

OPEXA THERAPEUTICS, INC.

FORM S-1 (Securities Registration Statement)

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**OPEXA THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Texas 2834 76-0333165
(State or Other Jurisdiction of Incorporation or (Primary Standard Industrial Classification Code (I.R.S. Employer Identification Number)
Organization) Number)

2635 Technology Forest Blvd.
The Woodlands, Texas 77381
(281) 272-9331

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Neil K. Warma
President and Chief Executive Officer
OPEXA THERAPEUTICS, INC.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381
(281) 272-9331

(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: From time to time after this registration statement becomes effective, as determined by the selling shareholder.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. ☒If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐If this Form is a post-effective amendment filed pursuant to Rule 462(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. (Check one):

Large accelerated filer ☐Accelerated filer ☐Non-accelerated filer ☐Smaller reporting company ☒

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price Per Share(3)	Proposed Maximum Aggregate Offering Price(3)	Amount of Registration Fee
Common Stock, \$0.01 par value	1,702,740	\$ 1.28	\$ 2,179,507	\$ 297.28

(1)The registrant is registering for resale, from time to time, up to 1,702,740 shares of its common stock that the registrant may sell and issue to

Lincoln Park Capital Fund, LLC (or Lincoln Park) pursuant to a Purchase Agreement (or the Purchase Agreement), dated November 2, 2012, by and between Lincoln Park and the registrant relating to the sale of up to \$15,000,000 in shares of common stock of the registrant. Pursuant to Rule 416(a) under the Securities Act of 1933, the registrant is also registering hereunder an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

- (2) Represents (i) up to 1,600,000 shares that may be sold to Lincoln Park pursuant to the Purchase Agreement and (ii) up to 102,740 shares that may be issued to Lincoln Park as commitment shares on a pro rata basis as shares are sold under the Purchase Agreement.
- (3) Estimated pursuant to Rule 457(c) solely for the purpose of calculating the registration fee, based upon the average of the high and low prices for the registrant's common stock as reported on The NASDAQ Capital Market on December 21, 2012, a date within five business days of the filing of this registration statement, of \$1.28 per share.

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

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

Subject To Completion, Dated December 28, 2012

PROSPECTUS

1,702,740 Shares of Common Stock



OPEXA THERAPEUTICS, INC.

This prospectus relates to the resale, from time to time, of up to 1,702,740 shares of our common stock by Lincoln Park Capital Fund, LLC (or Lincoln Park). The shares of common stock being offered by Lincoln Park are issuable pursuant to a \$15,000,000 Purchase Agreement we entered into with Lincoln Park on November 2, 2012. See the section of this prospectus entitled “The Lincoln Park Transaction” for a description of the \$15,000,000 Purchase Agreement and the section entitled “Selling Shareholder” for additional information about Lincoln Park. Such registration does not mean that Lincoln Park will actually offer or sell any of these shares. We will not receive any proceeds from the sales of shares of our common stock by Lincoln Park; however, we may receive proceeds of up to \$15,000,000 under the Purchase Agreement.

Lincoln Park is an “underwriter” within the meaning of the Securities Act of 1933, as amended. Lincoln Park may offer the shares pursuant to this prospectus for resale in a number of different ways through public or private transactions and at varying prices. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in privately negotiated transactions. See “Plan of Distribution” for additional information.

Our common stock is traded on the NASDAQ Capital Market under the symbol “OPXA.” On December 27, 2012, the last reported sales price for our common stock was \$1.19 per share.

Investing in our securities involves a high degree of risk. See the section entitled “Risk Factors” beginning on page 9 in this prospectus and in the documents we incorporate by reference in this prospectus. You should carefully consider these risk factors, as well as the information contained in this prospectus, before you invest.

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

The date of this Prospectus is _____, 2012.

TABLE OF CONTENTS

	<u>Page</u>
About this Prospectus	ii
Prospectus Summary	1
Our Company	1
Recent Developments	4
The Offering	7
Risk Factors	8
Forward-Looking Statements	26
Use of Proceeds	27
Description of Common Stock	27
Market Price of our Common Stock and Related Stockholder Matters	28
Security Ownership of Certain Beneficial Owners and Management	29
The Lincoln Park Transaction	32
Selling Shareholder	37
Dilution	38
Plan of Distribution	38
Experts	39
Legal Matters	39
Where You Can Find More Information	40
Incorporation of Certain Information by Reference	40

ABOUT THIS PROSPECTUS

The registration statement we filed with the SEC includes exhibits that provide more detail of the matters discussed in or incorporated by reference into this prospectus. You should read this prospectus and the related exhibits filed with the SEC, together with the additional information described under the heading “Where You Can Find More Information” and “Incorporation of Certain Information by Reference,” before making your investment decision.

You should rely only on the information incorporated by reference or provided in this prospectus and the documents incorporated herein and therein by reference, or in a prospectus supplement or amendment thereto. We have not authorized anyone else to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any state where the offer or sale is not permitted. You should assume that the information in this prospectus, or incorporated by reference, is accurate only as of the dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

Unless the context otherwise requires, references in this prospectus to “Opexa,” “the Company,” “we,” “us” and “our” refer to Opexa Therapeutics, Inc. References to “Lincoln Park” or “the selling shareholder” are to Lincoln Park Capital Fund, LLC.

PRESENTATION NOTE: We implemented a 1-for-4 reverse stock split of our common stock on December 14, 2012. All share numbers and prices in this prospectus have been adjusted to reflect the reverse stock split, unless indicated otherwise.

PROSPECTUS SUMMARY

This summary contains basic information about us and this offering. Because it is a summary, it does not contain all of the information that you should consider before investing. Before you decide to invest in our common stock, you should read this entire prospectus carefully, including the section entitled “Risk Factors,” and our consolidated financial statements and the related notes and other documents incorporated by reference into this prospectus.

OUR COMPANY

Our Business

Opexa is a biopharmaceutical company developing personalized cellular therapies with the potential to treat major illnesses, including multiple sclerosis (MS). These therapies are based on our proprietary T-cell technology. The information discussed related to our product candidate is preliminary and investigative. Our product candidate has not been approved by the U.S. Food and Drug Administration (FDA) for marketing.

Our product candidate, Tcelna™ (formerly known as Tovaxin®), is a personalized T-cell therapy licensed from Baylor College of Medicine, which is in clinical development for the treatment of MS.

Opexa was incorporated in Texas in March 1991. Our principal executive offices are located at 2635 Technology Forest Blvd., The Woodlands, Texas 77381, and our telephone number is (281) 775-0600. Our website address is www.opexatherapeutics.com. The information on our website is not incorporated by reference into this prospectus and should not be relied upon with respect to this offering.

T-Cell Therapy and Tcelna™

Tcelna™ is a novel T-cell immunotherapy in Phase IIb clinical development for the treatment of patients with secondary progressive MS (SPMS). It is also positioned to enter Phase III clinical development for the treatment of patients with relapsing remitting MS (RRMS), subject to the availability of sufficient resources. Tcelna is a personalized therapy that is specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath™, our proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Initiation of Phase IIb Clinical Study in Patients with SPMS

We recently initiated a Phase IIb clinical trial of Tcelna in patients with SPMS. The trial is entitled: *A Phase II Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of Tcelna in Subjects with Secondary Progressive Multiple Sclerosis* and has been named the “Abili-T” trial. The newly-initiated Abili-T trial is a double-blind, 1:1 randomized, placebo-controlled study in SPMS patients who demonstrate evidence of disease progression without associated relapses. The trial is expected to enroll 180 patients at approximately 30 leading clinical sites in the U.S. and Canada and is expected to take approximately three years to complete. According to the study protocol, patients will receive two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the trial is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS including disease progression as measured by Expanded Disability Status Scale (EDSS), annualized relapse rate (ARR) and changes in disability as measured by EDSS and the Multiple Sclerosis Functional Composite (MSFC). The Abili-T clinical trial is expected to enroll over a 12-month period and the resulting top-line data is expected by the end of 2015.

Tcelna is the first ever personalized T-cell therapy for MS patients and has received Fast Track designation from the FDA in SPMS. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

The costs of our Phase IIb clinical study of Tcelna in SPMS, as well as the ongoing expenses of our operations through the expected completion date of such study, are estimated at approximately \$35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (*i.e.*, the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study in North America of Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to continue and complete the Phase IIb study and to support ongoing operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all.

SPMS Overview

SPMS is characterized by a steady accrual of irreversible disability, despite, in some cases, reversible relapses, remissions or clinical plateaus. Older age at onset of MS diagnosis is the strongest predictor of conversion to SPMS. Males have a shorter time to conversion to SPMS compared with females. Available immunomodulating and immunosuppressive therapies used for RRMS have not been effective in SPMS. In clinical trials, these therapies have demonstrated anti-inflammatory properties as measured by the reduction in number and volume of contrast-enhancing or acutely inflammatory central nervous system (CNS) lesions most commonly seen in patients with RRMS. The typical SPMS patient, however, has little or no radiographic evidence of acute inflammation. It is commonly observed that contrast-enhancing CNS lesions are uncommon among these patients, despite a clearly deteriorating neurologic course. The lack of effect of conventional MS therapeutics in SPMS suggests that the cerebral deterioration characterizing progressive disease may be driven by factors other than acute inflammation. For instance, the immunopathology of SPMS is more consistent with a transition to a chronic T-cell dependent inflammatory type, which may encompass the innate immune response and persistent activation of microglia cells. Radiographic features that stand out among patients with SPMS include significantly more atrophy of gray matter compared with RRMS patients. Of note, long-term disability in MS in general appears more closely correlated to gray matter atrophy than to white matter inflammation. Such atrophy may be suggestive of progressive clinical disability. Both clinically and radiographically, SPMS represents a disease process with certain features distinct from those of RRMS, and one with extremely limited treatment options.

Current Treatment Options for SPMS

Only one product, mitoxantrone, is currently approved for the indication of SPMS. However, as of 2005, this drug carries a black box warning, due to significant risks of decreased systolic function, heart failure, and leukemia. The American Academy of Neurology has issued a report indicating that these risks are even higher than suggested in the original report leading to the black box warning. Hence, a safe and effective treatment for SPMS remains a significant unmet medical need.

Tcelna Clinical Overview in SPMS

In multiple previously conducted clinical trials for the treatment of patients with MS (which have been weighted significantly toward patients with RRMS), Tcelna has demonstrated one of the safest side effect profiles for any marketed or development-stage MS therapy, as well as encouraging efficacy signals. A total of 142 MS patients have received Tcelna in previously conducted trials for RRMS and SPMS. The therapy has been well tolerated in all subjects and has demonstrated an excellent overall safety profile. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. Tcelna has been administered to a total of 36 subjects with SPMS across three previous clinical studies. Based on preliminary data suggesting stabilized or improved disability among SPMS subjects receiving Tcelna, Opexa believes that further development of this product candidate in SPMS is warranted.

Summary of TERMS Phase IIb Clinical Trial Data in RRMS

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tcelna in RRMS patients completed in 2008. Although the study did not show statistical significance in its primary endpoint (the cumulative number of gadolinium-enhanced brain lesions using MRI scans summed at various points in the study), the study showed compelling evidence of efficacy in various clinical and other MRI endpoints.

The TERMS study was a multi-center, randomized, double blind, placebo-controlled trial in 150 patients with RRMS or high risk Clinically Isolated Syndrome. Patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Key results from the TERMS trial included:

- In the modified intent to treat patient population (n=142), the ARR for Tcelna-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tcelna as compared to placebo in the general population;
- In a prospective group of patients with more active disease (ARR>1, n=50), Tcelna demonstrated a 55% reduction in ARR as compared to placebo, and a 73% reduction in relapse rate was observed in Tcelna patients in this population compared to placebo during the 24-week period following the administration of the full course of treatment; and
- In a retrospective analysis in patients naïve to previous disease modifying treatment (*i.e.*, patients who had not previously used any drug other than steroids to treat their disease), the results showed that patients, when treated with Tcelna, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

We remain committed to further advancing Tcelna in RRMS at a later date assuming the availability of sufficient resources. For Opexa, however, progressive MS is an area which we believe represents a higher unmet medical need.

Cash Position and Liquidity

As of September 30, 2012, we had cash and cash equivalents of \$2,237,618. During July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately \$4.1 million in gross proceeds (of which \$1.0 million is held in a controlled account). Our burn rate during the nine months ended September 30, 2012, inclusive of the cost of preparations to commence the Phase IIb clinical study, was approximately \$885,000 per month. We will need to raise additional capital to fund our current business plan and support our clinical trial operations. Based on our current burn rate in conjunction with our expanded clinical trial activities, we believe we have sufficient liquidity to support operations through December 2012. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our current business plan and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

Other Opportunities

Our proprietary T-cell technology has enabled us to develop intellectual property and a comprehensive sample database that may enable discovery of novel biomarkers and other relevant peptides to be used to treat MS patients.

We have developed (and, in part, in-licensed from the University of Chicago) a proprietary adult stem cell technology to produce monocyte-derived stem cells (MDSC) from blood. These MDSC can be derived from a patient's monocytes, expanded *ex vivo*, and then administered to the same patient. Our initial focus for this technology is the further development of this monocyte-derived stem cell technology as a platform for the *in vitro* generation of highly specialized cells for potential application in autologous cell therapy for patients with diabetes mellitus. The diabetes program is in an early (pre-clinical) development stage.

RECENT DEVELOPMENTS

Agreements with Lincoln Park Capital Fund, LLC

We previously entered into two purchase agreements and a registration rights agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park.

