

OPEXA THERAPEUTICS, INC.

FORM 424B5

(Prospectus filed pursuant to Rule 424(b)(5))

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The information in this preliminary prospectus supplement and the accompanying prospectus, relating to an effective registration statement under the Securities Act of 1933, as amended, is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 7, 2011

PROSPECTUS SUPPLEMENT
To Prospectus dated November 23, 2009

[_____] Shares
Warrants to Purchase [_____] Shares



OPEXA THERAPEUTICS

OPEXA THERAPEUTICS, INC.

Common Stock

Warrants to Purchase Common Stock

We are offering up to an aggregate of [_____] shares of our common stock and warrants to purchase an aggregate of up to [_____] shares of our common stock (and the shares of common stock issuable from time to time upon exercise of the warrants) in this offering. The common stock and warrants will be sold in units, with each unit consisting of one share of common stock and a warrant to purchase [_____] of a share of common stock at an exercise price of \$[_____] per share. Each unit will be sold at a public offering price of \$[_____] per unit. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately.

Our common stock is traded on the NASDAQ Capital Market under the symbol "OPXA." On February 4, 2011, the last reported sales price for our common stock was \$2.36 per share. The aggregate market value of our outstanding common equity held by non-affiliates on January 24, 2011 was \$43,931,149, based on 18,851,683 shares of outstanding common stock, of which 3,245,591 shares are held by affiliates, and a price of \$2.815 per share, which was the average of the bid and ask price of our common stock as quoted on the NASDAQ Capital Market on that date. During the 12 calendar months prior to and including the date hereof, we have sold 384,759 shares of our common stock for gross proceeds of \$1,077,111 pursuant to General Instruction I.B.6 of Form S-3. There is no established public trading market for the offered warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page S-5 of this prospectus supplement and in the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. You should carefully consider these risk factors, as well as the information contained in this prospectus supplement and the accompanying 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.

	Per Unit	Total
Public offering price	\$[_____]	\$[_____]
Underwriting discounts and commissions	\$[_____]	\$[_____]
Proceeds, before expenses, to OpeXa Therapeutics, Inc.	\$[_____]	\$[_____]

We estimate the total expenses of this offering, excluding underwriting discounts and commissions, will be approximately \$[_____]. We expect that delivery of the securities being offered pursuant to this prospectus supplement will be made through the facilities of the Depository Trust Company on or about February [____], 2011.

Sole Book-Running Manager

Lazard Capital Markets

The date of this Prospectus Supplement is February [____], 2011.

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You should rely only on the information incorporated by reference or provided in this prospectus supplement, the accompanying prospectus and the documents incorporated herein and therein by reference. 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 supplement and the accompanying 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.

ABOUT THIS PROSPECTUS SUPPLEMENT

We are providing this information to you about this offering of securities in two parts. The first part is this prospectus supplement, which provides the specific details regarding the shares of our common stock and the warrants that we are selling in this offering and also adds to and updates information contained in or incorporated by reference into the accompanying prospectus. The second part is the base prospectus dated November 23, 2009, included in our registration statement on Form S-3, as amended (SEC File No. 333-163108), which provides a general description of the securities we may offer from time to time under that registration statement. This prospectus supplement and the accompanying prospectus are part of a “shelf” registration statement that we filed with the U.S. Securities and Exchange Commission. Under the shelf registration process, we may offer from time to time shares of our common stock up to an aggregate amount of \$35,000,000, of which this offering is a part.

We have previously sold 2,550,000 shares of our common stock and common stock warrants to purchase an additional 1,275,000 shares of our common stock for aggregate gross proceeds of \$5.1 million (net proceeds of approximately \$4.7 million) pursuant to a prospectus supplement dated December 9, 2009, to the prospectus dated November 23, 2009. During January 2011, we sold an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an “at the market” continuous offering program pursuant to a prospectus supplement dated May 17, 2010.

To the extent there is a conflict between information contained in this prospectus supplement, on the one hand, and information contained in the accompanying prospectus or any document incorporated by reference, on the other hand, the information in this prospectus supplement shall control.

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

Unless the context otherwise requires, references in this prospectus and the accompanying prospectus supplement to “Opexa,” “the Company,” “we,” “us” and “our” refer to Opexa Therapeutics, Inc.

PROSPECTUS SUPPLEMENT 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 and warrants, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the section entitled “Risk Factors,” and our consolidated financial statements and the related notes and other documents incorporated by reference in the accompanying prospectus.

OUR COMPANY

Our Business

We are 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. Information related to our product candidates is preliminary and investigative. Our product candidates are not approved by the Food and Drug Administration (FDA).

Our lead product candidate, Tovaxin®, is a personalized T-cell therapeutic vaccine 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.

T-Cell Therapy and Tovaxin ®

Tovaxin ® is a novel T-cell immunotherapy positioned to enter Phase III clinical development for the treatment of relapsing remitting MS (RR-MS). It is a personalized therapy that is specifically tailored to each patient’s disease profile. Tovaxin is manufactured using 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 raised against selected peptides from myelin basic protein, myelin oligodendrocyte glycoprotein and proteolipid protein, 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.

Summary of TERMS Phase IIb Clinical Trial Data

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tovaxin in RR-MS patients. 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 RR-MS 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 include:

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

Tovaxin has demonstrated a favorable side effect profile throughout the clinical development program. In four clinical trials to date, including the Phase IIb TERMS trial, there have been no serious adverse events associated with Tovaxin treatment. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. We believe the favorable safety profile of Tovaxin is a key differentiator when compared to marketed or other developmental MS drugs.

T-Cell Therapy Regulatory Status

In late 2010, we completed face-to-face discussions with the U.S. Food and Drug Administration (FDA) regarding our planned development program for Tovaxin. Based on positive feedback from the FDA, we believe that we are now positioned from a regulatory perspective to advance with a pivotal Phase III clinical study of Tovaxin in MS, subject to securing the appropriate financing to conduct such a study. We are in the process of completing necessary preparations to be able to initiate such a study.

Our recent discussions with the FDA consisted of two separate meetings to review both the complete Tovaxin manufacturing process as well as the prospective clinical trial plan for Tovaxin. The first meeting focused on the improvements and modifications we have incorporated into Tovaxin's manufacturing and CMC (chemistry, manufacturing and control) process in an effort to improve efficiency, reduce overall costs and implement commercial stage requirements. As part of this meeting, we presented data and details supporting an optimized manufacturing process, including a transition to fewer process steps, comparability plans and complete reagent profiles. The FDA agreed that the optimized Tovaxin manufacturing process would meet the requirements for a pivotal Phase III clinical trial, although additional supporting data is expected to be submitted to the FDA prior to initiating such a study.

The second meeting was an "end of Phase II" clinical meeting in which we presented our rationale and trial design for a Phase III pivotal study with Tovaxin in RR-MS patients. The FDA concurred in general with our proposed clinical trial protocol, including the patient population, end points, patient numbers and overall trial design. The FDA also offered several recommendations to further enhance such a Phase III trial.

Intended Use of Proceeds

We currently intend to use the proceeds from this offering for general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from this offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.* , the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Cash Position and Liquidity

As of December 31, 2010, we had cash and cash equivalents of \$3,812,535. During January 2011, we sold an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an "at the market" continuous offering program pursuant to a prospectus supplement dated May 17, 2010. Our current burn rate, which is in the absence of any clinical trial as well as significant activities in preparation for such a trial, is approximately \$380,000 per month. If we do not commence a clinical trial using our own resources, or undertake substantial activities in preparation for such a trial, we believe we have sufficient liquidity before receiving any proceeds from this offering to support our operations through 2011.

Given our need for substantial amounts of capital, in addition to the proceeds of this offering, to undertake a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase III study and to support the operations of the Company 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.

Assuming we are able to achieve financing which is sufficient to support the planned Phase III study in the United States and to support our operations during the pendency of such study, we are also preparing for a second pivotal Phase III clinical study in Europe. Any such second study would also depend upon the availability of sufficient resources.

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.

Stem Cell Therapy

In 2009, Novartis Pharmaceuticals acquired our stem cell technology platform, which had been in early preclinical development, and took over all future responsibilities and opportunities for this technology, although we retain an option on certain manufacturing rights. As part of the transaction, we were paid an upfront fee of \$3 million and a milestone payment of \$500,000 for certain technology transfer activities. We remain eligible to receive a second technology transfer milestone fee in addition to potential clinical and commercial milestones and royalty payments from the sale of any products resulting from the use of the technology. However, there can be no assurance that we will receive any future payments in respect of the stem cell technology.

THE OFFERING

Common stock offered by Opexa	Up to [_____] shares
Warrants to purchase common stock offered by Opexa	Warrants to purchase up to [_____] shares of common stock. This prospectus supplement also relates to the offering of shares of common stock issuable upon exercise of the warrants.
Common stock outstanding after this offering	Up to [_____] shares
Use of proceeds	We currently intend to use the proceeds from this offering for general corporate purposes and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from this offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (<i>i.e.</i> , the dosing of the first patient) or to complete such study or any significant portion of it. See “Use of Proceeds” on page S-[____] of this prospectus supplement.
Risk factors	See the “Risk Factors” beginning on page S-[____] of this prospectus supplement for factors to consider before deciding to purchase our securities.
Warrant terms	The warrants will be exercisable at a price of \$[_____] per share and have a term of five years.
NASDAQ listing	Our common stock is listed on the NASDAQ Capital Market under the symbol “OPXA.”

