 to 2014. Mr. Smith served as Senior Managing Director of Bear Wagner Specialists LLC from April 2001 to 2006. Mr. Smith served as a Managing Director of Hunter Specialists LLC from January 1997 to April 2001. He served as a Partner of CMJ Partners, LLC, a firm he served at from 1979 to 1996. He served as Vice President of Mitchell, Hutchins & Co. from 1978 to 1979. Mr. Smith began his career on Wall Street as an independent broker on the New York Stock Exchange in 1972. He served as Chairman of Saint Vincents Catholic Medical Centers Of New York from 2006 to 2010. Mr. Smith was a Director of Genco Shipping & Trading Ltd from 2012 to 2014. He was an Independent Director of Rica Foods Inc. from 1994 to 2003. He served as Member of the

Strategic Advisory Board at Next Health, LLC from 2012 to 2014. Mr. Smith served as a member of the Board of Trustees of Iona Prep School, Saint Agnes Hospital, and Lady of Mercy Medical Center. He served as Director of Saint Vincent Catholic Medical Centers from 1986 to 2012. He founded Hackers for Hope in 1989 and has been its Chairman since 1989. He serves as Dinner Chairman, Secretary and Director of the Alfred Emanuel Smith Memorial Foundation. Mr. Smith is a Member of the Association of the Sovereign Military Order

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of Malta. He was a Member of the President s Council of Memorial Sloan Kettering Hospital from 1986 to 1996, and is a Member of the New York City Advisory Board of the Enterprise Foundation. Mr. Smith serves on the boards of directors of the Tony Blair Faith Foundation and Mutual of America Capital Management LLC. He was Director at the Catholic Youth Organization until 1997. He has been the Chairman of the Cardinal s Committee for the Laity-Wall Street Division since 1985. He has received numerous awards for his charity humanitarian work, including Wall Street 50 Honoree Humanitarian Award, Terence Cardinal Cooke Center in 1999; Man of the Year Award at Iona Prep in 1986, Club of Champions Gold Medal Award of the Catholic Youth Organization, Ellis Island Medal of Honor, the National Brotherhood Award of the National Conference of Christians and Jews, the Graymoor Community Service Award by the Franciscan Friars of the Atonement, the American Cancer Society s Gold Sword of Hope Award, and the Terence Cardinal Cooke Humanitarian Award by Lady of Mercy Medical Center. Mr. Smith attended Villanova University.

Board Leadership Structure

Our Board of Directors consists of five members, Timothy C. Scott, Eric Wachter, Jan E. Koe, Kelly M. McMasters and Alfred E. Smith, IV. Mr. Smith serves as chairman of our Board of Directors effective February 27, 2016. H. Craig Dees served as our Chief Executive Officer and Chairman of the Board of Directors until his resignation effective February 27, 2016. Three members of our Board of Directors, Mr. Koe, Dr. McMasters and Mr. Smith, are considered independent under the independence standards of the NYSE MKT.

We believe that it was appropriate to separate the positions of Chairman and Chief Executive Officer following Dr. Dees resignation because this new leadership structure enhances the ability of our Board of Directors to ensure that the appropriate level of independent oversight is applied to all management decisions and avoids any potential conflicts of interest. It also permits our Interim Chief Executive Officer, who has served in that capacity for only seven months, to focus on Company operations while our Chairman can focus on critical Board matters. Our entire Board of Directors is responsible for our risk oversight function due to the fact that we have only three employees, two of whom are members of our Board of Directors, and an independent contractor serving as our Interim Chief Financial Officer.

EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

The primary objectives of our compensation committee with respect to executive compensation are to attract, retain, and motivate the best possible executive talent. Our focus is to tie short- and long-term cash and equity incentives to achievement of measurable corporate and individual performance objectives, and to align our executive officers incentives with stockholder value creation. To achieve these objectives, our compensation committee has maintained, and continues to develop, compensation plans that tie a substantial portion of executives overall compensation to our scientific, medical and clinical milestones. Our compensation committee has reviewed these compensation practices and now also takes into consideration commercial and operational performance in addition to our scientific, medical and clinical milestones in determining the amount and types of compensation awarded to our executive officers.