\$1,500,000 Purchase Agreement

On November 5, 2012, we entered into a purchase agreement with Lincoln Park (or the \$1,500,000 Purchase Agreement) pursuant to which Lincoln Park has agreed to purchase from us securities for gross proceeds to us of up to \$1,500,000, subject to certain limitations. Under the terms of the \$1,500,000 Purchase Agreement, we may, from time to time and at our sole discretion during a 30-month period commencing November 5, 2012, subject to the conditions of the \$1,500,000 Purchase Agreement, direct Lincoln Park to purchase shares of our common stock up to an aggregate amount of \$1,500,000. The amount we receive and the per share purchase price depends on whether the purchase is a Regular Purchase or an Accelerated Purchase. None of the shares issued or issuable to Lincoln Park under the \$1,500,000 Purchase Agreement are being offered pursuant to this prospectus.

By means of a Regular Purchase, so long as at least one business day has passed since the most recent purchase, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock at the Regular Purchase Price, increasing to amounts up to 300,000 shares of our common stock depending upon the closing sale price of our common stock. The Regular Purchase Price is the lower of (i) the lowest sale price for our common stock reported on the NASDAQ Capital Market on the purchase date of such shares or (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days immediately preceding the purchase date of such shares.

Additionally, we may direct Lincoln Park to purchase additional amounts as Accelerated Purchases if on the date of a Regular Purchase the closing sale price of our common stock equals or exceeds \$0.75. In such event, we may direct Lincoln Park to purchase on the following day, as an Accelerated Purchase and at the Accelerated Purchase Price, up to the lesser of (i) two times the number of shares for a Regular Purchase or (ii) up to 30% of the following day's volume. The Accelerated Purchase Price is the lower of (i) 95% of the volume weighted average price during (a) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the \$1,500,000 Purchase Agreement, or (b) the portion of the trading day on the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum, or (ii) the closing sale price of our common stock on the purchase date.

There is no upper limit on the price per share that Lincoln Park must pay for our common stock under the \$1,500,000 Purchase Agreement, but in no event will shares be sold to Lincoln Park under a Regular Purchase on a day our closing price is less than the adjusted minimum floor price of \$1.00 per share (effective as of our 1-for-4 reverse stock split on December 14, 2012). The Regular Purchase Price and the Accelerated Purchase Price will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute the Regular Purchase Price or Accelerated Purchase Price.

As consideration for Lincoln Park's commitment to purchase our common stock pursuant to the \$1,500,000 Purchase Agreement, we previously issued to Lincoln Park 56,507 shares of our common stock (or the Initial Commitment Shares) on November 5, 2012 as consideration for its commitment to purchase shares pursuant to the \$1,500,000 Purchase Agreement. As additional consideration to Lincoln Park, in connection with each of its purchases of shares pursuant to the \$1,500,000 Purchase Agreement, we will issue to Lincoln Park a number of shares (or Additional Commitment Shares) equal to the product of (x) 10,274 and (y) a fraction, the numerator of which is the purchase amount for the relevant shares purchased by the Lincoln Park and the denominator of which is \$1,500,000. For example, if we elect, at our sole discretion, to require Lincoln Park to purchase \$100,000 worth of our common stock, then we would issue 685 shares as a pro rata additional commitment fee, which is the product of \$100,000, the amount we have elected to sell, divided by \$1,500,000, the total amount we can sell to Lincoln Park under the \$1,500,000 Purchase Agreement, multiplied by 10,274, the maximum number of Additional Commitment Shares. The Additional Commitment Shares will only be issued pursuant to this formula if, as and when we elect to sell shares of our common stock to Lincoln Park under the \$1,500,000 Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the \$1,500,000 Purchase Agreement.

To date we have sold an aggregate of 265,000 shares to Lincoln Park pursuant to the \$1,500,000 Purchase Agreement, and we have issued an aggregate of 2,611 Additional Commitment Shares in connection therewith. Up to \$1,118,691 in shares of our common stock remain available to be sold to Lincoln Park under the \$1,500,000 Purchase Agreement, and we may issue up to 7,663 Additional Commitment Shares in connection therewith.

The \$1,500,000 Purchase Agreement limits our sales of shares of common stock to Lincoln Park to the lesser of the following (such lesser number referred to as the Maximum Share Cap): (i) the maximum number of shares of our common stock that we may issue without breaching our obligations under applicable rules of the NASDAQ Capital Market (approximately 1,151,848 shares, or 19.99% of our total outstanding common stock as of the date of the \$1,500,000 Purchase Agreement) or obtaining shareholder approval under such rules, unless the average price of all applicable sales of common stock exceed a "Base Price" (or \$3.10, representing our closing consolidated bid price on November 2, 2012, as adjusted to reflect our 1-for-4 reverse stock split effective December 14, 2012, plus an incremental amount to account for the issuance of commitment shares) such that the sales to Lincoln Park are considered to be at least "at market" under applicable NASDAQ rules, and (ii) the maximum number of shares of our common stock that we may issue without exceeding the limitations set forth in General Instruction I.B.6 of Form S-3 and the interpretive guidance of the SEC applicable to these transactions.

The \$1,500,000 Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of our common stock (currently, approximately 303,703 shares), as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder. The \$1,500,000 Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

\$15,000,000 Purchase Agreement

In addition to the \$1,500,000 Purchase Agreement, on November 2, 2012, we entered into a second purchase agreement (or the \$15,000,000 Purchase Agreement) and a Registration Rights Agreement (or the Registration Agreement) with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to \$15,000,000 in shares of our common stock subject to certain limitations from time to time over the 30-month period commencing on the date of the effectiveness of the registration statement, of which this prospectus is a part, which provides for the resale of such shares that we have filed with the SEC pursuant to the Registration Agreement. The shares issuable to Lincoln Park under the \$15,000,000 Purchase Agreement are being offered pursuant to this prospectus.

Upon the effectiveness of the registration statement, and subject to the satisfaction of the other conditions of the \$15,000,000 Purchase Agreement, we may direct Lincoln Park from time to time and at our sole discretion to purchase shares of our common stock up to an aggregate amount of \$15,000,000. The \$15,000,000 Purchase Agreement contains similar Regular Purchase and Accelerated Purchase share limitations, pricing formulas, minimum prices, aggregate share volume and other terms and conditions as in the \$1,500,000 Purchase Agreement discussed above, except that (i) the limitations set forth in General Instruction I.B.6 of Form S-3 are not applicable to the \$15,000,000 Purchase Agreement and (ii) the \$15,000,000 Purchase Agreement prohibits us from directing Lincoln Park to purchase any shares if those shares, when aggregated with all other shares of our common stock then beneficially owned, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock (currently, approximately 608,015 shares).

As consideration for Lincoln Park's commitment to purchase our common stock pursuant to the \$15,000,000 Purchase Agreement, we will issue a number of shares (or Commitment Shares) equal to the product of (x) 102,740 shares and (y) a fraction, the numerator of which is the purchase amount for the relevant shares purchased by Lincoln Park and the denominator of which is \$15,000,000. The 102,740 Commitment Shares are also covered by this prospectus.

The proceeds received by us under the \$15,000,000 Purchase Agreement are expected to be used for working capital and general corporate purposes as described further in this prospectus.

Although the \$15,000,000 Purchase Agreement provides that we may sell up to \$15,000,000 in shares of our common stock to Lincoln Park, only 1,702,740 shares are being offered under this prospectus, which represents (i) up to 1,600,000 shares that we may sell and issue to Lincoln Park from time to time in the future pursuant to the \$15,000,000 Purchase Agreement after the registration statement of which this prospectus forms a part is declared effective, and (ii) up to 102,740 shares as Commitment Shares we are obligated to issue to Lincoln Park in the future pro rata as shares are sold under the \$15,000,000 Purchase Agreement. This aggregate number of shares may or may not cover all of such shares to be purchased by and issued to Lincoln Park under the \$15,000,000 Purchase Agreement, depending on the purchase price per share. We have agreed to register the maximum number of shares that may be issuable to Lincoln Park under the \$15,000,000 Purchase Agreement, and, in the event the initial registration statement is insufficient to cover all of the shares issuable under the \$15,000,000 Purchase Agreement, to amend the initial registration statement or file a new registration statement so as to cover all of the shares potentially issuable.

As of December 28, 2012, there were 6,086,240 shares of our common stock issued and outstanding, of which 5,274,842 shares were held by non-affiliates. If all of the 1,702,740 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof (without taking into account the 19.99% shareholder approval limitation), such shares would represent approximately 28% of the total common stock outstanding and approximately 32% of the total number of outstanding shares held by non-affiliates.

The actual number of shares to be purchased by Lincoln Park under the \$15,000,000 Purchase Agreement is variable, depending on the market price of our common stock at the time of each sale. Accordingly, we cannot predict the actual total number of shares to be issued to Lincoln Park. This prospectus covers 1,702,740 shares of common stock. As of the date hereof, we do not currently have any plans or intent to issue to Lincoln Park any shares pursuant to the \$15,000,000 Purchase Agreement beyond the 1,702,740 shares offered hereby. However, if we elect to issue and sell to Lincoln Park pursuant to the \$15,000,000 Purchase Agreement more than the 1,702,740 shares offered under this prospectus, which we have the right but not the obligation to do, up to the \$15,000,000 maximum in shares of our common stock, we would first be required to register for resale under the Securities Act any additional shares we may elect to sell to Lincoln Park before we can sell such additional shares, which could cause additional substantial dilution to our shareholders. The number of shares issued pursuant to the \$15,000,000 Purchase Agreement and ultimately offered for resale by Lincoln Park depends on the number of shares purchased by Lincoln Park under the \$15,000,000 Purchase Agreement.

There are substantial risks to our shareholders as a result of the sale and issuance of common stock to Lincoln Park under the \$15,000,000 Purchase Agreement. These risks include substantial dilution, significant declines in our stock price and our inability to draw sufficient funds when needed. See "Risk Factors." Issuance of our common stock to Lincoln Park under the \$15,000,000 Purchase Agreement will not affect the rights or privileges of our existing shareholders, except that the economic and voting interests of our existing shareholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing shareholders own will not decrease, the shares owned by our existing shareholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

THE OFFERING

Common stock offered by selling shareholder	Up to 1,702,740 shares of common stock
Common stock outstanding before this offering	6,086,240 shares of common stock
Common stock outstanding after this offering	7,788,980 shares of common stock
Selling shareholder	Lincoln Park Capital Fund, LLC. See “Selling Shareholder” on page 38 of this prospectus.
Use of proceeds	We will not receive any proceeds from the sales of shares of our common stock by Lincoln Park; however, we may receive proceeds of up to \$15,000,000 under the Purchase Agreement for the sale of such shares to Lincoln Park. Such proceeds will be used for general corporate purposes, including activities related to further clinical development of Tcelna and the Phase IIb study in patients with SPMS, and for other working capital and operational purposes. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the Phase IIb study (<i>i.e.</i> , the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial. See “Use of Proceeds” on page 27 of this prospectus.
Risk factors	See the “Risk Factors” section beginning on page 9 of this prospectus for factors to consider before deciding to purchase our securities.
NASDAQ Capital Market Symbol	OPXA

Except as otherwise specifically indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes or gives effect to no exercise of options or warrants outstanding on the date of this prospectus or in the future.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider the following risk factors, as well as other information contained or incorporated by reference in this prospectus, before deciding to invest in our common stock. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we currently consider immaterial may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Business

We will be required to raise significant additional capital, or secure a development partner, in the near-term, and our ability to obtain funding is uncertain. If sufficient capital is not available, we may not be able to continue our operations as proposed (including any Phase IIb clinical trial initiated or ongoing for Tcelna), which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

As of September 30, 2012, we had cash and cash equivalents of \$2,237,618. During July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately \$4.1 million in gross proceeds (of which \$1.0 million is held in a controlled account). Our current burn rate, inclusive of the cost of preparations to commence the Phase IIb clinical study, during the first nine months of 2012 was approximately \$885,000 per month. We believe we have sufficient liquidity to support our current clinical trial activities through December 2012. The Phase IIb clinical study of Tcelna in patients with SPMS is expected to involve 180 patients and take approximately three years to complete. The costs of the study, as well as the ongoing expenses of our operations through the expected completion date of such study, are estimated at approximately \$35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (i.e., the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study for Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to continue and complete the Phase IIb study and to support our operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

Assuming we are able to achieve financing which is sufficient to support the Phase IIb study of Tcelna in SPMS and to support our operations during the pendency of such study, we are also exploring a pivotal Phase III clinical study of Tcelna in RRMS. Any such study of Tcelna in RRMS would also depend upon the availability of sufficient resources.

Other than the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement with Lincoln Park, each of which is subject to certain limitations and conditions (see “Recent Developments – Agreements with Lincoln Park Capital Fund, LLC – \$1,500,000 Purchase Agreement” and “– \$15,000,000 Purchase Agreement”), we have no sources of debt or equity capital committed for funding and we must rely upon best efforts third-party debt or equity funding. We can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;

- the accuracy of the assumptions underlying our estimates for capital needs in 2012 and beyond as well as for the clinical study of Tcelna
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

If we raise additional funds through any collaboration, partnering or licensing arrangements with third parties, we may need to relinquish some rights to our product candidate Tcelna, including commercialization rights, which may harm our ability to generate revenues and achieve or sustain profitability.

If we raise additional funds by issuing equity securities (including pursuant to the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement with Lincoln Park), stockholders may experience substantial dilution. Debt financing, if available, may involve restrictive covenants that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. There is no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations.

If we are unable to obtain additional funding or secure a development partner, we may not be able to continue or complete the Phase IIB clinical study of Tcelna in SPMS or otherwise continue our operations as proposed, which may require us to modify our business plan or curtail various aspects of our operations. If these measures are not sufficient to maintain an adequate level of capital, it may be necessary to cease operations or seek relief under applicable bankruptcy laws. In such event, our stockholders may lose a portion or even all of their investment.