The number of shares of common stock outstanding after the offering is based on 18,851,683 shares of common stock outstanding as of February 4, 2011, and excludes:

- 1,717,072 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$2.09 per share;
- 11,459,584 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$2.75 per share; and
- Up to [_____] shares of common stock issuable upon the exercise of the warrants offered hereby.

RISK FACTORS

Investing in our common stock and warrants 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 supplement and accompanying prospectus, before deciding to invest in our common stock and warrants. The following factors affect our business and the industry in which we operate. 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 in our securities.

Risks Related to Our Business

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

Our business is at an early stage of development. We do not have any product candidates in late-stage clinical trials nor do we have any products on the market. We have only one product candidate, Tovaxin, which has progressed to the stage of being studied in human clinical trials in the United States. We are still in the very early stages of identifying and conducting research on any other potential products. Tovaxin, 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 Tovaxin, to enter clinical trials (or any development activities) for any other product candidates, or to commercialize any products. Tovaxin, and any other potential products, may prove to have undesirable and 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 have a history of operating losses and do not expect to be profitable in the near 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.

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 clinical trial for Tovaxin), 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 December 31, 2010, we had cash and cash equivalents of \$3,812,535. During January 2011, we sold an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an “at the market” continuous offering program pursuant to a prospectus supplement dated May 17, 2010. Our current burn rate, which is in the absence of any clinical trial as well as significant activities in preparation for such a trial, is approximately \$380,000 per month. If we do not commence a clinical trial using our own resources, or undertake substantial activities in preparation for such a trial, we believe we have sufficient liquidity before receiving any proceeds from this offering to support our operations through 2011.

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 offered by this prospectus supplement

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and the accompanying prospectus to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the net proceeds from this offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (i.e. , the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital, in addition to the proceeds of this offering, to undertake a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase III study and to support the operations of the Company 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.

Assuming we are able to achieve financing which is sufficient to support the planned Phase III study in the United States and to support our operations during the pendency of such study, we are also preparing for a second pivotal Phase III clinical study in Europe. Any such second study would also depend upon the availability of sufficient resources.

As we have no sources of debt or equity capital committed for funding, we must rely upon best efforts third-party debt or equity funding and 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 2011 and beyond as well as for any clinical study of Tovaxin;
- 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 Tovaxin, 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, 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 undertake, or complete, the planned pivotal Phase III clinical study in the United States of Tovaxin in RR-MS 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.

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We will depend on strategic collaborations with third parties to develop and commercialize product candidates, such as Tovaxin, 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 Tovaxin, 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 Tovaxin. However, we will need to raise significant additional capital in order to undertake the planned pivotal Phase III clinical study in the United States of Tovaxin in RR-MS as the total costs of conducting this study, if commenced in the near-term, 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 such as 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 a collaboration, including with respect to Tovaxin, 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 a collaboration on acceptable terms, we may not be able to complete development of, or commercialize any product candidate, including Tovaxin. In particular, we may be unable to undertake, or complete, the planned pivotal Phase III clinical study in the United States of Tovaxin in RR-MS. 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, including Novartis, to whom we have transferred 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 Tovaxin, 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 Tovaxin, 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 a pivotal Phase III clinical trial in the United States of our lead product candidate, Tovaxin, in RR-MS will take approximately two and one-half years to complete. In addition, we anticipate that a second Phase III clinical trial, which we are currently planning to conduct in Europe, would be necessary before we could submit an application for approval of Tovaxin for RR-MS. 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.

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The commencement and completion of clinical trials, including the commencement of the planned pivotal Phase III clinical trial in the United States of Tovaxin in RR-MS, 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 Tovaxin, 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 Tovaxin.

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 Tovaxin. 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;

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- 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 Tovaxin. 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.

Given that we have limited internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to 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 a number of 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.

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Our current research and manufacturing facility is not large enough to manufacture product candidates, such as Tovaxin, for 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 800 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our current facility should have the capacity to support a U.S. pivotal Phase III trial for the development of Tovaxin for RR-MS. It is not sufficient, however, to support potential European clinical studies, if required, or the commercial launch of Tovaxin. 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.

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Any product candidate that we develop, such as Tovaxin, 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 Tovaxin, 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 determine that our internal control over financial reporting was not effective. In addition, our 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 Tovaxin.

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 Tovaxin, 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 Tovaxin, 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 be mature 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 Tovaxin, 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 Tovaxin;

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- 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 Tovaxin. 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 Tovaxin, or their methods of use, manufacturing or other technologies or activities infringe the intellectual

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property rights of such third parties. If our product candidates, such as Tovaxin, 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 Tovaxin. Consequently, no assurance can be given that third-party patents containing claims covering Tovaxin, 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 Tovaxin, which could delay development and commercialization.

We, our third-party contractors, suppliers and partners, and our product candidates, such as Tovaxin, 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 Tovaxin, 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 Tovaxin. 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

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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 Tovaxin, 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

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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 Tovaxin, 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 Tovaxin, 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.

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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 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. 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. It is also possible that we would otherwise fail to satisfy another NASDAQ requirement for continued listing of our common stock. We may receive additional future notices from NASDAQ that we have failed to meet these requirements. If we are unable to cure any such failures in a timely manner and our common stock is delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

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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 Tovaxin, 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; or
- regulatory developments in the United States and in foreign countries.

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.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. Upon completion of this offering, we will have outstanding an aggregate of [] shares of common stock, assuming no exercise of outstanding options or warrants. A substantial majority of the outstanding shares of our common stock are, and all of the shares sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act of 1933 unless these shares are purchased by affiliates. In addition, we sold 2,550,000 shares of our common stock, and warrants to acquire another 1,275,000 shares, in a registered direct transaction in December 2009. Further, we sold an aggregate of 384,759 shares of common stock in January 2011 pursuant to an "at the market" continuous offering program. 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 undertake the planned pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, 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

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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.

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 the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a class of convertible preferred stock, these securities may provide for rights, preferences or privileges senior to, and thus adverse to, those of holders of our common stock.

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.

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 offered by this prospectus supplement and the accompanying prospectus to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from this offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.* , the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Depending on future developments and circumstances, we may use some of the proceeds of this offering for other purposes. Notwithstanding our intention as to the use of the net proceeds of this offering, our management will have significant flexibility in applying such proceeds. 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.

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You will 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 is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Assuming we sell 3,500,000 shares of our common stock in this offering at an assumed public offering price of \$2.36 per share (the closing price of our common stock on February 4, 2011), and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, you will experience immediate dilution of \$1.77 per share, representing the difference between our as adjusted net tangible book value per share as of September 30, 2010 after giving effect to this offering and the assumed public offering price. See the section entitled “Dilution” below for a more detailed illustration of the dilution you would incur if you purchase common stock in this offering.

FORWARD-LOOKING STATEMENTS

When used in this prospectus supplement, the accompanying prospectus and the documents incorporated by referenced in this prospectus supplement, the words “*expects*,” “*believes*,” “*anticipates*,” “*estimates*,” “*may*,” “*could*,” “*intends*,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements in this prospectus supplement 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, management’s strategy, 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, and management’s initiatives and strategies, 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: market conditions, our capital position, the ability of the Company to enter into and benefit from a partnering arrangement for the Company’s product candidate, Tovaxin, 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 Tovaxin, 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 treatment development program and to undertake and complete the pivotal Phase III study in the United States for Tovaxin in RR-MS that we currently intend to prepare for with the proceeds of this offerings, the success of our clinical trials, 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 Tovaxin), the risk of litigation regarding our intellectual property rights, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, 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 of this prospectus supplement. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in our 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

Assuming we offer 3,500,000 shares of our common stock in this offering, we estimate that the net proceeds to us from the sale of the shares offered by this prospectus supplement and the accompanying prospectus

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will be approximately \$7,473,100 based on an assumed public offering price of \$2.36 per share (which was the last reported sales price of our common stock on the NASDAQ Capital Market on February 4, 2011), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The actual net proceeds could be less or greater than \$7,473,100, depending on the actual offering price and the actual number of shares to be sold.

Except as described in any later prospectus supplement or post-effective amendment, we currently intend to use the net proceeds from the sale of the common stock offered by this prospectus supplement and the accompanying prospectus for general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from this offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.* , the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital, in addition to the proceeds of this offering, to undertake a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase III study and to support the operations of the Company 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.

Depending on future developments and circumstances, we may use some of the proceeds of this offering for other purposes. Notwithstanding our intention as to the use of the net proceeds of this offering, our management will have significant flexibility in applying such proceeds.

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

CAPITALIZATION

The following table presents our cash, cash equivalents and capitalization, as of September 30, 2010:

- on an actual basis; and
- on an as adjusted basis to give effect to the following: (i) the assumed sale of 3,500,000 shares of common stock and warrants to acquire [_____] shares of common stock offered by us in this offering at an assumed public offering price of \$2.36 per unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, but assuming no exercise of the warrants, and (ii) the sale in January 2011 of an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an “at the market” continuous offering program.