Our compensation committee has a pay-for-performance compensation philosophy, which is intended to bring base salaries and total executive compensation in line to ensure the competitiveness of the compensation packages we provide to our named executive officers. In 2012, we undertook a comprehensive review of our executive compensation practices with respect to compensation of our executive officers, other than base salaries, which

remained the same. We undertook this review because we had completed certain scientific, medical and clinical milestones, which was the basis for executive compensation (other than base salaries) until April 30, 2012. As a result of this review and feedback we received from our stockholders with respect to our executive compensation practices, we decided to eliminate, on a temporary basis, the payment of cash bonuses as part of our compensation package for executive officers after April 30, 2012. We determined at that time that any cash bonuses that the compensation committee awarded in the future would be made with the consideration of commercial and operational performance milestones, achievement of specific scientific, medical and clinical

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milestones, as well as peer company compensation data. Based on the Company s achievement of those specified scientific, medical and clinical milestones, the compensation committee approved cash bonuses in 2015 of $200,000 to each of our named executive officers.

We work within the framework of this pay-for-performance philosophy to determine each component of an executive officer s initial compensation package based on numerous factors, including:

- the individual s particular background and circumstances, including training and prior relevant work experience;
- the individual s role with us and the compensation paid to similar persons in the companies represented in the compensation data that we review;
- the demand for individuals with the individual s specific expertise and experience at the time of hire;
- performance goals and other expectations for the position;
- comparison to other executive officers within our company having similar levels of expertise and experience; and
- uniqueness of industry skills.

Our compensation committee has also maintained an annual performance management program, under which annual performance goals are determined and set forth in writing at the beginning of each calendar year for the company as a whole. These corporate goals specify the achievement of specific scientific, medical and clinical milestones. The named executive officers propose these annual corporate performance goals to the compensation committee for its review and approval. Any bonuses, and any stock option awards granted to our employees are tied to the achievement of these corporate goals, including each individual s contribution to the achievement of those specific corporate goals.

Our compensation committee, which is composed solely of independent directors, makes all compensation decisions for our executive officers.

Compensation Consultant

In 2015, to assist the compensation committee in assessing the market competitiveness of our compensation program and establishing executive officer and director compensation for 2016, the compensation committee retained Pearl Meyer, which is a nationally recognized compensation consulting firm, to:

compile market data and business performance statistics of comparable companies for compensation committee comparison and review;

assist in establishing a peer group of companies;

summarize trends and developments affecting executive compensation;

provide guidance on compensation structure as well as levels of compensation for our executive officers and directors;

review equity compensation grant practices and other topics as requested by the compensation committee; and

report directly to the compensation committee and participate in compensation committee meetings as requested by the compensation committee.

The compensation committee has the sole authority to establish the nature and scope of Pearl Meyer s engagement, to approve Pearl Meyer s fees and to terminate Pearl Meyer s engagement. Pearl Meyer does not provide any services to Provectus other than those requested by the compensation committee with respect to executive and director compensation. Based on these considerations, the compensation committee has

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determined that the advice it receives from Pearl Meyer is independent and objective. All of the decisions with respect to determining the amount or form of compensation for our named executive officers and directors are made by the compensation committee and may reflect factors and considerations other than the information and advice provided by Pearl Meyer.

While the compensation committee retained Pearl Meyer to provide guidance on compensation structure as well as levels of compensation for our executive officers and directors, the compensation committee has not yet made any changes to our executive officer or director compensation structure.

Compensation Components

The components of our compensation package are as follows:

Base Salary & Employment Agreements

We pay salaries to provide fixed compensation for the daily responsibilities of our named executive officers.