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

Our unaudited consolidated financial statements at September 30, 2012 and for the nine-month period then ended were prepared assuming that we will continue as a going concern, meaning that we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of September 30, 2012, we had cash and cash equivalents of \$2,237,618. We do not currently generate commercial revenues, and our burn rate during the nine months ended September 30, 2012, inclusive of the cost of preparations to commence the Phase IIB clinical study of Tcelna in SPMS, was approximately \$885,000 per month, thereby creating substantial doubt in the absence of significant additional funding about our ability to continue as a going concern. This may make it more difficult for us to raise funds. If we are unable to obtain additional financing for our operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, investors may lose a portion or all of their investment. Our consolidated financial statements contain no adjustment for the outcome of this uncertainty.

Funding from our purchase agreements with Lincoln Park may be limited or be insufficient to fund our operations or to implement our strategy.

Under our purchase agreements with Lincoln Park, we may direct Lincoln Park to purchase up to \$1,500,000 of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of the registration statement for resale of the shares offered by this prospectus, and subject to other conditions, we also may direct Lincoln Park to purchase up to \$15,000,000 of our shares of common stock over a 30-month period. Prior to the date of this prospectus, we sold an aggregate of 265,000 shares to Lincoln Park pursuant to the \$1,500,000 Purchase Agreement, and we issued an aggregate of 59,119 Initial Commitment Shares and Additional Commitment Shares in connection therewith. There can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us, including that the closing price of our stock is at least \$1.00 and that Lincoln Park own no more than 4.99% of our common stock under the \$1,500,000 Purchase Agreement or no more than 9.99% of our common stock under the \$15,000,000 Purchase Agreement. In addition, under the applicable rules of the NASDAQ Capital Market, if we seek to issue shares which may be aggregated with shares sold to Lincoln Park under the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement in excess of 1,151,848 shares or 19.99% of the total common stock outstanding as of the date of the \$15,000,000 Purchase Agreement, we may be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

The extent to which we rely on Lincoln Park as a source of funding will depend on a number of factors, including the amount of working capital needed, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we would need to secure another source of funding. Even if we sell all \$16,500,000 of common stock under the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement with Lincoln Park, we will still need additional capital to fully implement our current business, operating plans and development plans, including to complete the Phase IIB clinical study of Tcelna in patients with SPMS and to conduct our operations through the expected completion date of such study.

We have a history of operating losses and do not expect to be profitable in the foreseeable future.

We have not generated any profits since our entry into the biotechnology business and we have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future. We have not received, and we do not expect to receive for at least the next several years, any revenues from the commercialization of any potential products. We do not currently have any sources of revenues and may not have any in the foreseeable future.

Our business is at an early stage of development. We are largely dependent on the success of our product candidate, Tcelna, and we cannot be certain that Tcelna will receive regulatory approval or be successfully commercialized.

Our business is at an early stage of development. We do not have any product candidates that have completed late-stage clinical trials nor do we have any products on the market. We have only one product candidate, Tcelna, which has progressed to the stage of being studied in human clinical trials in the United States. We recently initiated a Phase IIB study of Tcelna in patients with SPMS. We are still in the very early stages of identifying and conducting research on any other potential products. Tcelna, and any other potential products, will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, to obtain regulatory approvals, to continue clinical development of Tcelna, to enter clinical trials (or any development activities) for any other product candidates or to commercialize any products. Tcelna, and any other potential products, may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We might be unable to service our current debt due to a lack of cash flow or otherwise fail to comply with terms of the convertible secured promissory notes or related agreements and might be subject to default. The convertible secured promissory notes are secured by a pledge of all of our assets. The antidilution adjustments applicable to the securities ultimately issuable upon conversion of these secured notes, as well as the antidilution adjustments of the warrants issued in tandem with the notes, could result in significant dilution to existing shareholders based upon any sale of shares under our purchase agreements with Lincoln Park.

On July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase shares of common stock which generated approximately \$4.1 million in gross proceeds (\$1.0 million of which is held in a controlled account). The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually in either cash or registered shares of common stock at our election. The notes are secured by substantially all of our assets and are convertible into a new class of non-voting Series A convertible preferred stock. The notes can be converted into Series A convertible preferred stock at the option of the investors at a price of \$100.00 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the notes into Series A convertible preferred stock if (i) our common stock closes at or above \$10.00 per share for 20 consecutive trading days or (ii) we achieve certain additional funding milestones to continue our clinical trial program. These milestones include (x) executing a strategic agreement with a partner or potential partner by which we will receive a minimum of \$5 million to partially fund, or an option to partner with us for, our Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of \$25 million in additional capital (including the note offering proceeds) from any partner, potential partner or any other source. The Series A convertible preferred stock accrues dividends at the rate of 8% per annum, which are cumulative and payable semi-annually in either cash or registered shares of the common stock at our election. The Series A convertible preferred stock is convertible into shares of our common stock at the option of the holders at a price of \$3.1225 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the Series A convertible preferred stock into common stock if our common stock closes at or above \$16.00 per share for 20 consecutive trading days. No shares of Series A convertible preferred stock are currently outstanding. The warrants have an exercise price of \$2.56 per share, a five-year term and are exercisable for 112.5% of the number of shares of common stock into which the initial principal amount of the notes is ultimately convertible, subject to certain limitations and adjustments. The warrants are exercisable after six months from the date of issuance. We can redeem the warrants at \$0.01 per share if our common stock closes at or above \$10.00 per share for 20 consecutive trading days. As part of the security interest in all of our assets granted to the noteholders, \$1.0 million of the proceeds is maintained in a controlled account. The noteholders were granted certain registration rights for the shares of underlying common stock.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach other terms of the convertible secured notes or related agreements, the noteholders could elect to declare all amounts outstanding, together with accrued and unpaid interest, to be immediately due and payable. Even if we were able to prepay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, the noteholders will have a first claim on our assets pledged under the convertible secured notes. If the noteholders should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the convertible secured notes and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

As a result of antidilution adjustments since the closing of the July 2012 financing: (i) up to 1,308,236 shares of common stock are issuable if all 12% convertible secured promissory notes issued in the July 2012 financing are converted to Series A convertible preferred stock and such stock is then converted into common stock; and (ii) the warrants issued to the purchasers of the 12% convertible secured promissory notes in the July 2012 financing are exercisable at an adjusted exercise price of \$2.56 per share for an aggregate of 1,436,121 shares of common stock.

We will depend on strategic collaborations with third parties to develop and commercialize product candidates, such as Tcelna, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

A key aspect of our strategy, including with respect to Tcelna, is to seek collaboration with a partner, such as a large pharmaceutical organization, that is willing to further develop and commercialize a selected product candidate. To date, we have not entered into any such collaborative arrangement with respect to Tcelna. However, we will need to raise significant additional capital in order to continue and complete the Phase IIb clinical study of Tcelna in SPMS as the total costs of conducting this study, as well as the ongoing expenses of our operations through the expected completion date of such study, are estimated at approximately \$35 million.

By entering into any such strategic collaboration, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture or obtain the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into collaboration, including with respect to Tcelna, on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting a partner and entering into collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate, including Tcelna. In particular, we may be unable to continue or complete the Phase IIb clinical study of Tcelna in SPMS. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

Third parties to whom we may license or transfer development and commercialization rights for products covered by intellectual property rights may not be successful in their efforts, and as a result, we may not receive future royalty or other milestone payments relating to those products or rights.

We will need regulatory approvals for any product candidate, including Tcelna, prior to introduction to the market, which will require successful testing in clinical trials. Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement. Any product candidate, such as Tcelna, may fail to achieve necessary safety and efficacy endpoints during clinical trials in which case we will be unable to generate revenue from the commercialization and sale of our products.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous FDA requirements, and must otherwise comply with federal, state and local requirements and policies of the medical institutions where they are conducted. The clinical trial process is also time-consuming. We estimate that the Phase IIb clinical trial in North America of our lead product candidate, Tcelna, in SPMS will take approximately three years to complete. In addition, we anticipate that a pivotal Phase III clinical trial would be necessary before we could submit an application for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and we could encounter problems that cause us to be unable to initiate a trial, or to abandon or repeat a clinical trial.

The commencement and completion of clinical trials, including the continuation and completion of the Phase IIb clinical trial of Tcelna in SPMS, may be delayed or prevented by several factors, including:

- FDA or IRB objection to proposed protocols;
- discussions or disagreement with the FDA over the adequacy of trial design to potentially demonstrate effectiveness, and subsequent design modifications;
- unforeseen safety issues;
- determination of dosing issues and related adjustments;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- product quality problems (e.g., sterility or purity);
- challenges to patient monitoring and data collection during or after treatment (for example, patients' failure to return for follow-up visits and
- failure of medical investigators to follow our clinical protocols.

In addition, we or the FDA (based on its authority over clinical studies) may delay a proposed investigation or suspend clinical trials in progress at any time if it appears that the study may pose significant risks to the study participants or other serious deficiencies are identified. Prior to approval of our product the FDA must determine that the data demonstrate safety and effectiveness. The large majority of drug candidates that begin human clinical trials fail to demonstrate the desired safety and efficacy characteristics.

Furthermore, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols, or otherwise modify our intended course of clinical development, to reflect these changes. This, too, may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even if we obtain regulatory approvals for any product candidate, such as Tcelna, that approval may be subject to limitations on the indicated uses for which it may be marketed. Our ability to generate revenues from the commercialization and sale of any potential products will be limited by any failure to obtain or limitation on necessary regulatory approvals.

We will rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize any product candidate, including Tcelna.

Although we have participated in the design and management of our past clinical trials, we do not have the ability to conduct clinical trials directly for any product candidate, including Tcelna. We will need to rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis.

Our clinical trials may be delayed, suspended or terminated if:

- any third party upon whom we rely does not successfully carry out its contractual duties or regulatory obligations or meet expected deadlines;
- any such third party needs to be replaced; or
- the quality or accuracy of the data obtained by the third party is compromised due to its failure to adhere to clinical protocols or regulatory requirements or for other reasons.

Failure to perform by any third party upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of any product candidate, including Tcelna. While we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.

We have targeted MS as the first disease to be pursued off our T-cell platform technology. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. Minimal work has been done outside the lead MS indication. Our business over the long term is substantially dependent on our ability to develop, license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to expand our existing platform or identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

Moreover, any product candidate acquisition that we do complete will involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new potential markets or technologies;
- inability to generate sufficient funding to offset acquisition costs; and
- delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

We are dependent upon our management team and a small number of employees.

Our business strategy is dependent upon the skills and knowledge of our management team. If any critical employee leaves, we may be unable on a timely basis to hire suitable replacements to operate our business effectively. We also operate with a very small number of employees and thus have little or no backup capability for their activities. The loss of the services of any member of our management team or the loss of just a few other employees could have a material adverse effect on our business and results of operations.

If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.

Our business depends on licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations diligently to pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform could be adversely affected.

Our current research and manufacturing facility is not large enough to manufacture product candidates, such as Tcelna, for certain clinical trials or, if such clinical trials are successful, commercial applications.

We conduct our research and development in a 10,200 square foot facility in The Woodlands, Texas, which includes an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our current facility should have the capacity to support full clinical development of Tcelna in North American trials for SPMS. It is not sufficient, however, to support clinical trials outside North America including Europe and Asia, if required, or the commercial launch of Tcelna. In this case, we would need to expand our manufacturing staff and facility, obtain a new facility or contract with corporate collaborators or other third parties to assist with future drug production and commercialization.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We do not have funds available for building a manufacturing facility, and we may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our commercial-scale manufacturing.

We may arrange with third parties for the manufacture of our future products, if any. However, our third-party sourcing strategy may not result in a cost-effective means for manufacturing our future products. If we employ third-party manufacturers, we will not control many aspects of the manufacturing process, including compliance by these third parties with cGMP and other regulatory requirements. We further may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

If any product we may eventually have is not accepted by the market or if users of any such product are unable to obtain adequate coverage of and reimbursement for such product from government and other third-party payors, our revenues and profitability will suffer.

Our ability to successfully commercialize any product we may eventually have will depend in significant part on the extent to which appropriate coverage of and reimbursement for such product and any related treatments are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider any product we may eventually have cost-effective or provide coverage of and reimbursement for such product, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that any product we may eventually have is less safe, less clinically effective, or less cost-effective than existing products, and third-party payors may not approve such product for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for any product we may eventually have from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of any such product would cause sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of any such product profitable.

In addition, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for any product we may eventually have. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, the use of formularies. The market for any product we may eventually have depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

Any product candidate that we develop, such as Tcelna, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

Even if a product candidate, such as Tcelna, is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, and our profitability and growth, will depend on a number of factors, including:

- demonstration of efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC and The NASDAQ Stock Market (NASDAQ). Changes in the laws and regulations affecting public companies, including the provisions of SOX and rules adopted by the SEC and by NASDAQ, have resulted in, and will continue to result in, increased costs to us as we respond to their requirements. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to conclude an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Under the corporate governance standards of NASDAQ, a majority of our Board of Directors and each member of our Audit Committee must be an independent director. If any vacancies on our Board or our Audit Committee occur that need to be filled by independent directors, we may encounter difficulty in attracting qualified persons to serve on our Board and, in particular, our Audit Committee. If we fail to attract and retain the required number of independent directors, we may be subject to SEC enforcement proceedings and delisting of our common stock from the NASDAQ Capital Market.

Risks Related to Our Intellectual Property

Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products, such as Tcelna.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make or use our potential products, such as Tcelna, and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop any affected product candidate, such as Tcelna, commercially. There can be no assurance that we will not be obliged to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

If we are unable to obtain patent protection and other proprietary rights, our operations will be significantly harmed.

Our ability to compete effectively is dependent upon obtaining patent protection relating to our technologies. The patent positions of pharmaceutical and biotechnology companies, including ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced before or after the patent is issued. Consequently, we do not know whether pending patent applications for our technology will result in the issuance of patents, or if any issued patents will provide significant protection or commercial advantage or will be circumvented by others. Since patent applications are secret until the applications are published (usually 18 months after the earliest effective filing date), and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that the inventors of our owned or licensed intellectual property rights were the first to make the inventions at issue or that any patent applications at issue were the first to be filed for such inventions. There can be no assurance that patents will issue from pending patent applications or, if issued, that such patents will be of commercial benefit to us, afford us adequate protection from competing products, or not be challenged or declared invalid.

