PROVECTUS BIOPHARMACEUTICALS, INC.
Form 424B5
August 24, 2016
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Registration No. 333-205704

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated August 24, 2016

Preliminary Prospectus Supplement

(To prospectus dated July 27, 2015)

Shares of Series B Convertible Preferred Stock

Shares of Common Stock Underlying the Series B Convertible Preferred Stock

Warrants to Purchase Shares of Common Stock

Shares of Common Stock Underlying the Warrants

We are offering up to shares of our Series B Convertible Preferred Stock (the Preferred Stock) and warrants (Warrants) to purchase up to shares of our common stock, par value $0.001 per share (the Common Stock), and the shares of Common Stock issuable from time to time upon conversion of the Preferred Stock, payment of dividends accrued on the Preferred Stock in shares of Common Stock upon conversion of the Preferred Stock and the shares of Common Stock upon exercise of the Warrants. Each share of Preferred Stock we sell in this offering will be accompanied by a Warrant to purchase shares of Common Stock at an exercise price of $ per share of Common Stock. Each share of Preferred Stock and accompanying Warrant is being offered at a price of $. The shares of Preferred Stock and Warrants will be issued separately but can only be purchased together in this offering. Each Warrant will be immediately exercisable and will expire on the five year anniversary of the date of issuance.

Our Common Stock is traded on the NYSE MKT LLC (the NYSE MKT) under the symbol PVCT. There is no established public trading market for the Preferred Stock or the Warrants, and we do not expect a market to develop for the Preferred Stock or the Warrants. We do not intend to apply for listing of the Preferred Stock or Warrants on any securities exchange, and we do not expect that the Preferred Stock or the Warrants will be quoted on the NYSE

MKT. On August 22, 2016, the last reported sale price of our Common Stock was $0.24 per share.

We are selling the securities offered hereby directly to investors. We have retained Maxim Group LLC to act as placement agent in connection with this offering and to use its best efforts to solicit offers to purchase the Preferred Stock and the Warrants. We have agreed to pay the placement agent a cash fee equal to 8.0% of the gross proceeds of the offering. There are no minimum purchase requirements. We may not sell the entire amount of the securities being offered pursuant to this prospectus supplement. The placement agent is not purchasing or selling any securities pursuant to this offering, nor are we requiring any minimum purchase or sale of any specific number of securities. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual public offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth below. See Plan of Distribution beginning on page S-19 of this prospectus supplement for more information regarding these arrangements.

Investing in our Preferred Stock and Warrants (and the Common Stock underlying such securities) involves a high degree of risk. Before making an investment decision, please read the information under the heading Risk Factors beginning on page S-7 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

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

	Per Share(1)	Total
Public offering price	$	$
Placement agent fees(2)	$	$
Proceeds, before expenses, to us	$	$

(1) Per share price represents the offering price for one share of Preferred Stock and a Warrant to purchase shares of Common Stock. The price of a share of Preferred Stock and accompanying Warrant is times $, the conversion price per share of the Preferred Stock.

(2) In addition to the placement agent fees, we have agreed to pay up to $100,000 of the out-of-pocket fees and expenses of the placement agent in connection with this offering, which includes the fees and expenses of the placement agent s counsel. See Plan of Distribution for more information.

Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus supplement. In addition, because there is no escrow account and no minimum offering amount in this offering, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. See Risk Factors for more information.

We estimate the expenses of this offering, excluding placement agent fees, commissions and expenses of the placement agent, will be approximately $120,000.

Affiliates and associated persons of Maxim Group LLC may invest in this offering on the same terms and conditions as the public investors participating in this offering.

The placement agent expects to deliver the shares of Preferred Stock and Warrants against payment in New York, New York on or about , 2016.

Placement Agent

Maxim Group LLC

The date of this prospectus supplement is , 2016.

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PROSPECTUS SUPPLEMENT

PROSPECTUS

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus, dated July 27, 2015, are part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. This prospectus supplement and the accompanying prospectus relate to the offer by us of shares of our Preferred Stock and Warrants to certain investors. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, dated July 27, 2015, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both documents combined. If information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus supplement and the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement as our business, financial condition, results of operations and prospects may have changed since the earlier dates. You should read this prospectus supplement, the accompanying prospectus, the documents and information incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering when making your investment decision. You should also read and consider the information in the documents we have referred you to under the headings Where You Can Find More Information and Information Incorporated by Reference.