On April 28, 2014, we entered into amended and restated executive employment agreements with each of H. Craig Dees, Ph.D., Peter R. Culpepper, Timothy C. Scott, Ph.D., and Eric A. Wachter, Ph.D., to serve as our Chief Executive Officer, Chief Financial Officer and Chief Operating Officer, President, and Chief Technology Officer, respectively. Each agreement provides that such named executive officer will be employed for a five-year term with automatic one-year renewals unless previously terminated pursuant to the terms of the agreement or either party gives notice that the term will not be extended. Each named executive officer s initial base salary is $500,000 per year and any increases to such base salary shall be determined by the compensation committee in its sole discretion. Named executive officers are also eligible for annual bonuses and annual equity incentive awards as determined by the compensation committee in its sole discretion. Named executive officers are entitled to reimbursement for all reasonable out-of-pocket expenses incurred during their performance of services under the agreements. Our named executive officers will be entitled to the payments upon termination of their employment, with or without a change of control, as described under the heading Potential Payments upon Termination or Change in Control below. The employment agreements for our named executive officers also include non-competition, non-solicitation and confidentiality obligations. Prior to April 28, 2014, each of our named executive officers was a party to an executive employment agreement with substantially similar terms as the agreements entered into on April 28, 2014. Effective February 27, 2016, Dr. Dees resigned from his position as Chief Executive Officer and Chairman of the Board of Directors and his employment agreement was terminated.

Bonus Awards

Our compensation committee terminated our former longevity bonus policy effective April 30, 2012 as a result of several considerations, including but not limited to feedback we received from our ongoing communications with our stockholders about our executive compensation practices. We did not award any cash bonuses to our named executive officers in 2013 or 2014, but the compensation committee awarded cash bonuses in 2015 to each of our named executive officers in the amount of $200,000 based on the Company s achievement of such pre-established scientific, medical and clinical milestones.

401(k) Profit Sharing Plan and Other Benefits

Our named executive officers participate in our 401(k) Profit Sharing Plan, which was formed in 2010. Contributions to the 401(k) Profit Sharing Plan by us are discretionary. Contributions by us in 2013 totaled approximately $226,000. Contributions by us in 2014 totaled approximately $320,000. Contributions by us in 2015 totaled approximately $212,000. We maintain broad-based benefits that are provided to all employees, including health insurance, life and disability insurance, dental insurance, and a vacation policy that requires a minimum amount of vacation time used but provides for cash compensation in lieu of vacation taken if appropriate.

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Long-Term Incentives

We believe that long-term performance is achieved through an ownership culture that encourages long-term participation by our executive officers in equity-based awards. Our Amended and Restated 2002 Stock Plan, or our 2002 Stock Plan, allowed the grant to employees of stock options, restricted stock, and other equity-based awards. The 2002 Stock Plan expired by its terms on April 22, 2012. At the 2012 annual meeting of stockholders, our stockholders approved the 2012 Stock Plan, which replaced the 2002 Stock Plan. The 2012 Stock Plan allowed the grant to employees of stock options, restricted stock, and other equity-based awards. At the 2014 annual meeting of stockholders, our stockholders approved the Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan (the 2014 Equity Compensation Plan). The 2014 Equity Compensation Plan authorizes our Board of Directors to grant the following types of equity-based awards: (i) options that qualify as incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986 (the Code), and (ii) options that do not qualify as incentive stock options under the Code (non-qualified stock options, and collectively with incentive stock options, options). We are authorized to grant options under the 2014 Equity Compensation Plan for up to 20,000,000 shares of our common stock. If any options granted under the 2014 Equity Compensation Plan are forfeited or terminated for any reason, the shares of common stock that were subject to the options will again be available for future distribution under the 2014 Equity Compensation Plan. We no longer issue any awards under the 2012 Stock Plan.