The number of shares of common stock outstanding as of September 30, 2010 in the table below excludes, as of February 4, 2011:

- 1,717,072 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$2.09 per share;

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- 11,459,584 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$2.75 per share; and
- Up to [_____] shares of common stock issuable upon the exercise of the warrants offered hereby.

You should read this information in conjunction with our consolidated financial statements and other financial information that are included in or incorporated by reference in this prospectus supplement and the accompanying prospectus.

	As of September 30, 2010	
	Actual	As Adjusted
	(Unaudited)	
Cash and cash equivalents ⁽¹⁾	\$ 4,733,445	\$ 13,283,656
Long-term liabilities	—	—
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized; none issued and outstanding, actual or as adjusted	—	—
Common stock, \$0.01 par value, 100,000,000 shares authorized;	184,670	223,517
Actual – 18,466,924 shares issued and outstanding		
As adjusted – 22,351,683 shares issued and outstanding		
Additional paid-in capital	98,402,585	106,913,949
Deficit accumulated during the development stage	(93,777,564)	(93,777,564)
Total stockholders' equity	4,809,691	13,359,902

⁽¹⁾ As of December 31, 2010, we had cash and cash equivalents of \$3,812,535.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price and the net tangible book value per share of our common stock after this offering. Net tangible book value per share is determined by dividing the number of shares of common stock outstanding into our total tangible assets (total assets less intangible assets) less total liabilities. Our net tangible book value as of September 30, 2010, was approximately \$4,809,691, or approximately \$0.26 per share, based on 18,466,924 shares of our common stock outstanding as of September 30, 2010.

Assuming we sell 3,500,000 shares of our common stock and warrants to acquire [_____] shares of our common stock in this offering at an assumed public offering price of \$2.36 per unit (the closing price of our common stock on February 4, 2011), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and reflecting the sale in January 2011 of an aggregate of 384,759 shares of our common stock for gross proceeds of \$1,077,111 under an “at the market” continuous offering program, but assuming no exercise of the warrants, our as adjusted net tangible book value as of September 30, 2010 would have been approximately \$13,359,902, or approximately \$0.59 per share of common stock. This represents an immediate increase in as adjusted net tangible book value of \$0.33 per share to our existing stockholders, and an immediate dilution of \$1.77 per share to new investors participating in this offering. The following table illustrates this dilution on a per share basis:

Public offering price per unit	\$2.36
Net tangible book value per share as of September 30, 2010, before this offering	\$0.26
Increase in pro forma net tangible book value per share attributable to new investors	0.33
Net tangible book value per share as of September 30, 2010, after giving effect to this offering	0.59
Dilution per share to new investors	\$1.77

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Each \$0.50 increase (decrease) in the assumed public offering price of \$2.36 per share would increase (decrease) our as adjusted net tangible book value after this offering by approximately \$1.64 million, or approximately \$0.07 per share, and the dilution per share to new investors by approximately \$0.43 per share, assuming that the number of shares offered by us, as set forth above, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering from the assumed number of shares set forth above. An increase of 1,000,000 shares in the number of shares offered by us from the assumed number of shares set forth above would increase our as adjusted net tangible book value after this offering by approximately \$2.2 million, or approximately \$0.07 per share, and the dilution per share to new investors would be approximately \$1.70 per share, assuming that the assumed public offering price remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a decrease of 1,000,000 shares in the number of shares offered by us from the assumed number of shares set forth above would decrease our as adjusted net tangible book value after this offering by approximately \$2.2 million, or approximately \$0.07 per share, and the dilution per share to new investors would be approximately \$1.85 per share, assuming that the assumed public offering price remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares that we offer in this offering, and other terms of this offering determined at pricing.

In addition, investors that purchase common stock upon the exercise of the warrants offered hereby may experience dilution depending on our net tangible book value at the time of exercise. The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the per share offering price to the public in this offering.

The number of shares of common stock outstanding as of September 30, 2010 excludes, as of February 4, 2011:

- 1,717,072 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$2.09 per share;
- 11,459,584 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$2.75 per share; and
- Up to [_____] shares of common stock issuable upon the exercise of the warrants offered hereby.

To the extent that any options or warrants are exercised, new options or shares of common stock are issued under our stock option plan or we issue additional shares of common stock in the future, there could be further dilution to investors participating in this offering.

DESCRIPTION OF WARRANTS

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in the form of warrant attached as Exhibits 4.1 to our current report on Form 8-K filed on February __, 2011. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.

Term. The warrants are exercisable beginning on the date of original issuance and at any time up to the date that is five (5) years after such date, at an exercise price of \$[____] per share of common stock being purchased.

Exercisability. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants is not available and an exemption from registration is otherwise not available for the resale of such shares of common stock underlying the warrants, the holder may exercise the warrant in whole or in part and, in lieu

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of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

Adjustment of Exercise Price . The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Transferability . Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing . We do not plan on making an application to list the warrants on The Nasdaq Capital Market, any other national securities exchange or other nationally recognized trading system.

Fundamental Transactions . We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

Rights as a Stockholder . Except as otherwise provided in the warrants or by virtue of such holder’s ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments . Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus supplement, the underwriter named below has agreed to purchase, and we have agreed to sell to it, the number of shares of our common stock and warrants to acquire shares of our common stock at the public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus supplement as indicated below:

Underwriter	Number of Shares	Number of Shares Subject to Warrants
Lazard Capital Markets LLC	[]	[]
Total	[]	[]

The underwriter is offering the shares of common stock and warrants to acquire common stock subject to its acceptance of the shares and warrants from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriter to pay for and accept delivery of the shares and warrants offered by this prospectus supplement are subject to certain conditions precedent, including the absence of any material adverse change in our business and the approval of certain legal matters by its counsel and the receipt of customary legal opinions, letters and certificates and to other conditions. The underwriter is obligated to take and pay for all of the shares of common stock and warrants to acquire common stock offered by this prospectus supplement if any such shares and warrants are taken.

The underwriter initially proposes to offer the shares of common stock and warrants to acquire common stock directly to the public at the public offering price listed on the cover page of this prospectus supplement. After the initial offering of the shares and warrants, the offering price and other selling terms may from time to time be varied by the underwriter.

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Commissions and Discounts

The following table summarizes the public offering price, underwriting discount and proceeds before expenses to us:

	Per Unit	Total
Public offering price	\$[_____]	\$[_____]
Underwriting discounts and commissions	\$[_____]	\$[_____]
Proceeds, before expenses, to us	\$[_____]	\$[_____]

The expenses of the offering, not including the underwriting discount and commissions, payable by us are estimated to be \$[_____], which includes up to \$125,000 that we have agreed to reimburse the underwriter for certain fees and legal expenses incurred by it in connection with this offering. In no event will the aggregate compensation, together with related reimbursed expenses, paid to the underwriter and any related persons exceed 8% of the gross offering proceeds.

The relationship between Lazard Frères & Co. LLC and Lazard Capital Markets LLC is governed by a business alliance agreement between their respective parent companies. Pursuant to such agreement, Lazard Frères & Co. LLC referred this offering to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith; however, such referral fee is not in addition to the fee paid by us to Lazard Capital Markets LLC described above.

Quotation on the NASDAQ Global Market and Transfer Agent

Our common stock is listed on the NASDAQ Capital Market under the symbol “OPXA.” The transfer agent for our common stock is Continental Stock Transfer & Trust Company, New York, New York.

Indemnification

We and the underwriter have agreed to indemnify each other, and we have also agreed to indemnify Lazard Frères & Co. LLC, against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement. We have also agreed to contribute to payments the underwriter and Lazard Frères & Co. LLC may be required to make in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

No Sales of Similar Securities

We and each of our executive officers and directors have agreed with the underwriter, subject to certain customary exceptions, not to dispose of or hedge any of our shares of common stock or securities convertible into or exercisable or exchangeable for common stock for 90 days after the date of this prospectus supplement without first obtaining the written consent of Lazard Capital Markets LLC. The 90-day “lock-up” period during which we and our executive officers and directors are restricted from engaging in transactions in our common stock or securities convertible into or exercisable or exchangeable for common stock is subject to extension in the event that either (i) during the last 17 days of the “lock-up” period, we issue an earnings or financial results release or material news or a material event relating to us occurs, or (ii) prior to the expiration of the “lock-up” period, we announce that we will release earnings or financial results during the 16-day period beginning on the last day of the “lock-up” period,

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then in either case the expiration of the “lock-up” period will be extended until the expiration of the 18-day period beginning on the issuance of the earnings or financial results release or the occurrence of the material news or material event, as applicable, unless Lazard Capital Markets LLC waives, in writing, such an extension.

Price Stabilization, Short Positions

In order to facilitate the offering of the shares of common stock and warrants to acquire common stock, the underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriter may sell more shares of common stock than it is obligated to purchase under the underwriting agreement, creating a short position. The underwriter must close out any short position by purchasing shares of common stock in the open market. A short position may be created if the underwriter is concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchased in this offering. As an additional means of facilitating this offering, the underwriter may bid for, and purchase, shares of our common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of our common stock above independent market levels or prevent or slow a decline in the market price of our common stock. The underwriter is not required to engage in these activities, and may end any of these activities at any time.