You should rely only on information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not, and Maxim Group LLC, or Maxim, has not, authorized anyone to provide you with information that is different. We are offering to sell and seeking offers to buy shares of our Preferred Stock and Warrants only in jurisdictions where offers and sales are permitted. The information contained in this prospectus supplement, the accompanying prospectus, the documents and information incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering are accurate only as of their respective dates, regardless of the time of delivery of this prospectus supplement or of any sale of our Preferred Stock and Warrants.

In this prospectus supplement, unless the context otherwise indicates, the terms Provectus, the Company, we, our a us or similar terms refer to Provectus Biopharmaceuticals, Inc., including our subsidiaries.

All references in this prospectus supplement to our financial statements include, unless the context indicates otherwise, the related notes.

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PROSPECTUS SUPPLEMENT SUMMARY

The items in the following summary are described in more detail later in this prospectus supplement and in the accompanying prospectus. This summary provides an overview of selected information and does not contain all the information you should consider before investing in our Preferred Stock and Warrants. Therefore, you should read the entire prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering carefully, including the Risk Factors section and other documents or information included or incorporated by reference in this prospectus supplement and the accompanying prospectus before making any investment decision.

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 will be published
PV-10 **Cancers of the Liver**	Orphan drug status obtained in April 2011 Phase 1 patient accrual and treatment completed

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	Phase 1 protocol expansion (Sep 2012 into 2016)
	Data communicated in 2015
	Phase 1b/2 being planned for West and East SOC
PV-10 **Breast Cancer**	Phase 1 study completed
	Further clinical development is being planned
PH-10 **Psoriasis**	Phase 2c randomized study completed and full report submitted to FDA
	Toxicity study R&D for advanced studies 2012 to 2016
PH-10 **Psoriasis (Mechanism of Action)**	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
PH-10 **Atopic Dermatitis**	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.

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 supplement or the accompanying prospectus and should not be considered part of this prospectus supplement or the accompanying prospectus.

Recent Developments

As disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 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.

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THE OFFERING

Securities Offered in This Offering	Up to shares of our Preferred Stock, par value $0.001 per share (shares of Common Stock issuable upon conversion of the Preferred Stock and payment of all dividends accrued on the Preferred Stock in an aggregate of shares of Common Stock upon conversion of the Preferred Stock).
	A Warrant to purchase shares of Common Stock will be issued for every one share of Preferred Stock sold in this offering (shares of our Common Stock issuable upon exercise of the Warrants).
Conversion	Our Preferred Stock is convertible into shares of our Common Stock at a conversion price equal to $ per share, 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 Preferred Stock is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities within 60 trading days of 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 eighty-five percent (85%) of the average of the forty-five (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) (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.
Liquidation Preference	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 any beneficial ownership limitation), 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.
Voting Rights	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.
Dividends	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, which includes 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 funds legally available for

such purpose, or in shares of Common Stock.

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	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.
Warrants We Are Offering	A Warrant to purchase shares of common stock will be issued for every one share of Preferred Stock sold in this offering (shares of our Common Stock issuable upon exercise of the Warrants). Each Warrant will have an exercise price of $ per share, will be immediately exercisable upon issuance and will expire on , 2021. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock. In addition, if the exercise price in effect on the 60th trading day following the date of issuance of the 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 Warrants and ending on the 60th trading day following the date of issuance of the Warrants (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period) (the Adjusted Exercise Price), then (i) the exercise price shall be reset to the Adjusted Exercise Price and shall be further subject to adjustment as provided in the Warrants and (ii) the number of shares of Common Stock issuable upon exercise of the Warrants shall 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 (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the Warrants. If a holder of Warrants exercises its 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 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. This prospectus supplement also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Common Stock Outstanding Immediately Before This Offering	212,829,352
Common Stock To Be Outstanding After This Offering	shares (assuming conversion of shares of Preferred Stock into shares of Common Stock and payment of all dividends accrued on the Preferred Stock in an aggregate of shares of Common Stock upon conversion of the Preferred Stock at the conversion price of $ per share and the stated value

of $ and no exercise of any of the Warrants offered hereby).