Our practice is to make periodic annual stock option awards as part of our overall performance management program, when approved by our compensation committee. Our compensation committee believes that stock options provide management with a strong link to long-term corporate performance and the creation of stockholder value. We intend that the periodic annual aggregate cumulative total of these awards will not exceed 10% of our fully diluted outstanding common stock. As is the case when the amounts of base salary and equity awards are determined, a review of all components of the executive officer s compensation is conducted when determining annual option awards to ensure that an executive officer s total compensation conforms to our overall philosophy and objectives. A pool of options is reserved for our non-employee directors to receive their annual grant and the pool of options is only increased for employees when approved by our stockholders.

Potential Payments Upon Termination or Change in Control

Each of the employment agreements for our named executive officers generally provides that in the event that the executive s employment is terminated (i) voluntarily by the executive without Good Reason (as defined in the respective employment agreement) or (ii) by the Company for Cause (as defined in the respective employment agreement), the Company shall pay the executive s compensation only through the last day of the employment period and, except as may otherwise be expressly provided, the Company shall have no further obligation to the executive. In the event that the executive s employment is terminated by the Company other than for Cause (including death or disability), or if the executive voluntarily resigns for Good Reason, for so long as the executive is not in breach of his continuing obligations under the non-competition, non-solicitation and confidentiality restrictions contained in such executive s employment agreement, the Company shall continue to pay the executive (or his estate) an amount equal to his base salary in effect immediately prior to the termination of his employment for a period of 24 months, to be paid in accordance with the Company s regular payroll practices through the end of the fiscal year in which termination occurs and then in one lump sum payable to the executive in the first month of the fiscal year following termination, as well as any prorated bonuses based upon the bonuses paid with regard to the prior fiscal year, plus benefits on a substantially equivalent basis to those which would have been provided to the executive in accordance with the terms of such benefit plans.

Under the terms of the Amended and Restated Executive Employment Agreement entered into by H. Craig Dees and the Company on April 28, 2014 (the Dees Agreement), Dr. Dees was owed no severance payments as a result of his resignation as the Company s Chief Executive Officer and Chairman of the Board of Directors effective February 27, 2016. Dr. Dees employment terminated due to his resignation without Good Reason (as that term is defined in the Dees Agreement). Under section 6 of the Dees Agreement (Effect of Termination) a resignation by Dr. Dees without Good Reason terminates any payments that would otherwise be due to Dr. Dees as of the last day of his employment.

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The following table shows the base salary compensation the named executive officers would have received under their employment agreements had a change in control occurred as of December 31, 2015 and had the named executive officers been terminated within six months following such change in control.

Name	Amount
H. Craig Dees, Ph.D.	$ 1,000,000
Timothy C. Scott, Ph.D.	1,000,000
Eric A. Wachter, Ph.D.	1,000,000
Peter R. Culpepper	1,000,000

Under the terms of our 2014 Equity Compensation Plan, prior to the occurrence of a change in control (as defined in the 2014 Equity Compensation Plan), and unless otherwise determined by our Board of Directors, any stock options outstanding on the date such change in control is determined to have occurred that are not yet exercisable and vested on such date shall become fully exercisable and vested. As of December 31, 2015, none of our named executive officers had outstanding unvested stock options.

Consideration and Effect of the Results of the Most Recent Stockholder Advisory Vote on Executive Compensation in Determining Compensation Policies and Decisions

In 2015, our compensation committee reviewed our compensation policies to ensure any bonuses and stock option grants are made with the consideration of commercial and operational performance milestones as well as peer company compensation data, in addition to the achievement of specific scientific, medical and clinical milestones. In determining executive compensation for 2015, our compensation committee considered our stockholders approval of our executive compensation at our June 19, 2015 Annual Meeting of Stockholders, as well as feedback we have received from ongoing communications with our stockholders. We will continue to consider stockholder feedback in the future with respect to both our stockholder advisory votes on executive compensation and informal feedback we receive from our stockholders.