For our licensed intellectual property, we have limited control over the amount or timing of resources that are devoted to the prosecution of such intellectual property. Due to this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any licensed patents will result from licensed applications or, if they do, that they will be maintained. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we do not maintain control over the payment of annuities, we cannot assure you that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of product candidates, such as Tcelna, involves complex legal and factual questions. To the extent that it would be necessary or advantageous for any of our licensors to cooperate or lead in the enforcement of our licensed intellectual property rights, we cannot control the amount or timing of resources such licensors devote on our behalf or the priority they place on enforcing such rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them, or our underlying licenses.

We cannot be certain that any of the patents issued to us or to our licensors will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates such as Tcelna;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights (owned or licensed) is uncertain. For example:

- we or our licensor might not have been the first to make the inventions covered by pending patent applications or issued patents owned by or licensed to, us;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of the technologies owned by, or licensed to, us;
- it is possible that none of the pending patent applications owned by, or licensed to, us will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws; or
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

We rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, T-cells, and other technologies potentially relevant to or required by our product candidate Tcelna. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware of a number of patent applications and patents claiming use of modified cells to treat disease, disorder or injury.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, such as Tcelna, or their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. If our product candidates, such as Tcelna, or their methods of manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to Tcelna. Consequently, no assurance can be given that third-party patents containing claims covering Tcelna, its method of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potentially treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or
- significant cost and expense, as well as distraction of our management from our business.

As a result, we could be prevented from commercializing current or future product candidates.

Risks Related to Our Industry

We are subject to stringent regulation of our product candidates, such as Tcelna, which could delay development and commercialization.

We, our third-party contractors, suppliers and partners, and our product candidates, such as Tcelna, are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. No product candidate of ours has been approved, and we may never receive FDA approval for any product candidate. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce our ability to generate revenues.

In addition, both before and after regulatory approval, we, our partners and our product candidates, such as Tcelna, are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates, such as Tcelna. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs resulted in the enactment of legislation addressing drug safety issues, the FDA Amendments Act of 2007. This legislation provides the FDA with expanded authority over drug products after approval and the FDA's exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Approval by the FDA does not automatically lead to the approval of authorities outside of the United States and, similarly, approval by other regulatory authorities outside the United States will not automatically lead to FDA approval. In addition, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our product candidates, such as Tcelna, may not be approved for all indications that we request, which would limit uses and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which any potential product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

We may need to change our business practices to comply with health care fraud and abuse regulations, and our failure to comply with such laws could adversely affect our business, financial condition and results of operations.

If we are successful in achieving approval to market one or more of our product candidates, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

If our operations are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.

Competition in the pharmaceutical industry, particularly the market for MS products, is intense, and we expect such competition to continue to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies. These companies have significantly greater capital resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing than we currently do. However, smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. In addition to the competitors with existing products that have been approved, many of our competitors are further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or further product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

Our competitors may also develop alternative therapies that could further limit the market for any products that we may develop.

Rapid technological change could make our products obsolete.

Biopharmaceutical technologies have undergone rapid and significant change, and we expect that they will continue to do so. As a result, there is significant risk that our product candidates, such as Tcelna, may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates, such as Tcelna, are rendered obsolete by advancements in biopharmaceutical technologies, our future prospects will suffer.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products.

In the event that any of our product candidates becomes an approved product and is commercialized, consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We have insurance that covers clinical trial activities. We believe our current insurance coverage is reasonably adequate at this time. However, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if any product candidate is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our products.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of reform that could affect our business is drug reimportation into the United States (i.e., the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices). Initiatives in this regard could decrease the price we or any potential collaborators receive for our product candidates if they are ever approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or adversely affect our ability to raise capital or to obtain strategic partnerships or licenses.

Risks Related to Our Securities and This Offering

There is currently a limited market for our securities, and any trading market that exists in our securities may be highly illiquid and may not reflect the underlying value of our net assets or business prospects.

Although our common stock and Series E warrants are traded on the NASDAQ Capital Market, there is currently a limited market for our securities and there can be no assurance that an active market will ever develop. Investors are cautioned not to rely on the possibility that an active trading market may develop.

Our stock may be delisted from NASDAQ, which could affect its market price and liquidity.

We are required to meet certain qualitative and financial tests (including a minimum stockholders' equity requirement of \$2.5 million and bid price for our common stock of \$1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market, and our common stock is in jeopardy of being delisted. During portions of 2008 and 2009, our stockholders' equity was below the continued listing standard requirement of \$2.5 million and the bid price for our common stock was below \$1.00 per share for periods of time, and our common stock was in jeopardy of being delisted. During 2010, the trading price of our common stock was minimally above \$1.00 per share for brief periods of time. During 2011, the trading price of our common stock was minimally above and below \$1.00 per share for periods of time, and our stock closed below \$1.00 per share from December 2011 through December 2012. In February 2012, we received a staff deficiency letter from NASDAQ indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the \$1.00 minimum closing bid price for 30 consecutive trading days. The notice further stated that we would be provided a period of 180 calendar days to regain compliance. In August 2012, we requested an additional 180-day grace period to regain compliance with NASDAQ's minimum bid price requirement because our stock has continued to trade below the \$1.00 minimum closing bid price subsequent to receiving the NASDAQ staff deficiency letter. NASDAQ granted our extension request and we now have until February 4, 2013 to achieve compliance with this listing standard (i.e., by our common stock maintaining a closing bid price of \$1.00 per share or more for a minimum of 10 consecutive business days during the additional grace period, or such longer period of time as the NASDAQ staff may require). At the November 15, 2012 annual meeting of shareholders, our shareholders approved a proposal to implement a reverse stock split of the common stock and our Board of Directors implemented the reverse stock split at the ratio of 1-for-4 on December 14, 2012. Our common stock has closed above the \$1.00 minimum closing bid price since it started trading on a split-adjusted basis on December 17, 2012; however, there can be no assurance that the reverse stock split will have the desired effect of raising the closing bid price of our common stock to meet the NASDAQ minimum bid price requirement, or if it does, that the closing bid price will continue to stay above the minimum continued listing standard.

On November 26, 2012, we received a letter from NASDAQ notifying us that the stockholders' equity of \$2,339,285 as reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2012 was below the minimum stockholders' equity of \$2,500,000 required for continued listing on NASDAQ. We have been provided 45 calendar days, or until January 10, 2013, to submit a plan to regain compliance with the minimum stockholders' equity standard. If our plan to regain compliance is accepted, NASDAQ may grant an extension of up to 180 calendar days from the date of the notification letter, or until May 25, 2013, to evidence compliance with the minimum stockholders' equity standard.

While we are exercising diligent efforts to maintain the listing of our common stock on NASDAQ, and intend to timely provide NASDAQ with our plan to regain compliance with the minimum stockholders' equity standard, there can be no assurance that the plan will be accepted or that if it is we will be able to regain compliance. If our plan to regain compliance is not accepted or if it is and we do not regain compliance by May 25, 2013, or if we fail to satisfy another NASDAQ requirement for continued listing, NASDAQ staff could provide notice that our common stock will become subject to delisting. In such event, NASDAQ rules permit us to appeal the decision to reject our proposed compliance plan or any delisting determination to a NASDAQ Hearings Panel.

It is also possible that we could fail to satisfy another NASDAQ requirement for continued listing of our stock, such as market value or number of publicly held shares or number of shareholders, or a corporate governance requirement. We may receive additional future notices from NASDAQ that we have failed to meet its requirements, and proceedings to delist our stock could be commenced. If we are unable to regain compliance in a timely manner or if we do not meet the other listing standards and our common stock is delisted, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

As our share price is volatile, and you may not be able to resell our shares at a profit or at all.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of any drug candidates, such as Tcelna, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques;
- regulatory developments in the United States and in foreign countries; or
- dilutive effects of sales of shares of common stock by us or our shareholders, including Lincoln Park pursuant to this prospectus, and sale of common stock acquired upon exercise or conversion by the holders of warrants, options or convertible notes.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

We may be or become the target of securities litigation, which is costly and time-consuming to defend.

In the past, following periods of market volatility in the price of a company's securities or the reporting of unfavorable news, security holders have often instituted class action litigation. If the market value of our securities experience adverse fluctuations and we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer.

Our "blank check" preferred stock could be issued to prevent a business combination not desired by management or our current majority stockholders.

Our articles of incorporation authorize the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined by our Board of Directors without stockholder approval. Our preferred stock could be utilized as a method of discouraging, delaying, or preventing a change in our control and as a method of preventing stockholders from receiving a premium for their shares in connection with a change of control.

Future sales of our common stock in the public market could lower our stock price.

During 2011, we sold (i) an aggregate of 96,190 shares of common stock in January pursuant to an "at the market" continuous offering program and (ii) an aggregate of 1,036,625 shares of our common stock, and warrants to acquire another 414,650 shares, in a public offering in February. In November and December 2012, we sold 265,000 shares to Lincoln Park pursuant to the \$1,500,000 Purchase Agreement and issued an additional 59,119 shares as Initial Commitment Shares and Additional Commitment Shares. Sales of a substantial number of additional shares of our common stock in the public market could cause the market price of our common stock to decline. An aggregate of 6,086,240 shares of common stock were outstanding as of December 28, 2012. As of such date, excluding the impact of the antidilution adjustments described below, another (i) 826,556 shares were issuable upon exercise of outstanding options, (ii) 3,579,109 shares of common stock were issuable upon the exercise of outstanding warrants, and (iii) 1,308,236 shares were issuable if all outstanding 12% convertible secured promissory notes were converted to Series A convertible preferred stock which was then ultimately converted into common stock.

A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of 1933. We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. Among other requirements, we will need to raise significant additional capital, or secure a partnering arrangement, in order to continue and complete the Phase IIb clinical study of Tcelna in SPMS, and this may require us to issue a substantial amount of securities (including common stock as well as securities convertible into or exercisable for common stock). We cannot predict the size of future issuances of our common stock, as well as securities convertible into or exercisable for common stock, or the effect, if any, that future issuances and sales of our securities will have on the market price of our common stock. Sales of substantial amounts of our common stock, as well as securities convertible into or exercisable for common stock, including shares issued in connection with an acquisition or securing funds to complete our clinical trial plans, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Under the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement with Lincoln Park, we may direct Lincoln Park to purchase up to \$1,500,000 of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of the registration statement for resale of the shares offered by this prospectus, and subject to other conditions, we may also direct Lincoln Park to purchase up to \$15,000,000 of our shares of common stock over a 30-month period. We have sold an aggregate of 265,000 shares under the \$1,500,000 Purchase Agreement as of the date of this prospectus. Additionally, we issued Lincoln Park 56,507 shares of common stock as Initial Commitment Shares and have issued an aggregate of 2,611 Additional Commitment Shares as of the date of this prospectus, and may in the future issue up to an additional 110,402 shares of common stock as Additional Commitment Shares, as a fee for its commitment to purchase the shares under the \$1,500,000 Purchase Agreement and the \$15,000,000 Purchase Agreement. The number of shares ultimately offered for sale by Lincoln Park under this prospectus is dependent upon the number of shares purchased by Lincoln Park under the \$15,000,000 Purchase Agreement. Depending on market liquidity at the time, sales of shares we issue to Lincoln Park may cause the trading price of our common stock to decline.

Subject to certain conditions, we generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the market price of our common stock is below \$1.00 per share or if Lincoln Park would own more than 4.99% of our common stock for stock sold to it under the \$1,500,000 Purchase Agreement or 9.99% of our common stock for stock sold to it under the \$15,000,000 Purchase Agreement. The purchase price for the shares that we may sell to Lincoln Park will fluctuate based on the price of our common stock and other factors determined by us. As such, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock offered pursuant to this prospectus and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us pursuant to either or both of the purchase agreements could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could cause the trading price of our common stock to decline and could make it more difficult for us to sell equity or equity-related securities in the future.

We presently do not intend to pay cash dividends on our common stock.

We currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 10,000,000 shares of preferred stock. In connection with the July 25, 2012 convertible note financing, 80,000 shares of preferred stock were designated as non-voting Series A convertible preferred stock. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering and dilution to our stockholders could result. We may sell shares or other securities in any other offering at a price per share that is less 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. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

For example, on July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately \$4.1 million in gross proceeds. The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually, payable in either cash or registered shares of common stock. The notes are secured by substantially all of our tangible and intangible assets, and \$1.0 million of the proceeds from the note offering is being held in a controlled account as part of the security interest granted to the noteholders. The notes are convertible into a new class of non-voting Series A convertible preferred stock at a conversion price of \$100.00, subject to certain limitations and adjustments. The Series A convertible preferred stock accrues cumulative dividends at the rate of 8% per annum, payable in either cash or registered shares of common stock, and carries a \$100.00 per share liquidation preference. The Series A convertible preferred stock is convertible into common stock at a conversion price of \$3.1225, subject to certain limitations and adjustments. As a result of antidilution adjustments since the closing of the July 2012 financing: (i) up to 1,308,236 shares of common stock are issuable if all 12% convertible secured promissory notes issued in the July 2012 financing are converted to Series A convertible preferred stock and such stock is then converted into common stock; and (ii) the warrants issued to the purchasers of the 12% convertible secured promissory notes in the July 2012 financing are exercisable at an adjusted exercise price of \$2.56 per share for an aggregate of 1,436,121 shares of common stock.

Our management has significant flexibility in using the net proceeds of this offering.