A prospectus in electronic format may be made available on websites maintained by the underwriter. Internet distributions will be allocated by the underwriter on the same basis as other allocations.

United Kingdom

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (e) of the Order (all such persons together being referred to as “relevant persons”). The shares of common stock and warrants to acquire common stock are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares and warrants will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

The underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 or FSMA) received by it in connection with the issue or sale of the shares and warrants in circumstances in which Section 21(1) of the FSMA does not apply to us, and
- (b) it has complied with, and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the shares and warrants in, from or otherwise involving the United Kingdom.

European Economic Area

To the extent that the offer of the shares of common stock and warrants to acquire common stock are made in any Member State of the European Economic Area that has implemented the Prospectus Directive before the date of publication of a prospectus in relation to the shares of common stock and warrants to acquire common stock which has been approved by the competent authority in the Member State in accordance with the Prospectus Directive (or, where appropriate, published in accordance with the Prospectus Directive and notified to the competent authority in the Member State in accordance with the Prospectus Directive), the offer (including any offer pursuant to this document) is only addressed to qualified investors in that Member State within the meaning of the Prospectus Directive or has been or will be made otherwise in circumstances that do not require us to publish a prospectus pursuant to the Prospectus Directive.

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In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”), the underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the “Relevant Implementation Date”) it has not made and will not make an offer of shares and warrants to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares and warrants which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares and warrants to the public in that Relevant Member State at any time:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities,
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts, or
- (c) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive. For the purposes of this provision, the expression an “offer of shares and warrants to the public” in relation to any shares and warrants in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares and warrants to be offered so as to enable an investor to decide to purchase or subscribe the shares and warrants, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The EEA selling restriction is in addition to any other selling restrictions set out below. In relation to each Relevant Member State, each purchaser of shares of common stock and warrants to acquire common stock (other than the underwriter) will be deemed to have represented, acknowledged and agreed that it will not make an offer of shares of common stock and warrants to acquire common stock to the public in any Relevant Member State, except that it may, with effect from and including the date on which the Prospectus Directive is implemented in the Relevant Member State, make an offer of shares of common stock and warrants to acquire common stock to the public in that Relevant Member State at any time in any circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive, provided that such purchaser agrees that it has not and will not make an offer of any shares of common stock and warrants to acquire common stock in reliance or purported reliance on Article 3(2)(b) of the Prospectus Directive. For the purposes of this provision, the expression an “offer of shares and warrants to the public” in relation to any shares of common stock and warrants to acquire common stock in any Relevant Member State has the same meaning as in the preceding paragraph.

EXPERTS

The financial statements of Opexa as of December 31, 2009, and for the years ended December 31, 2009 and 2008 incorporated in this prospectus supplement by reference to our Annual Report on Form 10-K for the year ended December 31, 2009, have been audited by MaloneBailey, LLP, an independent registered public accounting firm, and are incorporated in reliance upon their report dated March 4, 2010, given upon such firm’s authority as experts in auditing and accounting.

LEGAL MATTERS

The validity of any securities offered by this prospectus supplement will be passed upon for us by Pillsbury Winthrop Shaw Pittman LLP, San Diego, California. Certain legal matters will be passed upon for the underwriter by Proskauer Rose LLP, New York, New York.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC under the Securities Act of 1933. This prospectus supplement and the accompanying 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 address of that site on the world wide web is <http://www.sec.gov>. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site 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 supplement and the accompanying prospectus. Information that is incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus and you should read it with the same care that you read this prospectus supplement and the accompanying 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 supplement and the accompanying prospectus, and will be considered to be a part of this prospectus supplement and the accompanying prospectus from the date those documents are filed. We have filed with the SEC, and incorporate by reference in this prospectus supplement and the accompanying prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2009;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010, June 30, 2010 and September 30, 2010;
- our Current Reports on Form 8-K dated April 21, 2010, May 14, 2010, June 3, 2010, October 19, 2010, January 5, 2011 and February [], 2011; 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 also incorporate by reference all additional documents that we file with the SEC under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made between the date of this prospectus supplement and the termination of any offering of securities offered by this prospectus supplement or the accompanying prospectus. 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.

You may request a copy of any or all of the documents incorporated by reference but not delivered with this prospectus, at no cost, by writing or telephoning us at the following address and number: Investor Relations, Opexa Therapeutics, Inc., 2635 Technology Forest Blvd., The Woodlands, Texas 77381, telephone (281) 775-0600. We will not, however, send exhibits to those documents, unless the exhibits are specifically incorporated by reference in those documents. We also maintain a website at <http://www.opexatherapeutics.com>. However, the information on our website is not part of this prospectus.

* * *

ANNEX A

OPEXA THERAPEUTICS, INC.

F O R M O F W A R R A N T T O P U R C H A S E C O M M O N S T O C K

Warrant No.: [_____]

Number of Shares of Common Stock: [_____]

Date of Issuance: February [____], 2011 (“ **Issuance Date** ”)

Opexa Therapeutics, Inc., a Texas corporation (the “ **Company** ”), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [_____], the registered holder hereof or its permitted assigns (the “ **Holder** ”), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the “ **Warrant** ”), at any time or times on or after the date hereof (the “ **Exercisability Date** ”), but not after 11:59 p.m., New York time, on the Expiration Date (as defined below), [_____] [(_____)] ¹ fully paid nonassessable shares of Common Stock (as defined below) (the “ **Warrant Shares** ”). Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 15. This Warrant is the Warrant to purchase Common Stock (this “ **Warrant** ”) issued pursuant to (i) Section 1 of that certain Underwriting Agreement (the “ **Underwriting Agreement** ”), dated as of February [____], 2011 (the “ **Pricing Date** ”), by and between the Company and Lazard Capital Markets LLC, as underwriter and (ii) the Company’s Registration Statement on Form S-3 (File number 333-163108) (the “ **Registration Statement** ”). Notwithstanding any provision herein to the contrary, all rights of the Holder hereunder shall expire at 11:59 p.m., New York time, on the Expiration Date.

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof, this Warrant may be exercised by the Holder on any day on or after the Exercisability Date, in whole or in part, by (i) delivery of a written notice, in the form attached hereto as Exhibit A (the “ **Exercise Notice** ”), of the Holder’s election to exercise this Warrant and (ii) (A) payment to the Company of an amount equal to the applicable Exercise Price multiplied by the number of Warrant Shares as to which this Warrant is being exercised (the “ **Aggregate Exercise Price** ”) in cash or by wire transfer of immediately available funds or (B) provided the conditions for cashless exercise set forth in Section 1(d) are satisfied, by notifying the Company that this Warrant is being exercised pursuant to a Cashless Exercise (as defined in Section 1(d)). The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice with respect to less than all of the Warrant Shares shall have the same effect as cancellation of the original Warrant and issuance of a new Warrant evidencing the right to purchase the remaining number of Warrant Shares.

¹ Insert a number of shares equal to [____]% of the number of shares of common stock purchased under the Underwriting Agreement.

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Within one (1) Business Day following the date on which the Company has received each of the Exercise Notice and the Aggregate Exercise Price (or notice of a Cashless Exercise) (collectively, the “ **Exercise Delivery Documents** ”), the Company shall transmit by facsimile or electronic mail an acknowledgment of receipt of the Exercise Delivery Documents to the Holder and Continental Stock Transfer & Trust Company or the then current transfer agent for the Common Stock (the Company’s “ **Transfer Agent** ”). On or before the third (3rd) Business Day following the date on which the Company has received all of the Exercise Delivery Documents (the “ **Share Delivery Date** ”), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company (“ **DTC** ”) Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder’s or its designee’s balance account with DTC through its Deposit/Withdrawal At Custodian (“ **DWAC** ”) system, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program or the Holder does not request delivery of the Warrant Shares via DWAC, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Delivery Documents, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder’s DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be. If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than three Business Days after any exercise and at its own expense, issue a new Warrant (in accordance with Section 7(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded down to the nearest whole number. The Company shall pay any and all taxes which may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant.

(b) Exercise Price . For purposes of this Warrant, “ **Exercise Price** ” means \$[____], subject to adjustment as provided herein.

(c) Company’s Failure to Timely Deliver Securities . If the Company shall fail for any reason or for no reason to issue to the Holder within three (3) Business Days of receipt of the Exercise Delivery Documents in compliance with the terms of this Section 1, a certificate for the number of shares of Common Stock to which the Holder is entitled and register such shares of Common Stock on the Company’s share register or to credit the Holder’s balance account with DTC for such number of shares of Common Stock to which the Holder is entitled upon the Holder’s exercise of this Warrant, and if on or after such Trading Day the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of shares of Common Stock issuable upon such exercise that

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the Holder anticipated receiving from the Company (a “**Buy-In**”), then the Company shall, within three (3) Business Days after the Holder’s request and in the Holder’s discretion, either (i) pay cash to the Holder in an amount equal to the Holder’s total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the “**Buy-In Price**”), at which point the Company’s obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate, or (ii) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of shares of Common Stock, times (B) the Closing Bid Price on the date of exercise.