Compensation-Related Risk Assessment

SEC regulations require that we assess our compensation policies and practices and determine whether those policies and practices are reasonably likely to result in a material adverse effect upon Provectus. Based upon a review by our Board of Directors and management of our compensation policies and practices, we have determined that our current compensation policies and practices are not reasonably likely to result in a material adverse effect on us. In reaching this conclusion, we considered the multiple performance metrics in the annual incentive plan, combination of short-term and longer-term incentives, using periodic stockholder approved equity grants, stock ownership guidelines for executive officers, clawback of compensation in event of restatement of financial statements in cases of fraud, and a further review of our compensation policies in the future to maximize stockholder value.

Conclusion

Our compensation policies are designed to retain and motivate our employees; namely, our executive officers, and to ultimately reward them for outstanding individual and corporate performance.

Compensation Committee Report on Executive Compensation

Our compensation committee has reviewed and discussed with management the Compensation Discussion and Analysis appearing in this Proxy Statement. Based on the review and discussions noted above, our Board of Directors recommended that the Compensation Discussion and Analysis be included in this Proxy Statement and incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2015.

Jan E. Koe

Kelly M. McMasters

Alfred E. Smith, IV (Chairman)

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Recent Developments

Stockholders holding 57% of the shares voting on the non-binding advisory vote on the compensation of our named executive officers, which we refer to as Say on Pay, at our annual meeting of stockholders held on June 16, 2016 voted to approve the compensation paid to our named executive officers, while stockholders holding 39% of the shares voting on Say on Pay voted against such compensation. Although Say on Pay passed by a majority of the shares that were voted at the annual meeting, our compensation committee considers it significant that (i) stockholders holding less than 60% of the voting shares voted for Say on Pay and (ii) stockholders holding more than 35% of the voting shares voted against Say on Pay.

As a result of the results of the Say on Pay vote, our compensation committee immediately initiated and directed a comprehensive review of our compensation policies and practices. Our compensation committee had previously retained Pearl Meyer, an independent executive compensation consultant, to update the market pay analysis for executive officers and non-employee directors based on a review of peer group proxy statement filings and published compensation surveys. As part of its comprehensive review, our compensation committee studied the data provided by Pearl Meyer and met in executive session with Pearl Meyer to discuss Pearl Meyer s reports. Our compensation committee also conducted additional analysis on execute compensation for the peer companies identified by Pearl Meyer. Members of our compensation committee also reached out to certain of our stockholders representing approximately 10% of our outstanding shares of common stock to better understand the reasons for the relatively low percentage of for votes on Say on Pay and held direct conversations with each of these stockholders. The primary focus of these stockholder meetings was to seek specific feedback on executive compensation and review potential changes to existing compensation practices. The feedback received from these participating stockholders was incorporated into our compensation committee s discussion and determination of the changes to executive compensation.

Executive Compensation

The following is a summary of the material changes to our executive compensation and decisions made by our compensation committee in response to our compensation committee s comprehensive review and best practices:

2016 Base Salaries

Under each executive officer s employment agreement, the compensation committee has the sole discretion to increase each executive s base salary. The compensation committee opted not to increase the base salary for any of our executive officers in 2016.

Annual Cash Bonus Incentives

2015 cash bonuses. The compensation committee decided to defer any decision with respect to cash bonuses for our executive officers for 2015 performance until a later date.

Eligibility for 2016 cash bonuses. In prior years, decisions on cash bonuses were decided based upon achievement of only our goals, and all executive officers received the same bonus amount. In March 2016, management submitted our proposed corporate goals for 2016. The compensation committee thereafter determined that, in addition to corporate goals, the cash bonus for fiscal year 2016 will also be based upon the achievement of personal goals that each executive officer individually submits to the compensation committee by July 1. After the compensation committee

has approved each executive officer s personal goals, the compensation committee will monitor progress toward achievement of those goals, and will retain the sole discretion to determine whether each executive officer has achieved his applicable individual performance goals. The compensation committee determined that cash bonuses will not exceed 20% of such executive officer s base

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salary and may be awarded upon achievement of both corporate and individual performance goals; provided, however, the compensation committee may award a cash bonus of as much as 33% of an executive officer s base salary, but only in the event of superior performance. Finally, the compensation committee will suspend its historical practice of paying the executive officers the same bonus amount.