In addition to general corporate purposes (including working capital and operational purposes), we currently intend to use the net proceeds from the sale of the common stock that we may sell to Lincoln Park under the purchase agreements from time to time which is offered by this prospectus to continue the Phase IIb clinical study of Tcelna in SPMS. The Phase IIb clinical study in North America of Tcelna is expected to involve 180 patients and take approximately three years to complete. The costs of the study, as well as the ongoing expenses of our operations through the expected completion date of the study, are estimated at approximately \$35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (i.e., the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial.

Depending on future developments and circumstances, we may use some of our available cash for other purposes. Notwithstanding our current intention to use our available cash for further clinical studies of Tcelna, our management will have significant flexibility in using our current available cash. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount and timing of cash used in our operations and our research and development efforts. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

You may experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock 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 shares of common stock in this offering at the current market value, 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 offering.

FORWARD-LOOKING STATEMENTS

When used in this prospectus and the documents incorporated by referenced in this prospectus, the words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements in this prospectus under the headings "Our Company" and "Risk Factors." These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, costs, returns, royalties, performance and position, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, management's initiatives and strategies, and the development of the Company's product candidate, Tcelna, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, but are not limited to, those risks discussed in "Risk Factors," as well as, without limitation, risks associated with: our capital position; the rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); our ability to enter into and benefit from a partnering arrangement for our product candidate, Tcelna, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tcelna; our ability to compete with larger, better financed pharmaceutical and biotechnology companies; new approaches to the treatment of our targeted diseases; our expectation of incurring continued losses; our uncertainty of developing a marketable product; our ability to raise additional capital to continue our development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna), including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock); our ability to regain and maintain compliance with NASDAQ listing standards; the success of our clinical trials; the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS; our ability to develop and commercialize products; our ability to obtain required regulatory approvals; our compliance with all Food and Drug Administration regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna); the risk of litigation regarding our intellectual property rights or the rights of third parties; the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer; our limited manufacturing capabilities; our dependence on third-party manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

USE OF PROCEEDS

We will not receive any proceeds from the sales of shares of our common stock by Lincoln Park; however, we may receive proceeds of up to \$15,000,000 under the \$15,000,000 Purchase Agreement over the 30-month period following the effective date of the registration statement of which this prospectus is a part assuming that we sell all of the shares available thereunder and excluding the cost of the shares issued to Lincoln Park for its commitment. However, there can be no assurance we will sell any or all of the shares to Lincoln Park or that they will resell such shares offered hereby. Because there is no minimum offering amount required, we may sell less than all of the shares offered hereby, which may significantly reduce the amount of proceeds received by us.

We currently intend to use such proceeds for general corporate purposes, including activities related to further clinical development of Tcelna and the Phase IIb study in patients with SPMS, and for other working capital and operational purposes. General corporate purposes may include additions to working capital, financing of capital expenditures, repayment or redemption of existing indebtedness, and future acquisitions and strategic investment opportunities, although we have no current commitments for any such acquisition or investment. Our management will retain broad discretion as to the allocation of the net proceeds from this offering.

The Phase IIb clinical study in North America of Tcelna is expected to involve 180 patients and take approximately three years to complete. The costs of the study, as well as the ongoing expenses of our operations through the expected completion date of the study, are estimated at approximately \$35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (i.e., the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial.

As of September 30, 2012, we had cash and cash equivalents of \$2,237,618. During July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately \$4.1 million in gross proceeds (of which \$1.0 million is held in a controlled account). Our burn rate during the nine months ended September 30, 2012, inclusive of the cost of preparations to commence the Phase IIb clinical study, was approximately \$885,000 per month. We will need to raise additional capital to fund our current business plan and support our clinical trial operations. Based on our current burn rate in conjunction with our expanded clinical trial activities, we believe we have sufficient liquidity to support operations through December 2012. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our current business plan and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study for Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to continue and complete the Phase IIb study and to support our operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all.

Until we use the net proceeds of this offering, we intend to invest the funds in short-term, interest bearing investments.

DESCRIPTION OF COMMON STOCK

This section describes the general terms and provisions of the shares of our common stock, \$0.01 par value. This description is only a summary and is qualified in its entirety by reference to the description of our common stock incorporated by reference in this prospectus. Our restated certificate of formation and our amended and restated bylaws have been filed as exhibits to our periodic reports filed with the SEC, which are incorporated by reference in this prospectus. You should read our restated certificate of formation and our amended and restated bylaws for additional information before you buy any of our common stock or other securities. See “Where You Can Find More Information.”

We have 100,000,000 shares of authorized common stock. As of December 28, 2012, there were 6,086,240 shares of common stock issued and outstanding. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of formation. This means that the holders of a majority of the shares voted can elect all of the directors then standing for election. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of assets legally available at the times and in the amounts that our board of directors may determine from time to time. Upon our liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any outstanding preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock offered, when issued, will be fully paid and nonassessable.

Certain Provisions of our Charter and Bylaws

Certain provisions of our restated certificate of formation and our amended and restated bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us. Our restated certificate of formation and amended and restated bylaws provided that:

- Our board of directors is authorized to issue preferred stock without shareholder approval; and
- We will indemnify officers and directors against losses that they may incur in investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

Transfer Agent

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the NASDAQ Capital Market under the symbol “OPXA.” Our common stock has, from time to time, traded on a limited, sporadic and volatile basis. The table below shows the high and low sales prices for our common stock for the periods indicated, as reported by NASDAQ.

	Price Ranges	
	High ⁽¹⁾	Low ⁽¹⁾
<i>Fiscal Year Ended December 31, 2012 to date</i>		
First Quarter	\$ 4.60	\$ 2.80
Second Quarter	3.04	1.21
Third Quarter	3.48	1.16
<i>Fiscal Year Ended December 31, 2011</i>		
First Quarter	\$ 11.96	\$ 5.68
Second Quarter	9.20	6.00
Third Quarter	7.00	4.44
Fourth Quarter	6.12	3.56
<i>Fiscal Year Ended December 31, 2010</i>		
First Quarter	\$ 11.44	\$ 7.28
Second Quarter	12.28	5.72
Third Quarter	8.40	4.08
Fourth Quarter	6.64	5.16

⁽¹⁾ We implemented a 1-for-4 reverse stock split on December 14, 2012. The high and low prices in the table reflect the impact of the reverse stock split for all periods shown in the table.

The closing price of our common stock on December 27, 2012 was \$1.19 per share. We implemented a 1-for-4 reverse stock split of our common stock on December 14, 2012. There are approximately 250 holders of record of our common stock, excluding shareholders for whom shares are held in “nominee” or “street name.”

Dividends

We have never declared or paid any cash dividends on our common stock and we do not intend to pay cash dividends in the foreseeable future. We currently expect to retain any future earnings to fund the operation and expansion of our business.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of December 28, 2012, the number and percentage of outstanding shares of our common stock beneficially owned by: (a) each person who is known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock; (b) each of our directors; (c) the named executive officers; and (d) all current directors and executive officers, as a group. As of December 28, 2012, there were 6,086,240 shares of common stock issued and outstanding. All numbers in the table and the footnotes thereto have been adjusted to reflect the 1-for-4 reverse stock split of our common stock that was implemented December 14, 2012.

Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. Under this rule, certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire shares (for example, upon exercise of an option or warrant) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares is deemed to include the amount of shares beneficially owned by such person by reason of such acquisition rights. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person’s actual voting power at any particular date.

To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.

Beneficial Ownership Table

Name and Address of Beneficial Owner ⁽¹⁾	Number of Shares Owned	Percentage of Class
Beneficial Owners of more than 5%:		
Albert and Margaret Alkek Foundation ⁽²⁾	624,960 ⁽³⁾	9.9%
Alkek & Williams Ventures Ltd. ⁽⁴⁾	642,235 ⁽⁵⁾	9.9%
DLD Family Investments, LLC ⁽⁶⁾	603,180 ⁽⁷⁾	9.3%
Charles E. Sheedy ⁽⁸⁾	479,621 ⁽⁹⁾	7.6%
Visium Balanced Master Fund Ltd. ⁽¹⁰⁾	352,946 ⁽¹¹⁾	5.8%
Officers and Directors:		
Scott B. Seaman ⁽⁴⁾	523,652 ⁽¹²⁾	8.2%
David E. Jorden	399,334 ⁽¹³⁾	6.4%
Neil K. Warma	176,196 ⁽¹⁴⁾	2.8%
Donna R. Rill	57,585 ⁽¹⁵⁾	*
Michael S. Richman	41,910 ⁽¹⁶⁾	*
Jaye L. Thompson	21,816 ⁽¹⁷⁾	*
Gail J. Maderis	10,589 ⁽¹⁸⁾	*
All directors and executive officers as a group (7 persons)**	1,231,082 ⁽¹⁹⁾	17.9%

* Less than 1%

** Includes only current directors and officers serving in such capacity as of the date of the table.

(1) Unless otherwise indicated in the footnotes, the mailing address of the beneficial owner is c/o Opexa Therapeutics, Inc., 2635 Technology Forest Boulevard, The Woodlands, Texas 77381.

(2) This information is based on the Schedule 13D/A filed with the SEC on August 23, 2012, by Albert and Margaret Alkek Foundation (or the Foundation), Alkek & Williams Ventures, Ltd. (or Ventures), Scott Seaman, DLD Family Investments, LLC (or DLD Family), and the other reporting persons named therein (or the Foundation 13D) and other information available to us. The Foundation acts through an investment committee of its board of directors, which includes Mr. Charles Williams, Mr. Daniel Arnold, Mr. Joe Bailey, Mr. Scott Seaman and Ms. Randa Duncan Williams. Mr. Seaman is the executive director of the Foundation and chairman of the investment committee. The investment committee has sole voting and investment power over all of the shares of common stock beneficially owned by the Foundation. However, pursuant to the Foundation 13D, neither the executive director nor any member of the investment committee may act individually to vote or sell shares of common stock held by the Foundation; therefore, the Foundation has concluded that no individual committee member is deemed to beneficially own, within the meaning of Rule 13d-3 of the Exchange Act, any shares of common stock held by the Foundation solely by virtue of the fact that he or she is a member of the investment committee. Additionally, pursuant to the Foundation 13D, the Foundation has concluded that because Mr. Seaman, in his capacity as executive director or chairman of the investment committee, cannot act

in such capacity to vote or sell shares of common stock held by the Foundation without the approval of the investment committee, he is not deemed to beneficially own, within the meaning of Rule 13d-3 of the Exchange Act, any shares of common stock held by the Foundation by virtue of his position as executive director or chairman of the investment committee. The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

- (3) Consisting of: (i) 358,241 shares of common stock; (ii) 5,000 shares of common stock underlying Series E warrants; (iii) 62,500 shares of common stock underlying Series G warrants; (iv) 93,750 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; and (v) 105,469 shares of common stock underlying Series I warrants. Pursuant to the Foundation 13D, the Foundation and other reporting persons named therein may be deemed to constitute a group for purposes of Section 13(d) or Section 13(g) of the Exchange Act. However, the Foundation, Ventures, Chaswil, Ltd. and Mr. Seaman expressly disclaim (i) that, for purposes of Section 13(d) or Section 13(g) of the Exchange Act, they are a member of a group with respect to securities of Opexa held by DLD Family, Mr. Arnold, Mr. Bailey or Ms. Williams and (ii) that they have agreed to act together with DLD Family, Mr. Arnold, Mr. Bailey or Ms. Williams as a group other than as described in the Foundation 13D. Therefore, this does not include the following securities: (i) 201,148 shares of common stock held by DLD Family; (ii) 25,000 shares of common stock underlying Series E warrants held by DLD Family; (iii) 25,000 shares of common stock underlying Series G warrants held by DLD Family; (iv) 20,000 shares of common stock underlying Series H warrants held by DLD Family; (v) 156,250 shares of common stock issuable if a 12% convertible secured promissory note held by DLD Family was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (vi) 175,781 shares of common stock underlying Series I warrants held by DLD Family; (vii) 6,667 shares of common stock held by Mr. Arnold; (viii) 12,500 shares of common stock held by Mr. Bailey; (ix) 210,204 shares of common stock held by Ventures; (x) 50,000 shares of common stock underlying Series E warrants held by Ventures; (xi) 50,000 shares of common stock underlying Series G warrants held by Ventures; (xii) 156,250 shares of common stock issuable if a 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (xiii) 175,781 shares of common stock underlying Series I warrants held by Ventures; (xiv) 10,914 shares of common stock held by Mr. Seaman; (xv) 2,500 shares of common stock underlying Series E warrants held by Mr. Seaman; and (xvi) 43,785 shares of common stock underlying currently exercisable stock options held by Mr. Seaman.
- (4) Chaswil, Ltd. is the investment manager of Ventures and holds voting power and investment power with respect to Company securities held by Ventures pursuant to a written agreement. Scott B. Seaman is a principal of Chaswil, Ltd. and has shared voting power and shared investment power over all of the shares of common stock beneficially owned by Ventures. The information in this footnote is primarily based on the Foundation 13D and other information provided to us. The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.
- (5) Consisting of: (i) 210,204 shares of common stock; (ii) 50,000 shares of common stock underlying Series E warrants; (iii) 50,000 shares of common stock underlying Series G warrants; (iv) 156,250 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; and (v) 175,781 shares of common stock underlying Series I warrants.
- (6) Randa Duncan Williams is the principal of DLD Family and she may be deemed to exercise voting and investment power with respect to such shares. The information in this footnote is primarily based on the Foundation 13D and other information provided to us. The mailing address of the beneficial owner is P.O. Box 4735, Houston, Texas 77210-4735.