Use Of Proceeds	We estimate that our net proceeds from this offering will be approximately $, after deducting estimated placement agent fees and other estimated offering expenses payable by us (assuming no exercise of any Warrants offered hereby). We intend to use the net proceeds from this offering for clinical development, working capital and general corporate purposes. See Use of Proceeds on page S-12.
Risk Factors	You should read the Risk Factors section of this prospectus supplement and in the Risk Factors section of the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to purchase shares of our Preferred Stock and Warrants.
NYSE MKT Symbol	Our Common Stock currently trades on the NYSE MKT under the symbol PVCT. There is no established public trading market for the Preferred Stock or the Warrants, and we do not expect a market to develop for the Preferred Stock or the Warrants. We do not intend to apply for listing of the Preferred Stock or Warrants on any securities exchange.

The number of shares of Common Stock shown above to be outstanding after this offering is based on 212,829,352 shares of Common Stock outstanding as of August 22, 2016, and excludes:

- 77,874,685 shares of Common Stock issuable upon the exercise of warrants outstanding as of August 22, 2016, at a weighted average exercise price of $1.00 per share; and

- 6,800,000 shares of Common Stock issuable upon the exercise of options outstanding as of August 22, 2016, at a weighted average exercise price of $0.92 per share.

Unless otherwise stated, all information contained in this prospectus supplement assumes no exercise of the Warrants issued in this offering.

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RISK FACTORS

You should consider carefully the risks described below and discussed under the section captioned Risk Factors contained in our annual report on Form 10-K for the year ended December 31, 2015 and in our subsequent quarterly reports on Form 10-Q and annual reports on Form 10-K, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, each of which is incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety, together with other information in this prospectus supplement, the accompanying prospectus and the information and documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our securities. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our Common Stock to decline and you may lose all or part of your investment. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations.

Risks Relating to this Offering

If you purchase the Preferred Stock sold in this offering and assuming its conversion into shares of our Common Stock, you will experience immediate and substantial dilution.

Since the price per share of our Preferred Stock being offered in this offering exceeds the net tangible book value per share of our Common Stock outstanding prior to this offering, you will suffer immediate and substantial dilution with respect to the net tangible book value of the Preferred Stock you purchase in this offering, assuming conversion of the Preferred Stock into shares of our common stock. After giving effect to the sale by us all shares of Preferred Stock covered by this prospectus supplement, based on a public offering price of $ per share of Preferred Stock and accompanying Warrant (which is equal to $ per share on an as-converted-to-Common Stock basis) and deducting estimated placement agent fees and other estimated offering expenses payable by us and assuming conversion of the Preferred Stock into shares of our Common Stock and payment of all dividends accrued on the Preferred Stock in shares of Common Stock upon conversion of the Preferred Stock at the conversion price of $ per share and the stated value per share of $, you will experience immediate dilution of $ per share of Common Stock, representing the difference between our as adjusted net tangible book value per share of Common Stock as of June 30, 2016 and the public offering price. For the purpose of this calculation, the entire purchase price for the shares of Preferred Stock and accompanying Warrants is being allocated to the shares of Preferred Stock, and shares issuable upon exercise of the Warrants have not been included. If the holders of outstanding options or warrants exercise those options or warrants at prices below the public offering price, you will incur further dilution. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you participate in this offering.

Purchasers in this offering may experience additional dilution in the book value of their investment in the future.

We are not restricted from issuing additional securities in the future, including shares of Common Stock and securities that are convertible into or exchangeable for Common Stock or substantially similar securities. The issuance of these securities may cause further dilution to our stockholders. In order to raise additional capital, we may in the future offer such additional securities at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase securities in this offering. The price per share at which we sell additional shares of our Common Stock or securities convertible into or exercisable for Common Stock in future transactions may be higher or lower than the price per share in this offering.

Because our offering will be conducted on a best efforts basis, there can be no assurance that we can raise the money we need.

The placement agent is offering the securities on a best efforts basis with no minimum, and the placement agent is under no obligation to purchase any securities for its own account. The placement agent is not required to sell any specific number or dollar amount of securities in this offering but will use its best efforts to sell the securities offered in this prospectus supplement. As a best efforts offering, there can be no assurance that the offering contemplated hereby will ultimately be consummated. If the offering is not consummated or we receive less than the maximum proceeds, our business plans, including the completion of our phase 3 clinical trial of PV-10 treat locally advanced cutaneous melanoma, and prospects could be materially adversely affected.

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus supplement.

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

A continued low trading price could lead the NYSE MKT to take 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, the NYSE MKT could take action to delist our Common Stock in the event that our Common Stock trades at levels viewed as abnormally low for a substantial period of time. Our Common Stock has traded at prices less than $1.00 since November 2014. The closing price of our Common Stock on the NYSE MKT on August 22, 2016 was $0.24 per share, and the dilutive effect of this offering may result in our Common Stock trading below this price and lead NYSE MKT to suspend trading in our Common Stock.