Long-Term Incentive Awards

The compensation committee deferred any decision on equity compensation to our executive officers for 2015 performance until a later date. For 2016, any stock options that may be awarded to our executive officers will be a mix of 50% stock options with time-based vesting and 50% performance-based stock options, which performance-based stock options will be awarded only after the achievement of both the corporate performance goals and the executive officer s respective individual performance goals described above.

Perquisites

Payment for accrued but unused vacation. In the past, our executive officers received a total of eight weeks of vacation annually, and an executive officer could receive a cash payment for accrued but unused vacation up to a maximum of six weeks of unused vacation per year. The compensation committee elected to (i) reduce the amount of vacation executive officers are entitled to receive to a total of six weeks per year, effective immediately, and (ii) limit the cash payment for accrued but unused vacation to two weeks per year beginning in 2017, which will be paid on the last business day of each fiscal year. Any accrued but unused vacation days in excess of two weeks will be forfeited. Because the compensation committee approved these changes at the midpoint of our fiscal year, the compensation committee approved the payment of up to a maximum of four weeks of accrued but unused vacation for 2016.

401(k) contributions for 2017. In prior years, we contributed the maximum amount permitted to be contributed by us with regard to each executive officer pursuant to our 401(k) plan, regardless of the amount, if any, contributed by the respective executive officers. Beginning in 2017, we will match the 401(k) contributions of each executive officer participating in our 401(k) plan in an amount equal to such executive officer s own contribution, up to an amount equal to half of the maximum amount we are permitted to contribute.

Board Compensation

The compensation committee also reviewed and analyzed Board and committee compensation, noting that cash compensation for board service and committee service is in-line with a selected group of what the compensation committee viewed as our peers, that equity compensation to Board members is lower than that of our peer companies, and that we are alone in our peer group in failing to pay our chairman/lead independent director for service in that capacity.

Accordingly, the compensation committee adopted the following policies and practices regarding non-employee director compensation:

Retainers

Committee and Chairperson retainers modified.

Audit committee member compensation will be increased to $20,000 per year from $15,000 per year; the audit committee chairperson will receive $25,000 per year, up from $20,000 per year.

Corporate governance and nominating committee members will receive $10,000 per year, down from $15,000 per year, while the corporate governance and nominating committee chairperson compensation will be $15,000 per year, down from $20,000 per year.

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Compensation committee members will continue to be paid $15,000 per year; the compensation committee chairperson will still be paid $20,000 per year.

Each non-employee member of the search committee for the chief executive officer will receive $20,000 per year; the chairperson of the search committee will receive $25,000 per year.

Compensation for serving as Chairperson of the Board of Directors or lead independent director, as applicable, will be set at $20,000 per year.

Chairpersons of Committees. Kelly M. McMasters, M.D., Ph.D has replaced Alfred E. Smith, IV as chairperson of the corporate governance and nominating committee, and Jan E. Koe has replaced Alfred E. Smith, IV as the chairperson of the compensation committee. Alfred E. Smith, IV remains chairperson of the audit committee.

Restricted Stock

The compensation committee has opted to amend our 2014 Equity Compensation Plan to allow for restricted stock awards to non-employee directors, subject to approval by our stockholders. If the amendment to the Plan is approved by our stockholders, each non-employee director will be awarded 100,000 restricted stock awards annually.

Summary Compensation Table

The table below shows the compensation for services in all capacities we paid during the years ended December 31, 2015, 2014 and 2013 to our Chief Executive Officer, Chief Financial Officer and our two other executive officers during 2015 (whom we refer to collectively as our named executive officers):

Name and Principal Position	**Year**