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary, if a registration statement covering the Warrant Shares that are the subject of the Exercise Notice (the “**Unavailable Warrant Shares**”) is not available and an exemption from registration is otherwise not available for the resale of such Unavailable Warrant Shares, the Holder may exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the “Net Number” of shares of Common Stock determined according to the following formula (a “**Cashless Exercise**”):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

- A = the total number of shares with respect to which this Warrant is then being exercised.
- B = the arithmetic average of the Closing Sale Prices of the shares of Common Stock for the five (5) consecutive Trading Days ending on the Trading Day immediately preceding the date of the Exercise Notice.
- C = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For sake of clarity, in the event that neither a registration statement nor an exemption from registration is available, there is no circumstance that requires the Company to effect a net cash settlement of the Warrant.

(e) Rule 144. For purposes of Rule 144(d) promulgated under the Securities Act, as in effect on the date hereof, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Underwriting Agreement.

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(f) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed, and all such disputes shall be resolved pursuant to Section 12.

(g) Beneficial Ownership. The Company shall not effect the exercise of this Warrant, and the Holder shall not have the right to exercise this Warrant, to the extent that after giving effect to such exercise, such Person (together with such Person's affiliates) would beneficially own in excess of [4.99/9.99]% (the "**Maximum Percentage**") of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Person and its affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant beneficially owned by such Person and its affiliates and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such Person and its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent Form 10-K, Form 10-Q, Current Report on Form 8-K or other public filing with the Securities and Exchange Commission, as the case may be, (2) a more recent public announcement by the Company or (3) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. To the extent that the limitation contained in this Section 1(g) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, and the submission of an Exercise Notice shall be deemed to be each Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. For any reason at any time, upon the written or oral request of the Holder, the Company shall within two (2) Business Days confirm to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder and its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Holder may from time to time increase or decrease the Maximum Percentage to any other percentage not in excess of 9.99% specified in such notice; *provided* that (i) any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, and (ii) any such increase or decrease will apply only to the Holder. The provisions

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of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(g) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES . The Exercise Price and the number of Warrant Shares shall be adjusted from time to time as follows:

(a) Adjustment upon Subdivision or Combination of Common Stock . If the Company at any time on or after the Pricing Date subdivides (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Pricing Date combines (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2(a) shall become effective at the close of business on the date the subdivision or combination becomes effective.

3. RIGHTS UPON DISTRIBUTION OF ASSETS . If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “ **Distribution** ”), at any time after the issuance of this Warrant, then, in each such case, any Exercise Price in effect immediately prior to the close of business on the record date fixed for the determination of holders of shares of Common Stock entitled to receive the Distribution shall be reduced, effective as of the close of business on such record date, to a price determined by multiplying such Exercise Price by a fraction of which (i) the numerator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date minus the value of the Distribution (as determined in good faith by the Company’s Board of Directors) applicable to one share of Common Stock, and (ii) the denominator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date.

4. FUNDAMENTAL TRANSACTIONS .

(a) Fundamental Transactions . The Company shall not enter into or be party to a Fundamental Transaction unless the Successor Entity assumes this Warrant in accordance with the provisions of this Section (4)(a), including agreements to deliver to each holder of Warrants in exchange for such Warrants a security of the Successor Entity evidenced

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by a written instrument substantially similar in form and substance to this Warrant, including, without limitation and if applicable, an adjusted exercise price equal to the value for the shares of Common Stock reflected by the terms of such Fundamental Transaction, and exercisable for the Substitute Consideration (defined below). Upon the occurrence of any Fundamental Transaction, and subject to the provisions of this Section 4(a), the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of the Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation (and the Holder agrees) that there shall be issued upon exercise of this Warrant at any time after the consummation of the Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had this Warrant been converted immediately prior to such Fundamental Transaction, as adjusted in accordance with the provisions of this Warrant (the “**Substitute Consideration**”). In addition to and not in substitution for any other rights hereunder, prior to the consummation of any Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a “**Corporate Event**”), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, the Substitute Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied without regard to any limitations on the exercise of this Warrant.

5. **NONCIRCUMVENTION**. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation, Bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (i) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, (ii) shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of

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Common Stock upon the exercise of this Warrant, and (iii) shall, so long as this Warrant is outstanding, take all action necessary to reserve and keep available out of its authorized and unissued shares of Common Stock, solely for the purpose of effecting the exercise of this Warrant, 100% of the number of shares of Common Stock issuable upon exercise of this Warrant then outstanding (without regard to any limitations on exercise).

6. WARRANT HOLDER NOT DEEMED A STOCKHOLDER . Except as otherwise specifically provided herein, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

7. REISSUANCE OF WARRANTS .

(a) Transfer of Warrant . If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company together with a written assignment of this Warrant in the form attached hereto as Exhibit B duly executed by the Holder or its agent or attorney, whereupon the Company will forthwith, subject to compliance with any applicable securities laws, issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 7(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 7(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant . Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 7(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants . This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 7(d)) representing in the aggregate

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the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, that no Warrants for fractional shares of Common Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 7(a) or Section 7(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant, which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

8. NOTICES. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant, including in reasonable detail a description of such action and the reason therefor. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in writing, will be mailed (a) if within the domestic United States by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, or by facsimile or (b) if delivered from outside the United States, by International Federal Express or facsimile, and (c) will be deemed given (i) if delivered by first-class registered or certified mail domestic, three business days after so mailed, (ii) if delivered by nationally recognized overnight carrier, one business day after so mailed, (iii) if delivered by International Federal Express, two business days after so mailed and (iv) if delivered by facsimile, upon electronic confirmation of receipt, and will be delivered and addressed as follows:

(a) if to the Company, to :

Opexa Therapeutics, Inc.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381
Attention: John Ginzler, Vice President–Finance
Facsimile: (281) 872-8585

with copies to :

Pillsbury Winthrop Shaw Pittman LLP
12255 El Camino Real, Suite 300
San Diego, CA 92130
Attention: Mike Hird, Esq.
Facsimile: 858-509-4010

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(b) if to the Holder, at its address on the Exercise Notice in the form attached as Exhibit A hereto, or at such other address or addresses as may have been furnished to the Company in writing.

9. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended only with the written consent of the Company and the Holder, and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only with the written consent of the Holder.

10. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York.

11. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

12. DISPUTE RESOLUTION. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile or electronic mail within two (2) Business Days of receipt of the Exercise Notice giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within three Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two (2) Business Days submit via facsimile or electronic mail (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause at its expense the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten Business Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

13. REMEDIES, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant.

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14. TRANSFER. Subject to compliance with any applicable securities laws, this Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company.

15. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) “ **Bloomberg** ” means Bloomberg Financial Markets.

(b) “ **Business Day** ” means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed.

(c) “ **Closing Bid Price** ” and “ **Closing Sale Price** ” means, for any security as of any date, the last closing bid price and last closing trade price, respectively, for such security on the Principal Market, as reported by Bloomberg, or, if the Principal Market begins to operate on an extended hours basis and does not designate the closing bid price or the closing trade price, as the case may be, then the last bid price or the last trade price, respectively, of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Principal Market is not the principal securities exchange or trading market for such security, the last closing bid price or last trade price, respectively, of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing do not apply, the last closing bid price or last trade price, respectively, of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no closing bid price or last trade price, respectively, is reported for such security by Bloomberg, the average of the bid prices, or the ask prices, respectively, of any market makers for such security as reported in the “pink sheets” by Pink Sheets LLC (formerly the National Quotation Bureau, Inc.). If the Closing Bid Price or the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Bid Price or the Closing Sale Price, as the case may be, of such security on such date shall be the fair market value as determined by the Board of Directors of the Company in the exercise of its good faith judgment. All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(d) “ **Common Stock** ” means (i) the Company’s shares of Common Stock, par value \$0.01 per share, and (ii) any share capital of the Company into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

(e) “ **Convertible Securities** ” means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

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(f) “ **Eligible Market** ” means the Principal Market, The New York Stock Exchange, Inc., The American Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Capital Market.

(g) “ **Expiration Date** ” means the date five (5) years following the Issuance Date or, if such date falls on a day other than a Business Day or on which trading does not take place on the Principal Market (a “ **Holiday** ”), the next date that is not a Holiday.

(h) “ **Fundamental Transaction** ” means that the Company shall, directly or indirectly, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Person, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company to another Person, or (iii) allow another Person to make a purchase, tender or exchange offer that is accepted by the holders of more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock purchase agreement or other business combination), (v) reorganize, recapitalize or reclassify its Common Stock, or (vi) any “person” or “group” (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock.

(i) “ **Options** ” means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(j) “ **Parent Entity** ” of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(k) “ **Person** ” means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and a government or any department or agency thereof.

(l) “ **Principal Market** ” means The NASDAQ Capital Market.

(m) “ **Successor Entity** ” means the Person (or, if determined in good faith by the Company’s Board of Directors to be appropriate, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or with which such Fundamental Transaction shall have been entered into.

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(n) “ **Trading Day** ” means any day on which the Common Stock are traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock are then traded; *provided* that “Trading Day” shall not include any day on which the Common Stock are scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock are suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time).

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

OPEXA THERAPEUTICS, INC.