- (7) Consisting of: (i) 201,148 shares of common stock; (ii) 25,000 shares of common stock underlying Series E warrants; (iii) 25,000 shares of common stock underlying Series G warrants; (iv) 20,000 shares of common stock underlying Series H warrants; (v) 156,250 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; and (vi) 175,781 shares of common stock underlying Series I warrants.
- (8) Charles E. Sheedy exercises sole voting and dispositive power over all of the shares of common stock beneficially owned. The information in this footnote is primarily based on information reported on the Schedule 13G/A filed with the SEC on February 11, 2011 by Charles E. Sheedy and other information available to us. The mailing address of the beneficial owner is 909 Fannin Street, Suite 2907, Houston, Texas 77010.
- (9) Consisting of: (i) 249,606 shares of common stock; (ii) 37,500 shares of common stock underlying Series E warrants; (iii) 12,500 shares of common stock underlying Series G warrants; (iv) 14,000 shares of common stock underlying Series H warrants; (v) 78,125 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; and (vi) 87,891 shares of common stock underlying Series I warrants.
- (10) This information is based on the Schedule 13G filed with the SEC on February 10, 2012, by Visium Balanced Master Fund, Ltd. (or Visium), Visium Asset Management, LP (or VAM), JG Asset, LLC (or JGA), and Jacob Gottlieb (or the Visium 13G) and other information available to us. Pursuant to the Visium 13G, (i) as investment manager to the pooled investment funds, VAM may be deemed to beneficially own the shares beneficially owned by the funds, (ii) as general partner to VAM, JGA may be deemed to beneficially own the shares beneficially owned by VAM, and (iii) as managing member of JGA, Mr. Gottlieb may be deemed the beneficial owner of the shares beneficially owned by JGA, and he has sole voting and dispositive power over the shares. VAM, JGA and Mr. Gottlieb disclaim beneficial ownership of the securities, except to the extent of his or its pecuniary interest therein. The mailing address of the beneficial owner is 950 Third Avenue, New York, NY 10022.
- (11) Consisting of: (i) 304,946 shares of common stock and (ii) 48,000 shares of common stock underlying Series H warrants.
- (12) Consisting of: (i) 210,204 shares of common stock held by Ventures; (ii) 50,000 shares of common stock underlying Series E warrants held by Ventures; (iii) 50,000 shares of common stock underlying Series G warrants held by Ventures; (iv) 156,250 shares of common stock issuable if the 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 175,781 shares of common stock underlying Series I warrants held by Ventures; (vi) 43,785 shares underlying currently exercisable stock options held by Mr. Seaman; (vii) 2,500 shares of common stock underlying Series E warrants held by Mr. Seaman; and (viii) 10,914 shares of common stock held by Mr. Seaman. (See footnotes 4 and 5 for additional discussion of the information set forth in clauses (i) through (v) of the preceding sentence.) Pursuant to the Foundation 13D, this does not include the following shares which Mr. Seaman has determined he does not have beneficial ownership of or has disclaimed beneficial ownership: (i) 358,241 shares of common stock held by the Foundation; (ii) 5,000 shares of common stock underlying Series E warrants held by the Foundation; (iii) 62,500 shares of common stock underlying Series G warrants held by the Foundation; (iv) 93,750 shares of common stock issuable if the 12% convertible secured promissory note held by the Foundation was converted to Series A convertible preferred stock which was then ultimately converted into common stock; and (v) 105,469 shares of common stock underlying Series I warrants held by the Foundation. (See footnotes 2 and 3 for additional discussion of the information set forth in clauses (i) through (v) of the preceding sentence.) The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.
- (13) Consisting of: (i) 222,500 shares of common stock; (ii) 36,250 shares of common stock underlying Series E warrants; (iii) 25,000 shares of common stock underlying Series G warrants; (iv) 35,938 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 40,430 shares of common stock underlying Series I warrants; and (vi) 39,217 shares of common stock underlying currently exercisable stock options.

- (14) Consisting of: (i) 222,500 shares of common stock; (ii) 36,250 shares of common stock underlying Series E warrants; (iii) 25,000 shares of common stock underlying Series G warrants; (iv) 35,938 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 40,430 shares of common stock underlying Series I warrants; and (vi) 39,217 shares of common stock underlying currently exercisable stock options.
- (15) Consisting of: (i) 403 shares of common stock and (ii) 57,182 shares of common stock underlying currently exercisable stock options.
- (16) Consisting of: 41,910 shares of common stock underlying currently exercisable stock options.
- (17) Consisting of: (i) 1,078 shares of common stock and (ii) 20,738 shares of common stock underlying currently exercisable stock options.
- (18) Consisting of: 10,589 shares of common stock underlying currently exercisable stock options.
- (19) Consisting of: (a) the following held by Mr. Seaman or for which Mr. Seaman may be deemed to have voting and investment power: (i) 210,204 shares of common stock held by Ventures; (ii) 50,000 shares of common stock underlying Series E warrants held by Ventures; (iii) 50,000 shares of common stock underlying Series G warrants held by Ventures; (iv) 156,250 shares of common stock issuable if the 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 175,781 shares of common stock underlying Series I warrants held by Ventures; (vi) 43,785 shares underlying currently exercisable stock options held by Mr. Seaman; (vii) 2,500 shares of common stock underlying Series E warrants held by Mr. Seaman; and (viii) 10,914 shares of common stock held by Mr. Seaman; (b) the following held by Mr. Jorden: (i) 222,500 shares of common stock; (ii) 36,250 shares of common stock underlying Series E warrants; (iii) 25,000 shares of common stock underlying Series G warrants; (iv) 35,938 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 40,430 shares of common stock underlying Series I warrants; and (vi) 39,217 shares of common stock underlying currently exercisable stock options; (c) the following held by Mr. Warma: (i) 222,500 shares of common stock; (ii) 36,250 shares of common stock underlying Series E warrants; (iii) 25,000 shares of common stock underlying Series G warrants; (iv) 35,938 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 40,430 shares of common stock underlying Series I warrants; and (vi) 39,217 shares of common stock underlying currently exercisable stock options; (d) 403 shares of common stock and 57,182 shares of common stock underlying currently exercisable stock options held by Ms. Rill; (e) 41,910 shares of common stock underlying currently exercisable stock options held by Mr. Richman; (f) 1,078 shares of common stock and 20,738 shares of common stock underlying currently exercisable stock options held by Dr. Thompson; and (g) 10,589 shares of common stock underlying currently exercisable stock options held by Ms. Maderis.

THE LINCOLN PARK TRANSACTION

General

On November 2, 2012, we entered into the \$15,000,000 Purchase Agreement, together with a Registration Rights Agreement, with Lincoln Park Capital Fund, LLC (or Lincoln Park). Pursuant to the terms of the \$15,000,000 Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 in shares of our common stock, subject to certain limitations. Under the terms of the \$15,000,000 Purchase Agreement, we may, from time to time and at our sole discretion during a 30-month period commencing on the date of the effectiveness of the registration statement of which this prospectus is a part, subject to the conditions of the \$15,000,000 Purchase Agreement, direct Lincoln Park to purchase shares of our common stock up to an aggregate amount of \$15,000,000. The amount we receive and the per share purchase price depends on whether the purchase is a Regular Purchase or an Accelerated Purchase. An aggregate of 1,702,740 shares issuable to Lincoln Park under the \$15,000,000 Purchase Agreement are being offered pursuant to this prospectus. The proceeds received by us under the \$15,000,000 Purchase Agreement are expected to be used for working capital and general corporate purposes as described further in this prospectus.

Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act shares of common stock that may be issued and sold to Lincoln Park under the \$15,000,000 Purchase Agreement. Although the \$15,000,000 Purchase Agreement provides that we may sell up to \$15,000,000 in shares of our common stock to Lincoln Park, only 1,702,740 shares are being offered under this prospectus, which represents (i) up to 1,600,000 shares that we may sell and issue to Lincoln Park from time to time in the future pursuant to the \$15,000,000 Purchase Agreement after the registration statement of which this prospectus forms a part is declared effective, and (ii) up to 102,740 shares as Commitment Shares we are obligated to issue to Lincoln Park in the future pro rata as shares are sold under the \$15,000,000 Purchase Agreement.

We cannot predict the actual total number of shares to be issued to Lincoln Park. The aggregate number of shares offered under this prospectus may or may not cover all of such shares to be purchased by and issued to Lincoln Park under the \$15,000,000 Purchase Agreement, depending on the purchase price per share. We have agreed to register the maximum number of shares that may be issuable to Lincoln Park under the \$15,000,000 Purchase Agreement, and, in the event the initial registration statement is insufficient to cover all of the shares issuable under the \$15,000,000 Purchase Agreement, to amend the initial registration statement or file a new registration statement so as to cover all of the shares potentially issuable. As of the date hereof, we do not currently have any plans or intent to issue to Lincoln Park any shares pursuant to the \$15,000,000 Purchase Agreement beyond the 1,702,740 shares offered hereby. If we elect to issue and sell to Lincoln Park pursuant to the \$15,000,000 Purchase Agreement more than the 1,702,740 shares offered under this prospectus, up to the \$15,000,000 maximum, we would first be required to register for resale under the Securities Act such additional shares, which could cause substantial additional dilution to our stockholders.

Purchase of Shares under the \$15,000,000 Purchase Agreement

By means of a Regular Purchase, so long as at least one business day has passed since the most recent purchase, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock at the Regular Purchase Price, increasing to amounts up to 300,000 shares of our common stock depending upon the closing sale price of our common stock. The Regular Purchase Price is the lower of:

- the lowest sale price for our common stock reported on the NASDAQ Capital Market on the purchase date of such shares or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days immediately preceding the purchase date of such shares.

Additionally, we may direct Lincoln Park to purchase additional amounts as Accelerated Purchases if on the date of a Regular Purchase the closing sale price of our common stock equals or exceeds \$0.75. In such event, we may direct Lincoln Park to purchase on the following day, as an Accelerated Purchase and at the Accelerated Purchase Price, up to the lesser of:

- two times the number of shares for a Regular Purchase or
- up to 30% of the following day's volume.

The Accelerated Purchase Price is the lower of:

- 95% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the \$15,000,000 Purchase Agreement, or (ii) the portion of the trading day on the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum, or
- the closing sale price of our common stock on the purchase date.

There is no upper limit on the price per share that Lincoln Park must pay for our common stock under the \$15,000,000 Purchase Agreement, but in no event will shares be sold to Lincoln Park under a Regular Purchase on a day our closing price is less than the adjusted minimum floor price of \$1.00 per share (effective as of our 1-for-4 reverse stock split on December 14, 2012). The Regular Purchase Price and the Accelerated Purchase Price will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute the Regular Purchase Price or Accelerated Purchase Price.

The \$15,000,000 Purchase Agreement limits our sales of shares of common stock to Lincoln Park to the maximum number of shares of our common stock that we may issue without breaching our obligations under applicable rules of the NASDAQ Capital Market (approximately 1,151,848 shares, or 19.99% of our total outstanding common stock as of the date of the \$15,000,000 Purchase Agreement) or obtaining shareholder approval under such rules, unless the average price of all applicable sales of common stock exceed a "Base Price" (or \$3.10, representing our closing consolidated bid price on November 2, 2012, as adjusted to reflect our 1-for-4 reverse stock split effective December 14, 2012, plus an incremental amount to account for the issuance of commitment shares) such that the sales to Lincoln Park are considered to be at least "at market" under applicable NASDAQ rules.

The \$15,000,000 Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock (currently, approximately 608,015 shares), as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder.

Other than as set forth above, there are no trading volume requirements or restrictions under the \$15,000,000 Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. Generally, each time we direct Lincoln Park, subject to the terms of the \$15,000,000 Purchase Agreement, Lincoln Park will be obligated to purchase such amounts as directed by us. Lincoln Park does not have the right to require us to sell any shares of common stock to them under the \$15,000,000 Purchase Agreement. We have no obligation to sell any shares under the \$15,000,000 Purchase Agreement and the actual proceeds that we receive from sales to Lincoln Park could be substantially less than the maximum \$15,000,000.

Commitment Shares

As consideration for Lincoln Park's commitment to purchase our common stock pursuant to the \$15,000,000 Purchase Agreement, in connection with each of its purchases of shares pursuant to the \$15,000,000 Purchase Agreement, we will issue to Lincoln Park a number of shares (or Commitment Shares) equal to the product of (x) 102,740 and (y) a fraction, the numerator of which is the purchase amount for the relevant shares purchased by the Lincoln Park and the denominator of which is \$15,000,000. For example, if we elect, at our sole discretion, to require Lincoln Park to purchase \$100,000 worth of our common stock, then we would issue 685 shares as a pro rata additional commitment fee, which is the product of \$100,000, the amount we have elected to sell, divided by \$15,000,000, the total amount we can sell to Lincoln Park under the \$15,000,000 Purchase Agreement, multiplied by 102,740, the maximum number of Commitment Shares. The Commitment Shares will only be issued pursuant to this formula if, as and when we elect to sell shares of our common stock to Lincoln Park under the \$15,000,000 Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the \$15,000,000 Purchase Agreement.

Effect of Performance of the \$15,000,000 Purchase Agreement on Our Shareholders

All shares of common stock that are covered by this prospectus are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 30 months from the date of this prospectus. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Lincoln Park may ultimately acquire all, some or none of the shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Lincoln Park by us under the \$15,000,000 Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the \$15,000,000 Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

As of December 28, 2012, there were 6,086,240 shares of our common stock issued and outstanding, of which 5,274,842 shares were held by non-affiliates. If all of the 1,702,740 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof (without taking into account the 19.99% shareholder approval limitation), such shares would represent approximately 28% of the total common stock outstanding and approximately 32% of the total number of outstanding shares held by non-affiliates.