Our management team may invest or spend the proceeds of this 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 this offering. The net proceeds from this offering will be used for clinical development, 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.

The market price of our Common Stock has been highly volatile due to several factors that will continue to affect the price of our Common Stock.

Our Common Stock has traded as low as $0.18 per share and as high as $0.99 per share during the period beginning on January 1, 2015 and ending on August 22, 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 trades on the NYSE MKT, as well as the issuance of warrants or convertible equity or debt 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 debt or 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.

There is no public market for the Preferred Stock or the Warrants being offered in this offering.

The Preferred Stock and the Warrants being issued in this offering are new issues of securities with no established trading market. The Preferred Stock and Warrants will not be listed on any securities exchange, and we do not expect the Preferred Stock or Warrants to be quoted on any quotation system. A trading market for the Preferred Stock and Warrants is not expected to develop, and even if a market develops for the Preferred Stock and Warrants, it may not provide meaningful liquidity. The absence of a trading market or liquidity for the Preferred Stock or the Warrants may adversely affect their value.

The certificate of designation for the Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price for the Preferred Stock in the future. This feature may result in an indeterminate number of shares of Common Stock being issued upon conversion of the Preferred Stock.

The certificate of designation for the Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the conversion price to the purchase price of future offerings. If, within 60 trading days following the date of issuance of the Preferred Stock, we issue Common Stock or securities convertible into or exercisable for shares of Common Stock for less than the conversion price of our Preferred Stock, we will be required to further reduce the relevant conversion price, which will result in a greater number of shares of Common Stock being issuable upon conversion, which in turn will have a greater dilutive effect on our stockholders. In addition, because there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion of the Preferred Stock. As such, it is possible that we will not have sufficient available shares of Common Stock to satisfy the conversion of the Preferred Stock if we enter into a future transaction that lowers the conversion price. If we do not have sufficient available shares of Common Stock for any Preferred Stock conversions, we will be required to increase our authorized shares, which will require stockholder approval and will be time consuming and expensive. The potential for such issuances may depress the price of our Common Stock. We may find it more difficult to raise additional equity capital while our Preferred Stock is outstanding.

The Preferred Stock provides for the payment of dividends in cash or in shares of our Common Stock, and we may not be permitted to pay such dividends in cash, which will require us to have shares of Common Stock available for issuance to pay the dividends.

Each share 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 are payable, at our discretion, in cash, out of any funds legally available for such purpose, or in shares of our Common Stock calculated based on the conversion price, subject to adjustment as provided in the certificate of designation. The conversion price is subject to reduction if, within 60 trading days after the issuance of the Preferred Stock, we issue Common Stock or securities convertible into or exchangeable or exercisable for Common Stock for less than the conversion price of our Preferred Stock. As there is no floor price on the conversion price, we cannot determine the total number of shares of Common Stock issuable upon conversion or in connection with the dividend. As such, it is possible that we will not have sufficient available shares to pay the dividend in Common Stock, which would require the payment of the dividend in cash. We will not be permitted to pay the dividend in cash unless we are legally permitted to do so under Delaware law, which requires cash to be available from surplus or net profits, neither of which we currently have available. We do not expect to have cash available to pay the dividends on our Preferred Stock, and will be relying on having available shares of Common Stock to pay such dividends, which will result in dilution to our stockholders. If we do not have available such shares of Common Stock, we may not be able to satisfy our dividend obligations.

The Warrants contain a price reset provision that may result in the reduction of the exercise price for the Warrants in the future. This feature may result in an indeterminate number of shares of Common Stock being issued upon exercise of the Warrants.

The Warrants contain a price reset provision, which provision requires the lowering of the exercise price if the exercise price in effect on the 60th trading day following the date of issuance of the 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 Warrants and ending on the 60th trading day following the date of issuance of the Warrants (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period) (the Adjusted Exercise Price). In addition, the number of shares of Common Stock issuable upon exercise of the Warrants shall 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 (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the Warrants. If a holder of Warrants exercises its 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 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 addition, because there is no floor price on the exercise price, we cannot determine the total number of shares issuable upon exercise of the Warrants. As such, it is possible that we will not have sufficient available shares of Common Stock to satisfy the exercise of the Warrants if the exercise price exceeds the Adjusted Exercise Price. If we do not have sufficient available shares of Common Stock for any Warrant exercises, we will be required to increase our authorized shares, which will require stockholder approval and will be time consuming and expensive. The potential for such issuances may depress the price of our Common Stock. We may find it more difficult to raise additional equity capital while our Warrants are outstanding.