By: _____
Name:
Title:

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS
WARRANT TO PURCHASE COMMON STOCK

OPEXA THERAPEUTICS, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock (“ **Warrant Shares** ”) of **Opexa Therapeutics, Inc** , a Texas corporation (the “ **Company** ”), evidenced by the attached Warrant to Purchase Common Stock (the “ **Warrant** ”). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Form of Exercise Price. The Holder intends that payment of the Exercise Price shall be made as:

_____ a “ Cash Exercise” with respect to _____ Warrant Shares; and/or
_____ a “Cashless Exercise” with respect to _____ Warrant Shares.

2. Payment of Exercise Price. In the event that the holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the holder shall pay the Aggregate Exercise Price in the sum of \$ _____ to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver _____ Warrant Shares in the name of the undersigned holder or in the name of _____ in accordance with the terms of the Warrant to the following DWAC Account Number or by physical delivery of a certificate to:

Date: _____, _____

Name of Registered Holder

By: _____
Name:
Title:

ACKNOWLEDGMENT

The Company hereby acknowledges this Exercise Notice and hereby directs Continental Stock Transfer & Trust Company to issue the above indicated number of shares of Common Stock in accordance with the Transfer Agent Instructions dated [], 2011 from the Company and acknowledged and agreed to by Continental Stock Transfer & Trust Company.

OPEXA THERAPEUTICS, INC

By: _____
Name:
Title:

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [____] all of or [____] shares of the foregoing Warrant and all rights evidenced thereby are hereby
assigned to

_____ whose address is

_____ .

Dated: _____ , _____

Holder’s Signature: _____

Holder’s Address: _____

Signature Guaranteed: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or
enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a
fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

PROSPECTUS

\$35,000,000



OPEXA THERAPEUTICS

OPEXA THERAPEUTICS, INC.

Debt Securities
Common Stock
Preferred Stock
Depositary Shares
Warrants

We may, from time to time, offer and sell debt securities, preferred stock, either separately or represented by depositary shares, common stock or warrants, either separately or in units, in one or more offerings. The debt securities, preferred stock and warrants may be convertible into or exercisable or exchangeable for common or preferred stock or debt securities. We will specify in the accompanying prospectus supplement more specific information about any such offering. The aggregate initial offering price of all securities sold under this prospectus will not exceed \$35,000,000.

We may offer these securities independently or together in any combination for sale directly to investors or through underwriters, dealers or agents. We will set forth the names of any underwriters, dealers or agents and their compensation in the accompanying prospectus supplement.

This prospectus may not be used to sell any of these securities unless accompanied by a prospectus supplement.

Our common stock is traded on NASDAQ Capital Market under the symbol "OPXA." On November 12, 2009, the last reported sales price for our common stock was \$2.09 per share. The aggregate market value of our outstanding common equity held by non-affiliates on September 16, 2009 was \$43,908,622. During the 12 calendar months prior to and including the date hereof, we have offered securities with an aggregate market value of \$8,050,000 and sold securities with an aggregate market value of \$96,400 pursuant to General Instruction I.B.6. of Form S-3.

Investing in our securities involves risks. See the section entitled “ [Risk Factors](#) ” in the accompanying prospectus supplement and in the documents we incorporate by reference in this prospectus.

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 November 23, 2009.

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You should rely only on the information incorporated by reference or provided in this prospectus, any prospectus supplement and the registration statement. 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 and any prospectus supplement, 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.

A BOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration, or continuous offering, process. Under this shelf registration process, we may, from time to time, issue and sell any combination of debt securities, preferred stock, either separately or represented by depositary shares, common stock or warrants, either separately or in units, in one or more offerings with a maximum aggregate offering price of \$35,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering and the offered securities. Any prospectus supplement may also add, update or change information contained in this prospectus. Any statement that we make in this prospectus will be modified or superseded by any inconsistent statement made by us in a prospectus supplement. The registration statement we filed with the SEC includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the SEC and any prospectus supplement, together with additional information described under the heading “Where You Can Find More Information,” before making your investment decision.

Unless the context otherwise requires, references in this prospectus and the accompanying prospectus supplement to “Opexa,” “the Company,” “we,” “us” and “our” refer to Opexa Therapeutics, Inc.

R I S K F A C T O R S

Investing in our securities involves risk. The prospectus supplement relating to a particular offering will contain a discussion of risks applicable to an investment in the securities offered. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading “Risk Factors” in the applicable prospectus supplement together with all of the other information contained in the prospectus supplement or appearing or incorporated by reference in this prospectus.

O P E X A T H E R A P E U T I C S , I N C .

Our Business

We are a biopharmaceutical company developing autologous 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 candidates is preliminary and investigative. Our product candidates are not approved by the Food and Drug Administration (FDA).

Our lead product candidate, Tovaxin[®], is an individualized T-cell therapeutic vaccine licensed from Baylor College of Medicine, which is in clinical development for the treatment for MS.

Opexa was incorporated in Texas in March 1991. Our principal executive offices are located at 2635 N. Crescent Ridge Drive, The Woodlands, Texas 77381, and our telephone number is (281) 272-933.

T-Cell Therapy

Multiple sclerosis is the result of a person’s own T-cells attacking the myelin sheath that coats the nerve cells of the central nervous system (CNS). Tovaxin consists of attenuated patient-specific myelin reactive T-cells (MRTCs) against peptides from one or more of the primary proteins on the surface of the myelin sheath (myelin basic protein (MBP), proteolipid protein (PLP) and myelin oligodendrocyte glycoprotein (MOG)). Patient-specific MRTCs are expanded in culture with specific peptides identified by our proprietary test of the patient’s peripheral blood. The cells are then attenuated, or weakened, by gamma irradiation, and returned to the patient as a subcutaneous injection. Although further testing is necessary, results from our initial human trials appear to indicate that these attenuated T-cells cause an immune response directed at the autoreactive T-cells in the patient’s body, resulting in a reduction in the level of harmful T-cells. In 2008, we completed an FDA cleared Phase IIb clinical trial

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of Tovaxin which enrolled 150-patients. The trial was entitled, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Subcutaneous Tovaxin in Subjects with Clinically Isolated Syndrome or Relapsing Remitting Multiple Sclerosis. (Tovaxin for Early Relapsing-remitting MS, “TERMS”).

The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis (RRMS) or high risk Clinically Isolated Syndrome (CIS). The study involved 2:1 randomization with 100 patients receiving Tovaxin and 50 receiving placebo. According to the study protocol, patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Top-line data from the TERMS trial is as follows:

- Annualized relapse rate (ARR) for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tovaxin as compared to placebo in the general population.
- For patients who had more active disease as indicated by an $ARR > 1$ in the year prior to the study, Tovaxin demonstrated a 55% reduction in ARR as compared to placebo; and an 87% reduction in relapse rate was observed in Tovaxin patients in this population compared to placebo during the 24 week period following the administration of the full course of treatment ($p=0.039$).
- Patients who had an $ARR > 1$ at entry demonstrated a statistically significant improvement in disability score as measured by the Expanded Disability Status Scale (EDSS) ($p=0.045$) for patients treated with Tovaxin as compared to those receiving placebo. The EDSS score is a measure of disability ranging from 0-10. In addition 28.1% of the Tovaxin patients showed an improvement in EDSS of at least one point as compared to 5.6% in the placebo group.
- Patients who had an $ARR > 1$ at entry and were treated with Tovaxin experienced an 88% reduction in brain atrophy and a 59% reduction in absolute T-2 lesion volume as compared to placebo.
- Tovaxin was safe and well tolerated with no serious adverse events related to Tovaxin treatment. The most common adverse event was injection site irritation.

Further analysis of the TERMS clinical study of 150 patients with RRMS evaluated those patients with an annualized relapse rate of one or greater than or equal to one at study entry ($ARR \geq 1$). More than 83% of the Tovaxin-treated group ($n=85$) remained relapse free at one year and the annualized relapse rate after treatment decreased to 0.20, a 42% reduction compared to placebo. The results of this expanded analysis confirm those found in the previously-reported per-protocol analysis of patients in the TERMS study with $ARR > 1$. This *post-hoc* analysis which represents 86% of the total patient population in the TERMS study was conducted to evaluate Tovaxin treatment among study patients with the same baseline disease activity that is being targeted for inclusion in the forthcoming Phase IIb study. Along with a marked reduction in relapses, 73% of the Tovaxin-treated patients with $ARR \geq 1$ showed stabilization or improvement in MS disability, including 16.5% with a sustained improvement in the Expanded Disability Status Scale (EDSS) of at least one full point. On MRI, the Tovaxin-treated group also demonstrated a reduction in brain atrophy and fewer inflammatory brain lesions that progressed to “black holes,” as compared to the placebo-treated group. Treatment with Tovaxin was well tolerated, with no serious adverse events reported in any Tovaxin-treated patient.

Tovaxin is a personalized T-cell vaccine based on a patient’s individual immunologic profile. Detailed immunology data analysis from the TERMS trial indicate that Tovaxin can successfully induce changes in T-cell reactivity to all three targeted myelin antigens implicated in the autoimmune attacks causing neurologic damage in MS. These changes appear epitope-specific, are sustained for 6 months or more, and match each patient’s Tovaxin formulation. Tovaxin is not broadly immunosuppressive, an important feature of its favorable safety profile.

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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.