The number of shares ultimately offered for resale by Lincoln Park will be dependent upon the number of shares we sell to Lincoln Park under the \$15,000,000 Purchase Agreement. The following table shows the amount of proceeds we would receive from Lincoln Park from the sale of shares pursuant to the \$15,000,000 Purchase Agreement (without accounting for certain fees and expenses), to the extent covered by this prospectus, based on varying assumed average purchase prices:

Assumed Average Purchase Price	Number of Registered Shares to be Issued if Full Purchase ⁽¹⁾⁽⁴⁾	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park ⁽²⁾⁽⁴⁾	Proceeds from the Sale of Shares to Lincoln Park Under the \$15,000,000 Purchase Agreement
\$1.00 ⁽³⁾	1,600,000	20.54%	\$ 1,600,000
\$1.50	1,600,000	20.54%	\$ 2,400,000
\$2.00	1,600,000	20.54%	\$ 3,200,000
\$2.50	1,600,000	20.54%	\$ 4,000,000

⁽¹⁾ Excludes the 102,740 shares to be issued as Commitment Shares. Although the \$15,000,000 Purchase Agreement provides that we may sell up to \$15,000,000 in shares of our common stock to Lincoln Park, we are only registering 1,600,000 shares to be purchased thereunder, which may or may not cover all of such shares purchased by them under the \$15,000,000 Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares which are registered in this offering.

⁽²⁾ The denominator is based on 6,086,240 shares outstanding as of December 28, 2012, adjusted to include the 102,740 shares to be issued as Commitment Shares, and the number of shares set forth in the adjacent column which we would have sold to Lincoln Park. The numerator is based on the number of shares issuable under the \$15,000,000 Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

⁽³⁾ Under the \$15,000,000 Purchase Agreement, we may not sell any shares to Lincoln Park in the event the purchase price of such shares is below \$1.00.

⁽⁴⁾ If we seek to issue shares, including shares from other transactions but not included in this offering that may be aggregated with this transaction under the applicable rules of the NASDAQ Capital Market, in excess of 1,151,848 or 19.99% of the total common stock outstanding as of the date of the \$15,000,000 Purchase Agreement, we may be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

There are substantial risks to our shareholders as a result of the sale and issuance of common stock to Lincoln Park under the \$15,000,000 Purchase Agreement. These risks include substantial dilution, significant declines in our stock price and our inability to draw sufficient funds when needed. See “Risk Factors.” Issuances of our common stock to Lincoln Park under the \$15,000,000 Purchase Agreement will not affect the rights or privileges of our existing shareholders, except that the economic and voting interests of our existing shareholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing shareholders own will not decrease, the shares owned by our existing shareholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

Representations and Warranties; Indemnification

The \$15,000,000 Purchase Agreement includes customary representations and warranties by us to Lincoln Park. In addition, we have agreed to customary indemnification of Lincoln Park in connection with the \$15,000,000 Purchase Agreement.

Events of Default

Pursuant to the \$15,000,000 Purchase Agreement, we cannot sell any shares of common stock to Lincoln Park if an event of default has occurred. Lincoln Park does not have the right to terminate the \$15,000,000 Purchase Agreement upon any of the events of default set forth below. The following events constitute events of default under the \$15,000,000 Purchase Agreement, all of which are outside the control of Lincoln Park:

- the effectiveness of the registration statement, of which this prospectus is a part, lapses for any reason (including, without limitation, the issuance of a stop order), or this prospectus is unavailable for sale by us or the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of three consecutive business days;

- the de-listing of our common stock from the NASDAQ Capital Market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, NYSE MKT, the NASDAQ Global Market, the NASDAQ Global Select Market, the NYSE ARCA or the OTC Bulletin Board (or nationally recognized successor thereto);
- the transfer agent's failure for five business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the \$15,000,000 Purchase Agreement;
- any breach of the representations or warranties or covenants contained in the \$15,000,000 Purchase Agreement or any related agreements which has a material adverse effect on us;
- any participation in insolvency or bankruptcy proceedings by or against us;
- our common stock is not eligible to be transferred electronically; or
- if we reach the share limit to the extent applicable under the NASDAQ Capital Market rules, and we have not obtained any necessary shareholder approval.

We may suspend the sale of shares to Lincoln Park pursuant to this prospectus for certain periods of time for certain reasons, including if this prospectus is required to be supplemented or amended to include additional material information.

Termination of \$15,000,000 Purchase Agreement; No Assignment

We have the unconditional right at any time for any reason to give notice to Lincoln Park terminating the \$15,000,000 Purchase Agreement without any cost to us.

In addition, the \$15,000,000 Purchase Agreement will terminate as follows:

- if any insolvency or bankruptcy proceedings are instituted by or against us;
- if the registration statement has not been declared effective by April 30, 2013, then the non-breaching party shall have the option to terminate this \$15,000,000 Purchase Agreement;
- upon our selling the full \$15,000,000 in shares of common stock to Lincoln Park; and
- on the first day of the month immediately following the 30-month anniversary of the date that sales commence under the \$15,000,000 Purchase Agreement (i.e., after the registration statement has been declared effective).

Lincoln Park may not assign or transfer its rights and obligations under the \$15,000,000 Purchase Agreement.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that any time prior to the termination of the \$15,000,000 Purchase Agreement neither it nor any of its affiliates shall engage in or enter into, directly or indirectly, any short-sale of our common stock or any hedging transaction that establishes a net short position in our common stock.

No Variable Rate Transactions

We have agreed with Lincoln Park that we will not enter into any "variable rate transaction" with a third party until the expiration of the 30-month period following the commencement of sales under the \$15,000,000 Purchase Agreement. A "variable rate" transaction means any of the following transactions by us in which we enter into, or issue securities under, any "at-the-market" or similar agreement, including, but not limited to, an equity line of credit, whereby we may sell securities at a future determine price.

The prohibition on “variable rate transactions” does not apply to, and we are not restricted from entering into, the following exempt issuance transactions:

- if we issue shares of common stock under the “at-the-market” agreement that was in effect as of the date we entered into the \$15,000,000 Purchase Agreement, as it may be amended from time to time, with a third party broker so long as, for the 90-day period following November 2, 2012, we do not issue shares under such agreement that aggregate in excess of \$2.0 million in shares of our common stock during any consecutive 20 business day period, or
- if we issue common stock equivalents with conversion, exercise prices or amounts which may adjust based upon future events (including without limitation, in instances involving the issuance of securities for a purchase price which is less than any such conversion or exercise price prior to adjustment).

SELLING SHAREHOLDER

The shares of common stock offered under this prospectus may be sold from time to time for the account of Lincoln Park, the selling shareholder listed below. Lincoln Park is not a licensed broker-dealer or an affiliate of a licensed broker-dealer. Neither Lincoln Park nor any of its associates or affiliates has held any position, office or other material relationship with us in the past three years. See “Plan of Distribution.”

Lincoln Park is an “underwriter” within the meaning of the Securities Act. All expenses incurred with respect to the registration of the common stock will be borne by us, but we will not be obligated to pay underwriting fees, discounts, commissions or other expenses incurred by Lincoln Park in connection with the sale of such shares.

This prospectus covers the resale by Lincoln Park of up to an aggregate of 1,702,740 shares of common stock, which consist of (i) up to 1,600,000 shares that we may sell and issue to Lincoln Park from time to time in the future pursuant to the \$15,000,000 Purchase Agreement after the registration statement of which this prospectus forms a part is declared effective, and (ii) up to 102,740 shares as Commitment Shares we are obligated to issue to Lincoln Park in the future pro rata as shares are sold under the \$15,000,000 Purchase Agreement.

The table below contains information, to our knowledge, regarding Lincoln Park’s beneficial ownership of our common stock as of December 28, 2012, and the number of shares of common stock that Lincoln Park may offer and sell pursuant to this prospectus. The shares of common stock being offered hereby are being registered to permit public secondary trading, and Lincoln Park may offer all or part of the common stock from time to time. However, Lincoln Park is under no obligation to sell all or any portion of such shares. All information with respect to share ownership has been furnished by Lincoln Park. The column entitled “Shares Beneficially Owned After Offering” assumes the sale of all shares of common stock offered.

Selling Shareholder	Shares Beneficially Owned Before Offering	Percentage of Outstanding Shares Beneficially Owned Before Offering	Shares to be Sold in the Offering Assuming the Company Issues the Maximum Number of Shares under the \$15,000,000 Purchase Agreement	Shares Beneficially Owned After Offering	Percentage of Outstanding Shares Beneficially Owned After Offering
Lincoln Park Capital Fund, LLC ⁽¹⁾	249,617 ⁽²⁾	4.1%	1,702,740 ⁽³⁾	249,617 ⁽²⁾	3.2%

* Less than one percent.

⁽¹⁾ Joshua Scheinfeld and Jonathan Cope, the principals of Lincoln Park, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and disposition power over the shares being offered under this prospectus.

⁽²⁾ Consisting of: (i) 215,617 shares of our common stock already owned by Lincoln Park; and (ii) 34,000 shares of common stock underlying Series H warrants. Does not include shares we may issue and sell to Lincoln Park under the \$15,000,000 Purchase Agreement or the related pro rata commitment shares.

(3) Although the \$15,000,000 Purchase Agreement provides that we may sell up to \$15,000,000 in shares of our common stock to Lincoln Park, we are only registering 1,702,740 shares issuable under the \$15,000,000 Purchase Agreement on this registration statement. If we elect to issue more than 1,702,740 shares offered by this prospectus, which we have the right but not the obligation to do, up to a maximum of \$15,000,000 in shares of common stock, we must first register under the Securities Act any additional shares we may elect to sell to Lincoln Park before we can sell such additional shares.

DILUTION

Our net tangible book value as of September 30, 2012 was approximately \$2,339,285 or \$0.41 per share, based on 5,762,122 shares of our common stock outstanding on that date (as adjusted to reflect our 1-for-4 reverse stock split effective December 14, 2012). Net tangible book value per share is determined by dividing our total tangible assets (total assets less intangible assets), less total liabilities, by the number of shares of our common stock outstanding.

After giving effect to our assumed sale of all 1,600,000 shares of our common stock in this offering at an assumed public offering price of \$1.00 per share (based on the adjusted minimum floor price at which sales may be made), not including the shares to be issued to Lincoln Park as a fee for its commitment to purchase shares of our common stock, our as adjusted net tangible book value as of September 30, 2012 would have been approximately \$3,939,285, or \$0.54 per share of common stock. This represents an immediate increase in net tangible book value of \$0.13 per share to existing shareholders and immediate dilution in net tangible book value of \$0.46 per share to new investors participating in this offering at the assumed offering price. The following table illustrates this dilution on a per share basis:

Public offering price per share (assumed at adjusted minimum floor price for sales)	\$	1.00
Net tangible book value per share as of September 30, 2012, before this offering	\$	0.41
Increase in pro forma net tangible book value per share attributable to new investors	\$	0.13
Net tangible book value per share as of September 30, 2012, after giving effect to this offering	\$	0.54
Dilution per share to new investors	\$	0.46

Subsequent to September 30, 2012, we sold 265,000 shares to Lincoln Park under the \$1,500,000 Purchase Agreement for an aggregate purchase price of \$381,309 and issued to Lincoln Park 56,507 Initial Commitment Shares and 2,611 Additional Commitment Shares.

Except as otherwise specifically indicated herein, all information in this prospectus assumes or gives effect to no exercise of options or warrants outstanding on the date of this prospectus or in the future.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Lincoln Park Capital Fund, LLC, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Lincoln Park is an “underwriter” within the meaning of the Securities Act.

Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Lincoln Park, any other shareholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Lincoln Park and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Lincoln Park and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the \$15,000,000 Purchase Agreement.

We have advised Lincoln Park that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park or may be resold by Lincoln Park without restriction under Rule 144(b)(1)(i) under the Securities Act.

Our common stock is listed on the NASDAQ Capital Market under the symbol “OPXA.”

EXPERTS

The financial statements of Opexa as of December 31, 2011, and for the years ended December 31, 2011 and 2010, incorporated in this prospectus by reference to our Annual Report on Form 10-K for the year ended December 31, 2011, have been audited by MaloneBailey, LLP, an independent registered public accounting firm, and are incorporated in reliance upon their report dated February 27, 2012, given upon such firm’s authority as experts in auditing and accounting.

LEGAL MATTERS

The validity of any securities offered by this prospectus will be passed upon for us by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the Securities and Exchange Commission (or the SEC) under the Securities Act of 1933, as amended. This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy the registration statement and any document we file with the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The website address is www.sec.gov. The information on the SEC's website is not part of this prospectus, and any references to this website or any other website are inactive textual references only.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC permits us to "incorporate by reference" the information contained in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Later information that we file with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the SEC, and incorporate by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2011;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012, June 30, 2012 and September 30, 2012;
- our Current Reports on Form 8-K filed January 10, 2012, January 17, 2012, February 16, 2012, February 29, 2012, July 26, 2012, August 13, 2012, September 7, 2012, November 5, 2012, November 20, 2012, November 30, 2012 and December 14, 2012;
- our definitive proxy statement on Schedule 14A, relating to the annual meeting of shareholders held on November 15, 2012, as filed on October 9, 2012; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed on August 30, 2006, as amended by our Form 8-12B/ A filed on August 31, 2006 .

We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with SEC rules.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of the reports and documents that have been incorporated by reference in this prospectus, at no cost. Any such request may be made by writing or telephoning us at the following address or phone number: Investor Relations, Opexa Therapeutics, Inc., 2635 Technology Forest Blvd., The Woodlands, Texas 77381, telephone (281) 775-0600. We also maintain a website at www.opexatherapeutics.com. However, the information on our website is not part of this prospectus.

This prospectus or information incorporated by reference herein contains summaries of certain agreements that we have filed as exhibits to our various SEC filings. The descriptions of these agreements contained in this prospectus or information incorporated by reference herein do not purport to be complete and are subject to, or qualified in their entirety by reference to, the definitive agreements. Copies of the definitive agreements will be made available without charge to you by making a written or oral request to us in the manner specified above.

1,702,740 Shares of Common Stock



OPEXA THERAPEUTICS, INC.