As a result of this offering, we may be in breach of certain registration rights obligations.

As of August 23, 2016, we have outstanding obligations to register approximately 700,000 warrants to purchase shares of our Common Stock and 900,000 shares of our Common Stock issuable upon the exercise of these outstanding warrants under 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 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.

Holders of our Warrants will have no rights as a common stockholder until they acquire our Common Stock.

Until you acquire shares of our Common Stock upon exercise of your Warrants, you will have no rights with respect to our Common Stock. Upon exercise of your Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

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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.

We will be issuing Warrants to purchase shares of Common Stock as part of this offering. 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 these 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 ordinary shares and reduce the value of the shares issued to complete the business combination. Accordingly, our Warrants 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 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 Warrants are exercised, you may experience dilution to your holdings.

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 the Preferred Stock being issued in this offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, and any free writing prospectus that we have authorized for use in connection with this offering 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, believes, estimates, pre 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 in Risk Factors and in our periodic filings with the SEC, incorporated by reference or included in this prospectus supplement or the accompanying prospectus. 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 or incorporated by reference 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 and incorporated herein by reference, 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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USE OF PROCEEDS

We expect to receive approximately $ million in net proceeds from this offering. Net proceeds is what we expect to receive after paying the expenses of this offering, including the placement agent fees and the expenses, as described in Plan of Distribution below, and other estimated offering expenses payable by us, which include legal, accounting and printing fees. If a Warrant holder elects to exercise the Warrants issued in this offering, we may also receive proceeds from the exercise of the Warrants. If all of these Warrants were to be exercised at the exercise price of $ per share, then we would receive net proceeds of approximately $. We cannot predict when or if the Warrants will be exercised. It is possible that the Warrants may expire and may never be exercised.

We intend to use the net proceeds from this offering and the exercise of any Warrants for clinical development, working capital and general corporate purposes. We cannot estimate precisely the allocation of the net proceeds from this offering. The amounts and timing of the expenditures may vary significantly, depending on numerous factors. Some of these factors include the amount of cash used in our operations, progress of our clinical trials, and other development efforts, including immunology work for both our oncology and dermatology programs to determine the unique immuno-chemoablative and anti-inflammatory characteristics of our respective drug product candidates. Accordingly, our management will have broad discretion in the application of the net proceeds of this offering. Until we use the net proceeds of this offering, we intend to invest the funds in short-term, investment grade, interest-bearing securities and short-term U.S. Treasury bills.

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DILUTION

If you invest in our Preferred Stock, your interest will be diluted to the extent of the difference between the price per share of Preferred Stock you pay in this offering and the as adjusted net tangible book value per share of our Common Stock immediately after this offering (assuming the conversion of all of the Preferred Stock into shares of Common Stock). For the purpose of such calculation, the entire purchase price for the shares of Preferred Stock and accompanying Warrants is being allocated to the shares of Preferred Stock, and the shares issuable upon exercise of the accompanying Warrants have not been included. Our net tangible book value as of June 30, 2016 was approximately $6,563,138, or approximately $0.03 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.

After giving effect to the sale of shares of Preferred Stock and accompanying Warrants to purchase shares of our Common Stock in the aggregate amount of $ in this offering and deducting estimated placement agent fees and other estimated offering expenses payable by us, our net tangible book value as of June 30, 2016 would have been approximately $, or approximately $ per share of Common Stock based on shares of Common Stock outstanding on a pro forma basis at that time (assuming conversion of shares of Preferred Stock into shares of Common Stock, payment of all dividends accrued on the Preferred Stock in an aggregate of shares of Common Stock upon conversion of the Preferred Stock at the conversion price of $ per share and the stated value per share of $ and no exercise of any of the Warrants offered hereby). This represents an immediate increase in net tangible book value of $ per share to our existing stockholders and an immediate dilution of approximately $ per share to new investors participating in this offering (assuming conversion of all of the Preferred Stock into shares of Common Stock), as illustrated by the following table:

Public offering price per share of Common Stock	$	
Net tangible book value per share as of June 30, 2016 before giving effect to this offering	$	0.03
Increase in net tangible book value per share attributable to the offering	$	
Pro forma net tangible book value per share as of June 30, 2016 after giving effect to this offering	$	
Dilution in net tangible book value per share to new investors	$	

This discussion of dilution, and the table set forth above, is based on 212,829,352 shares of our Common Stock issued and outstanding as of June 30, 2016 before giving effect to this offering and shares of Common Stock issued and outstanding as of June 30, 2016 after giving effect to this offering (assuming conversion of shares of Preferred Stock into shares of Common Stock, payment of all dividends accrued on the Preferred Stock in an aggregate of shares of Common Stock upon conversion of the Preferred Stock at the conversion price of $ per share and the stated value per share of $ and no exercise of any of the Warrants offered hereby). 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 June 30, 2016:

- shares of our Common Stock issuable upon exercise of Warrants issued in this offering;
- 6,800,000 shares of our Common Stock issuable upon exercise of stock options outstanding as of June 30, 2016; and

77,874,685 shares of our Common Stock issuable upon exercise of warrants to purchase our Common Stock outstanding as of June 30, 2016.

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RATIOS OF EARNINGS TO FIXED CHARGES AND RATIOS OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED STOCK DIVIDENDS

Our ratio of earnings to combined fixed charges and preferred stock dividends for the six months ended June 30, 2016 and each of the fiscal years ended December 31, 2015, December 31, 2014, December 31, 2013, December 31, 2012 and December 31, 2011 are as follows:

	Six Months Ended June 30, 2016	December 31, 2015	December 31, 2014	December 31, 2013	December 31, 2012	December 31, 2011
Ratio of earnings to combined fixed charges and preferred stock dividends	(1)	(1)	(1)	(1)	(1)	(1)

(1) Our ratio of earnings to combined fixed charges and preferred stock dividends for the six months ended June 30, 2016 and each of the fiscal years ended December 31, 2015, December 31, 2014, December 31, 2013, December 31, 2012 and December 31, 2011 were insufficient to cover fixed charges and preferred stock dividend requirements for each period. For the six months ended June 30, 2016, earnings were insufficient to cover fixed charges and preferred stock dividend requirements by $5,052,082. For the years ended December 31, 2015, December 31, 2014, December 31, 2013, December 31, 2012, and December 31, 2011, earnings were insufficient to cover fixed charges and preferred stock dividend requirements by $24,518,340, $10,258,990, $27,713,744, $12,584,354, and $19,450,699, respectively. For each period, there were no preferred stock dividend requirements.

Our ratios of earnings to combined fixed charges and preferred stock dividends are computed by dividing earnings by the sum of fixed charges and preferred dividends. For these purposes, earnings consist of net loss plus fixed charges. Fixed charges consist of interest expense. Interest income is not included in this computation. Preferred dividends consist of the amount of pre-tax earnings required to pay dividends on the 8% convertible preferred stock and Series A 8% convertible preferred stock, which is $0. We paid dividends on the 8% convertible preferred stock and Series A 8% convertible preferred stock in shares of our common stock, other than the first dividend payment due to holders of the Series A 8% convertible preferred stock, which was paid in cash in the aggregate amount of $29,063.

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DESCRIPTION OF SECURITIES

The following description is a summary of some of the terms of our securities, our organizational documents and Delaware law. The descriptions in this prospectus supplement and the accompanying prospectus of our securities and our organizational documents do not purport to be complete and are subject to, and qualified in their entirety by reference to, our organizational documents, copies of which have been or will be filed or incorporated by reference as exhibits to the registration statement of which this prospectus supplement and the accompanying prospectus form a part. This summary supplements the description of our capital stock in the accompanying prospectus and, to the extent it is inconsistent, replaces the description in the accompanying prospectus.

In this offering, we are offering up to shares of Preferred Stock and Warrants to purchase shares of Common Stock.

Common Stock

Under our certificate of incorporation, as amended, we are authorized to issue up to 400,000,000 shares of Common Stock, par value $.001 per share. As of June 30, 2016, 212,829,352 shares of Common Stock were issued and outstanding.

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 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. Prior to the consummation of this offering, there were no shares of our preferred stock issued and outstanding.

Series B Convertible Preferred Stock Being Issued in this Offering

The following summary of certain terms and provisions of the Preferred Stock offered in this offering 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 will be attached as an exhibit to a Current Report on Form 8-K to be filed with the SEC in connection with the offering (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 $ 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.

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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 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