Stem Cell Therapy

In August 2009, we entered into an exclusive agreement with Novartis for the further development of our novel stem cell technology. This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa. Under the terms of the agreement, Novartis acquired the stem cell technology from us and Novartis will have full responsibility for funding and carrying out all research, development and commercialization activities. To date we have received \$3.5 million from Novartis of which \$3 million was attributable to an upfront cash payment and \$0.5 million resulted from the completion of the first of two technology transfer milestones. We will receive an additional \$0.5 million technology transfer fee upon the completion of the second technology transfer milestone which is anticipated to occur within the next six months. We are also eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and we retain an option on certain manufacturing rights.

FORWARD-LOOKING STATEMENTS

When used in this prospectus, the words “expects,” “believes,” “anticipates,” “estimates,” “may,” “could,” “intends,” and similar expressions are intended to identify forward-looking statements. These statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those projected or otherwise implied by the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We will discuss many of these risks and uncertainties in greater detail in any prospectus supplement under the heading “Risk Factors.” Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in the documents we incorporate by reference into this prospectus.

These forward-looking statements speak only as of the date of this prospectus. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our 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

Unless we state otherwise in the accompanying prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate 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. Pending the application of net proceeds, we expect to invest the net proceeds in investment grade, interest-bearing securities.

DESCRIPTION OF DEBT SECURITIES

The following is a summary of the general terms of the debt securities. We will file a prospectus supplement that may contain additional terms when we issue debt securities. The terms presented here, together with the terms in a related prospectus supplement, will be a description of the material terms of the debt securities. You should also read the indenture under which the debt securities are to be issued. We have filed a form of indenture governing different types of debt securities with the SEC as an exhibit to the registration statement of which this prospectus is a part. All capitalized terms have the meanings specified in the indenture.

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We may issue, from time to time, debt securities, in one or more series. The debt securities we offer will be issued under an indenture between us and the trustee named in the indenture. These debt securities that we may issue include senior debt securities, subordinated debt securities, convertible debt securities and exchangeable debt securities. The following is a summary of the material provisions of the indenture filed as an exhibit to the registration statement of which this prospectus is a part. For each series of debt securities, the applicable prospectus supplement for the series may change and supplement the summary below.

General Terms of the Indenture

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and they may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us. For each series of debt securities, any restrictive covenants for those debt securities will be described in the applicable prospectus supplement for those debt securities.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may, for United States federal income tax purposes, be treated as if they were issued with “original issue discount,” or OID, because of interest payment and other characteristics. Special United States federal income tax considerations applicable to debt securities issued with original issue discount will be described in more detail in any applicable prospectus supplement.

You should refer to the prospectus supplement relating to a particular series of debt securities for a description of the following terms of the debt securities offered by that prospectus supplement and by this prospectus:

- the title and authorized denominations of those debt securities;
- any limit on the aggregate principal amount of that series of debt securities;
- the date or dates on which principal and premium, if any, of the debt securities of that series is payable;
- interest rates, and the dates from which interest, if any, on the debt securities of that series will accrue, and the dates when interest is payable and the maturity;
- the right, if any, to extend the interest payment periods and the duration of the extensions;
- if the amount of payments of principal or interest is to be determined by reference to an index or formula, or based on a coin or currency other than that in which the debt securities are stated to be payable, the manner in which these amounts are determined and the calculation agent, if any, with respect thereto;
- the place or places where and the manner in which principal of, premium, if any, and interest, if any, on the debt securities of that series will be payable and the place or places where those debt securities may be presented for transfer and, if applicable, conversion or exchange;
- the period or periods within which, the price or prices at which, the currency or currencies in which, and other terms and conditions upon which those debt securities may be redeemed, in whole or in part, at our option or the option of a holder of those securities, if we or a holder is to have that option;
- our obligation or right, if any, to redeem, repay or purchase those debt securities pursuant to any sinking fund or analogous provision or at the option of a holder of those securities, and the terms and

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- conditions upon which the debt securities will be redeemed, repaid or purchased, in whole or in part, pursuant to that obligation;
- the terms, if any, on which the debt securities of that series will be subordinate in right and priority of payment to our other debt;
- the denominations in which those debt securities will be issuable;
- if other than the entire principal amount of the debt securities when issued, the portion of the principal amount payable upon acceleration of maturity as a result of a default on our obligations;
- whether those debt securities will be issued in fully registered form without coupons or in a form registered as to principal only with coupons or in bearer form with coupons;
- whether any securities of that series are to be issued in whole or in part the form of one or more global securities and the depositary for those global securities;
- if other than United States dollars, the currency or currencies in which payment of principal of or any premium or interest on those debt securities will be payable;
- if the principal of or any premium or interest on the debt securities of that series is to be payable, or is to be payable at our election or the election of a holder of those securities, in securities or other property, the type and amount of those securities or other property, or the manner of determining that amount, and the period or periods within which, and the terms and conditions upon which, any such election may be made;
- the events of default and covenants relating to the debt securities that are in addition to, modify or delete those described in this prospectus;
- conversion or exchange provisions, if any, including conversion or exchange prices or rates and adjustments thereto;
- whether and upon what terms the debt securities may be defeased, if different from the provisions set forth in the indenture;
- the nature and terms of any security for any secured debt securities;
- the terms applicable to any debt securities issued at a discount from their stated principal amount; and
- any other specific terms of any debt securities.

The applicable prospectus supplement will present material United States federal income tax considerations for holders of any debt securities and the securities exchange or quotation system on which any debt securities are to be listed or quoted.

Conversion or Exchange Rights

Debt securities may be convertible into or exchangeable for shares of our equity securities or other securities. The terms and conditions of conversion or exchange will be stated in the applicable prospectus supplement. The terms will include, among others, the following:

- the conversion or exchange price;
- the conversion or exchange period;

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- provisions regarding our ability or the ability of any holder to convert or exchange the debt securities;
- events requiring adjustment to the conversion or exchange price; and
- provisions affecting conversion or exchange in the event of our redemption of the debt securities.

Consolidation, Merger or Sale

The terms of the indenture prevent us from (i) consolidating or merging with or into, or transferring or leasing all or substantially all of our assets to, any person, unless the successor corporation or person to which our assets are transferred or leased is organized under the laws of the United States, any state of the United States or the District of Columbia and it expressly assumes our obligations under the debt securities and the indenture or (ii) completing such a transaction unless immediately after completing the transaction, no event of default under the indenture, and no event that, after notice or lapse of time or both, would become an event of default under the indenture, has occurred and is continuing. When the person to whom our assets are transferred or leased has assumed our obligations under the debt securities and the indenture, we will be discharged from all our obligations under the debt securities and the indenture except in limited circumstances.

This covenant would not apply to any recapitalization transaction, a change of control affecting us or a highly leveraged transaction, unless the transaction or change of control were structured to include a merger or consolidation or transfer or lease of all or substantially all of our assets.

Events of Default

The indenture provides that the following will be “events of default” with respect to any series of debt securities:

- failure to pay interest for 30 days after the date payment is due and payable;
- failure to pay principal or premium, if any, on any debt security when due, either at maturity, upon any redemption, by declaration or otherwise and, in the case of technical or administrative difficulties, only if such default persists for a period of more than three business days;
- failure to make sinking fund payments when due and continuance of such default for a period of 30 days;
- failure to perform other covenants for 60 days after notice that performance was required;
- events in bankruptcy, insolvency or reorganization relating to us; or
- any other event of default provided in the applicable officer’s certificate, resolution of our board of directors or the supplemental indenture under which we issue a series of debt securities.

An event of default for a particular series of debt securities does not necessarily constitute an event of default for any other series of debt securities issued under the indenture. For each series of debt securities, any modifications to the above events of default will be described in the applicable prospectus supplement for those debt securities.

The indenture provides that if an event of default specified in the first, second, third, fourth or sixth bullets above occurs and is continuing, either the trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series may declare the principal amount of all those debt securities (or, in the case of discount securities or indexed securities, that portion of the principal amount as may be specified in the terms of that series) to be due and payable immediately. If an event of default specified in the fifth bullet above occurs and is continuing, then the principal amount of all those debt securities (or, in the case of discount securities or indexed securities, that portion of the principal amount as may be specified in the terms of that series) will be due and

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payable immediately, without any declaration or other act on the part of the trustee or any holder. In certain cases, holders of a majority in principal amount of the outstanding debt securities of any series may, on behalf of holders of all those debt securities, rescind and annul a declaration of acceleration.

The indenture imposes limitations on suits brought by holders of debt securities against us. Except for actions for payment of overdue principal or interest, no holder of debt securities of any series may institute any action against us under the indenture unless:

- the holder has previously given to the trustee written notice of default and continuance of such default;
- the holders of at least 25% in principal amount of the outstanding debt securities of the affected series have requested that the trustee institute the action;
- the requesting holders have offered the trustee indemnity for the reasonable expenses and liabilities that may be incurred by bringing the action;
- the trustee has not instituted the action within 60 days of the request and offer of indemnity; and
- the trustee has not received inconsistent direction by the holders of a majority in principal amount of the outstanding debt securities of the affected series.

We will be required to file annually with the trustee a certificate, signed by one of our officers, stating whether or not the officer knows of any default by us in the performance, observance or fulfillment of any condition or covenant of the indenture.