PROSPECTUS

, 2012

PART II
Information Not Required In Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following is a statement of estimated expenses in connection with the issuance and distribution of the securities being registered, other than underwriting discounts and commission. All expenses incurred with respect to the registration of the common stock will be borne by us, but we will not be obligated to pay underwriting fees, discounts, commissions or other expenses incurred by the selling shareholder in connection with the sale of such shares.

	Amount to be Paid*
SEC Registration Fee	\$ 297
Printing Expenses*	2,000
Legal Fees and Expenses*	40,000
Accounting Fees and Expenses*	10,000
Miscellaneous*	2,000
	<u>\$ 54,297</u>

* All amounts shown, except the SEC registration fee, are estimated and may vary based upon, among other things, the number of issuances and amount of securities offered. We will pay all of these expenses.

Item 14. Indemnification of Directors and Officers.

Section 8.101 of the Texas Corporations Law (or the TCA) authorizes the Registrant to indemnify certain persons, including any person who was, is or is threatened to be made a named defendant or respondent in a threatened, pending or completed action or other proceeding, because the person is or was a director or officer, against judgments and reasonable expenses actually incurred by the person in connection with the threatened, pending or completed action or other proceeding. The Registrant is required by Section 8.051 of the TCA to indemnify a director or officer against reasonable expenses actually incurred by him or her in connection with a threatened, pending, or completed action or other proceeding in which he or she is a named defendant or respondent because he or she is or was a director or officer if he or she has been wholly successful, on the merits or otherwise, in the defense of the action or proceeding.

The Registrant's restated certificate of formation provides that none of its directors shall be personally liable to the Registrant or its shareholders for monetary damages for an act or omission in such director's capacity as a director; provided, however, that the liability of such director is not limited to the extent that such director is found liable for (i) a breach of the director's duty of loyalty to the Registrant or its shareholders, (ii) an act or omission not in good faith that constitutes a breach of duty of the director to the Registrant or an act or omission that involves intentional misconduct or a knowing violation of the law, (iii) a transaction from which the director received an improper benefit, whether or not the benefit resulted from an action taken within the scope of the director's office, or (iv) an act or omission for which the liability of the director is expressly provided by an applicable statute.

The Registrant's restated certificate of formation and amended and restated bylaws provide that the Registrant shall indemnify its officers, directors, agents and any other persons to the fullest extent permitted by applicable law. The Registrant's directors and officers are covered by insurance indemnifying them against certain liabilities which might be incurred by them in their capacities as such. Pursuant to terms of their employment contracts, certain of the Registrant's officers are entitled to indemnification in their capacity as such and to the fullest extent permitted by applicable law.

At the present time, there is no pending litigation or proceeding involving a director, officer, employee or other agent of the Registrant in which indemnification would be required or permitted. The Registrant is not aware of any threatened litigation or proceeding which may result in a claim for such indemnification.

Item 15. Recent Sales of Unregistered Securities .

The following is a summary of all securities that we have sold within the past three years without registration under the Securities Act of 1933, as amended. The transactions listed below were effected before our 1-for-4 reverse stock split which was recently implemented on December 14, 2012, and the amount and price of securities shown represents the original issuance and has not been adjusted to reflect the reverse split.

- On November 2, 2012, we completed a private placement to Lincoln Park Capital Fund, LLC pursuant to which we have the right to sell to Lincoln Park up to \$15,000,000 in shares of common stock, subject to certain limitations, from time to time over the 30-month period commencing on the date that a registration statement covering the resale of the shares is declared effective by the SEC. The issuance and sale was made without registration under the Securities Act in reliance on the exemptions provided by Section 4(2) of the Act and Regulation D promulgated thereunder based on the offering of such securities to one investor, the lack of any general solicitation or advertising in connection with such issuance, the representation of such investor that it was an accredited investor and that it was purchasing the shares for its own account and without a view to distribute them.
- On July 25, 2012, we completed a private offering of \$4,085,000 in principal amount of convertible secured promissory notes and Series I warrants to purchase an aggregate of 3,829,689 shares, subject to certain adjustments, of common stock at \$1.25 per share. The offers and sales were made without registration under the Securities Act in reliance on the exemptions provided by Section 4(2) of the Act and Regulation D promulgated thereunder based upon representations made by the investors, each of whom is an accredited investor.
- On April 18, 2011, we issued 50,305 restricted shares of common stock to a consultant for professional services. The common stock was issued in reliance on the exemption from registration contained in Section 4(2) of the Securities Act and the rules and regulations promulgated thereunder.
- On June, 23, 2010, we issued an aggregate of 2,660,181 shares of common stock to the holders of our 10% convertible promissory notes, consisting of (i) 2,504,000 shares pursuant to the conversion of all currently outstanding notes with an aggregate outstanding principal balance of \$1,252,000 and (ii) 156,181 shares in payment of one-half of the accrued and unpaid interest on said notes of \$78,091. On May 6, 2010, we issued 100,000 shares of common stock to a holder of a note pursuant to the conversion of such note with a principal balance of \$50,000. The common stock was issued in reliance on the exemptions from registration contained in Sections 3(a)(9) and 4(2) of the Securities Act and the rules and regulations promulgated thereunder.
- On August 18, 2010, we issued 55,000 restricted shares of common stock to a consultant for professional services. The common stock was issued in reliance on the exemption from registration contained in Section 4(2) of the Securities Act and the rules and regulations promulgated thereunder.

Item 16. Exhibits and Financial Statement Schedules .

(a) Exhibits

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial statement schedules

All schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the financial statements and related notes thereto.

Item 17. Undertakings .

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of The Woodlands, State of Texas, on December 28, 2012.

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Neil K. Warma and David E. Jorden, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, to this Registration Statement, and any registration statement relating to the offering covered by this Registration Statement and filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys in fact and agents or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Neil K. Warma</u> Neil K. Warma	President, Chief Executive Officer and Director (Principal Executive Officer)	December 28, 2012
<u>/s/ David E. Jorden</u> David E. Jorden	Acting Chief Financial Officer and Director (Principal Financial and Accounting Officer)	December 28, 2012
<u>/s/ Gail J. Maderis</u> Gail J. Maderis	Director	December 28, 2012
<u>/s/ Michael S. Richman</u> Michael S. Richman	Director	December 28, 2012
<u>/s/ Scott B. Seaman</u> Scott B. Seaman	Director	December 28, 2012

EXHIBIT INDEX

Exhibit No.	Description
2.1	Stock Purchase Agreement by and among Sportan United Industries, Inc., Jason G. Otteson, PharmaFrontiers Corp., Warren C. Lau and other PharmaFrontiers stockholders, dated May 5, 2004 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 4, 2004, File No. 000-25513).
2.2	Agreement and Plan of Reorganization by and among PharmaFrontiers Corp., Pharma Acquisition Corp and Opexa Pharmaceuticals, Inc. dated October 7, 2004 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on 8-K filed October 8, 2004, File No. 000-25513).
3.1	Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.2	Certificate of Amendment of the Company's Restated Certificate of Formation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 14, 2012).
3.3	Amended and Restated Bylaws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K filed on March 8, 2011).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108).
4.2	Form of Series E Warrant (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed December 20, 2007, File No. 333-147167).
4.3	Warrant Agent Agreement by and between the Company and Continental Stock Transfer & Trust Company dated February 13, 2008 for the Series E Warrants (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2008).
4.4	Form of Underwriters' Warrant Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2008).
4.5	Form of Underwriters' Warrant to Acquire Warrants Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed February 14, 2008).
4.6	Unit Purchase Agreement dated August 8, 2008 by and among the Company and the Investors named therein in connection with Unit offering of common stock and Series F Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 12, 2008).
4.7	Form of Series F Warrant issued in connection with August 8, 2008 financing (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 12, 2008).
4.8	Registration Rights Agreement dated August 8, 2008 between the Company and the Investors named therein in connection with common stock and Series F Warrants (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 12, 2008).
4.9	Unit Purchase Agreement dated April 14, 2009 by and among the Company and the Investors party thereto for the 10% Convertible Notes and Series G Warrants (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 16, 2009).
4.10	Form of Series G Warrant issued by the Company on April 14, 2009 (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed April 16, 2009).
4.11	Placement Agent Agreement dated December 9, 2009 by and between the Company and Rodman & Renshaw, LLC for Unit offering of Common Stock and Series A and Series B Warrants (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed December 10, 2009).

Exhibit No.	Description
4.12	Form of Securities Purchase Agreement dated as of December 9, 2009 by and between the Company and each investor signatory thereto for Unit offering of Common Stock and Series A and Series B Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.13	Form of Common Stock Purchase Warrant for Series A and Series B Warrants (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.14	Form of Series H Warrant issued by the Company on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011).
4.15	Form of Series I Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.16	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible preferred Stock of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.17	Form of Registration Rights Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed July 26, 2012).
4.18	Form of 12% Convertible Secured Promissory Note issued to investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 26, 2012).
5.1*	Opinion of Pillsbury Winthrop Shaw Pittman LLP.
10.1+	Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement on Schedule 14C filed on June 29, 2004, File No. 000-25513).
10.2+	Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed March 5, 2010).
10.3+	Employment Agreement dated June 16, 2008 by and between the Company and Neil K. Warma (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2008).
10.4+	Amended and Restated Employment Agreement entered into on April 21, 2010 by and between the Company and Donna R. Rill (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 27, 2010).
10.5+	Amended and Restated Employment Agreement entered into on June 27, 2011 by and between the Company and Jaye L. Thompson (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed June 30, 2011).
10.6	License Agreement dated September 5, 2001 by and between the Company and Baylor College of Medicine (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB filed April 15, 2005, File No. 000-25513).
10.7	Lease dated August 19, 2005 by and between the Company and Dirk D. Laukien (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB filed March 31, 2006, File No. 000-25513).
10.8	License Agreement dated January 13, 2006 by and between the Company and Shanghai Institute for Biological Services (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed February 9, 2006, File No. 333-126687).

Exhibit No.	Description
10.9	Fourth Amended and Restated License Agreement, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and the University of Chicago (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 4, 2011).
10.10+	Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's Schedule 14A definitive proxy statement filed September 14, 2010).
10.11+	Form of award agreement for awards to be made under the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed October 22, 2010).
10.12	Continuous Offering Program Agreement dated May 14, 2010 by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 17, 2010) (subsequently terminated February 7, 2011 as disclosed in the Company's Current Report on Form 8-K filed on February 7, 2011).
10.13	Assignment Agreement and General Release, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and Novartis Institutes for BioMedical Research, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 4, 2011).
10.14	Form of Note Purchase Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.15	Form of 12% Convertible Secured Promissory Note issued to investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.16	Form of Security Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., the investors signatory thereto, and Alkek & Williams Ventures, Ltd. as collateral agent for the investors (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.17	Deposit Account Control Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., Alkek & Williams Ventures, Ltd. as collateral agent for the investors, and Wells Fargo Bank, National Association (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.18	Form of Registration Rights Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.19	Sales Agreement, dated September 6, 2012, by and between Opexa Therapeutics, Inc. and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2012).
10.20	\$15,000,000 Purchase Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.21	\$1,500,000 Purchase Agreement, dated as of November 5, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.22	Registration Rights Agreement, dated as of November 2, 2012, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 5, 2012).

Exhibit No.	Description
21.1*	Lists of Subsidiaries.
23.1*	Consent of Pillsbury Winthrop Shaw Pittman LLP (included in Exhibit 5.1).
23.2*	Consent of MaloneBailey, LLP.
24.1*	Power of Attorney (included on the signature page hereof).

* Filed herewith
+ Management contract or compensatory plan or arrangement.

EXHIBIT 5.1



Pillsbury Winthrop Shaw Pittman LLP

Houston | London | Los Angeles | New York | Northern Virginia | Orange County | Sacramento | San Diego | San Diego North County | San Francisco | Shanghai | Silicon Valley | Tokyo | Washington, DC

December 28, 2012

Opexa Therapeutics, Inc.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381

Ladies and Gentlemen:

We are acting as counsel for Opexa Therapeutics, Inc., a Texas corporation (the "Company"), in connection with the issuance and sale of the following shares (collectively, the "Shares") of common stock, \$0.01 par value (the "Common Stock"), of the Company, all of which are authorized but heretofore unissued shares to be offered and sold by the Company pursuant to the Registration Statement on Form S-1 (the "Registration Statement") filed by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933 (the "Act") and related prospectus for the offer and sale of the Shares (the "Prospectus"): (i) up to 1,600,000 shares of Common Stock (the "Purchase Shares") issuable pursuant to the terms of that certain Purchase Agreement between the Company and Lincoln Park Capital Fund, LLC, dated as of November 2, 2012 (the "Purchase Agreement"); and (ii) up to 102,740 shares of Common Stock issuable as Commitment Shares (as defined in the Purchase Agreement).

We have reviewed and are familiar with such documents, corporate proceedings and other matters as we have considered relevant or necessary as a basis for the opinions in this letter. Based on the foregoing and the assumption that no Purchase Shares will be sold at a price which is less than the Floor Price (as defined in the Purchase Agreement), we are of the opinion that the Shares have been duly authorized and, when issued and sold by the Company in the manner described in the Registration Statement and the Prospectus and in accordance with the resolutions adopted by the Board of Directors of the Company, will be validly issued, fully paid and nonassessable.

The opinions set forth in this letter are limited to the Texas Corporations Law of the State of Texas, as in effect on the date hereof.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement and the incorporation thereof in the Registration Statement and to the use of our name under the caption "Legal Matters" in the Prospectus. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Pillsbury Winthrop Shaw Pittman LLP

EXHIBIT 21.1

LIST OF SUBSIDIARIES

Name

Jurisdiction of Incorporation

Opexa Hong Kong Limited

Hong Kong

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-1 of our report dated February 27, 2012 with respect to the audited financial statements of Opexa Therapeutics, Inc. for the year ended December 31, 2011.

We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ MaloneBailey, LLP
www.malone-bailey.com
Houston, Texas

December 28, 2012