Discharge, Defeasance and Covenant Defeasance

We can discharge or decrease our obligations under the indenture as stated below.

We may discharge obligations to holders of any series of debt securities that have not already been delivered to the trustee for cancellation and that have either become due and payable or are by their terms to become due and payable, or are scheduled for redemption, within one year. We may effect a discharge by irrevocably depositing with the trustee cash or government obligations denominated in the currency of the debt securities, as trust funds, in an amount certified to be enough to pay when due, whether at maturity, upon redemption or otherwise, the principal of, and any premium and interest on, the debt securities and any mandatory sinking fund payments.

Unless otherwise provided in the applicable prospectus supplement, we may also discharge any and all of our obligations to holders of any series of debt securities at any time, which we refer to as defeasance. We may also be released from the obligations imposed by any covenants of any outstanding series of debt securities and provisions of the indenture, and we may omit to comply with those covenants without creating an event of default under the trust declaration, which we refer to as covenant defeasance. We may effect defeasance and covenant defeasance only if, among other things:

- we irrevocably deposit with the trustee cash or government obligations denominated in the currency of the debt securities, as trust funds, in an amount certified to be enough to pay at maturity, or upon redemption, the principal (including any mandatory sinking fund payments) of, and any premium and interest on, all outstanding debt securities of the series; and
- we deliver to the trustee an opinion of counsel from a nationally recognized law firm to the effect that the holders of the series of debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and that defeasance or covenant defeasance will not otherwise alter the holders' U.S. federal income tax treatment of principal, and any premium and interest payments on, the series of debt securities.

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In the case of a defeasance by us, the opinion we deliver must be based on a ruling of the Internal Revenue Service issued, or a change in U.S. federal income tax law occurring, after the date of the indenture, since such a result would not occur under the U.S. federal income tax laws in effect on that date.

Although we may discharge or decrease our obligations under the indenture as described in the two preceding paragraphs, we may not avoid, among other things, our duty to register the transfer or exchange of any series of debt securities, to replace any temporary, mutilated, destroyed, lost or stolen series of debt securities or to maintain an office or agency in respect of any series of debt securities.

Modification of the Indenture

The indenture provides that we and the trustee may enter into supplemental indentures without the consent of the holders of debt securities to, among other things:

- evidence the assumption by a successor entity of our obligations;
- add to our covenants for the benefit of the holders of debt securities, or to surrender any rights or power conferred upon us;
- add any additional events of default;
- cure any ambiguity or correct any inconsistency or defect in the indenture;
- add to, change or eliminate any of the provisions of the indenture in a manner that will become effective only when there is no outstanding debt security which is entitled to the benefit of the provision as to which the modification would apply;
- secure any debt securities;
- establish the forms or terms of debt securities of any series;
- evidence and provide for the acceptance of appointment by a successor trustee and add to or change any of the provisions of the indenture as is necessary for the administration of the trusts by more than one trustee;
- modify, eliminate or add to the provisions of the indenture as shall be necessary to effect the qualification of the indenture under the Trust Indenture Act of 1939 or under any similar federal statute later enacted, and to add to the indenture such other provisions as may be expressly required by the Trust Indenture Act; and
- make any other provisions with respect to matters or questions arising under the indenture that will not be inconsistent with any provision of the indenture as long as the new provisions do not adversely affect the interests of the holders of any outstanding debt securities of any series created prior to the modification.

The indenture also provides that we and the trustee may, with the consent of the holders of not less than a majority in aggregate principal amount of debt securities of each series of debt securities affected by such supplemental indenture then outstanding, add any provisions to, or change in any manner, eliminate or modify in any way the provisions of, the indenture or any supplemental indenture or modify in any manner the rights of the holders of the debt securities. We and the trustee may not, however, without the consent of the holder of each outstanding debt security affected thereby:

- extend the final maturity of any debt security;

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- reduce the principal amount or premium, if any;
- reduce the rate or extend the time of payment of interest;
- reduce the amount of the principal of any debt security issued with an original issue discount that is payable upon acceleration;
- change the currency in which the principal, and any premium or interest, is payable;
- impair the right to institute suit for the enforcement of any payment on any debt security when due;
- if applicable, adversely affect the right of a holder to convert or exchange a debt security; or
- reduce the percentage of holders of debt securities of any series whose consent is required for any modification of the indenture or for waivers of compliance with or defaults under the indenture with respect to debt securities of that series.

The indenture provides that the holders of not less than a majority in aggregate principal amount of the then outstanding debt securities of any series, by notice to the relevant trustee, may on behalf of the holders of the debt securities of that series waive any default and its consequences under the indenture except:

- a default in the payment of, any premium and any interest on, or principal of, any such debt security held by a nonconsenting holder; or
- a default in respect of a covenant or provision of the indenture that cannot be modified or amended without the consent of the holder of each outstanding debt security of each series affected.

Registered Global Securities and Book Entry System

The debt securities of a series may be issued in whole or in part in book-entry form and will be represented by one or more fully registered global securities. We will deposit any registered global securities with a depositary or with a nominee for a depositary identified in the applicable prospectus supplement and registered in the name of such depositary or nominee. In such case, we will issue one or more registered global securities denominated in an amount equal to the aggregate principal amount of all of the debt securities of the series to be issued and represented by such registered global security or securities. This means that we will not issue certificates to each holder.

Unless and until it is exchanged in whole or in part for debt securities in definitive registered form, a registered global security may not be transferred except as a whole:

- by the depositary for the registered global security to its nominee;
- by a nominee of the depositary to the depositary or another nominee of the depositary; or
- by the depositary or its nominee to a successor of the depositary or a nominee of the successor.

The prospectus supplement relating to a series of debt securities will describe the specific terms of the depositary arrangement involving any portion of the series represented by a registered global security. We anticipate that the following provisions will apply to all depositary arrangements for debt securities:

- ownership of beneficial interests in a registered global security will be limited to persons that have accounts with the depositary for such registered global security, these persons being referred to as “participants,” or persons that may hold interests through participants;

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- upon the issuance of a registered global security, the depositary for the registered global security will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal amounts of the debt securities represented by the registered global security beneficially owned by the participants;
- any dealers, underwriters, or agents participating in the distribution of the debt securities will designate the accounts to be credited; and
- ownership of beneficial interest in the registered global security will be shown on, and the transfer of the ownership interest will be effected only through, records maintained by the depositary for the registered global security for interests of participants, and on the records of participants for interests of persons holding through participants.

The laws of some states may require that specified purchasers of securities take physical delivery of the securities in definitive form. These laws may limit the ability of those persons to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary for a registered global security, or its nominee, is the registered owner of the registered global security, the depositary or such nominee, as the case may be, will be considered the sole owner or holder of the debt securities represented by the registered global security for all purposes under the indenture. Except as stated below, owners of beneficial interests in a registered global security:

- will not be entitled to have the debt securities represented by a registered global security registered in their names;
- will not receive or be entitled to receive physical delivery of the debt securities in the definitive form; and
- will not be considered the owners or holders of the debt securities under the relevant indenture.

Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for the registered global security and, if the person is not a participant, on the procedures of a participant through which the person owns its interest, to exercise any rights of a holder under the indenture.

We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the indenture, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take the action, and the participants would authorize beneficial owners owning through the participants to give or take the action or would otherwise act upon the instructions of beneficial owners holding through them.

We will make payments of principal and premium, if any, and interest, if any, on debt securities represented by a registered global security registered in the name of a depositary or its nominee to the depositary or its nominee, as the case may be, as the registered owners of the registered global security. Neither we nor the trustee, or any other agent of ours or the trustee will be responsible or liable for any aspect of the records relating to, or payments made on account of, beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to the beneficial ownership interests.

We expect that the depositary for any debt securities represented by a registered global security, upon receipt of any payments of principal and premium, if any, and interest, if any, in respect of the registered global security, will immediately credit participants' accounts with payments in amounts proportionate to their respective beneficial interests in the registered global security as shown on the records of the depositary. We also expect that standing customer instructions and customary practices will govern payments by participants to owners of beneficial interests in the registered global security held through the participants, as is now the case with the securities held for

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the accounts of customers in bearer form or registered in “street name.” We also expect that any of these payments will be the responsibility of the participants.

If the depositary for any debt securities represented by a registered global security is at any time unwilling or unable to continue as depositary or stops being a clearing agency registered under the Exchange Act, we will appoint an eligible successor depositary. If we fail to appoint an eligible successor depositary within 90 days, we will issue the debt securities in definitive form in exchange for the registered global security. In addition, we may at any time and in our sole discretion decide not to have any of the debt securities of a series represented by one or more registered global securities. In that event, we will issue debt securities of the series in a definitive form in exchange for all of the registered global securities representing the debt securities. The trustee will register any debt securities issued in definitive form in exchange for a registered global security in the name or names as the depositary, based upon instructions from its participants, shall instruct the trustee.

We may also issue bearer debt securities of a series in the form of one or more global securities, referred to as “bearer global securities.” We will deposit these securities with a depositary identified in the prospectus supplement relating to the series. The prospectus supplement relating to a series of debt securities represented by a bearer global security will describe the applicable terms and procedures. These will include the specific terms of the depositary arrangement and any specific procedures for the issuance of debt securities in definitive form in exchange for a bearer global security, in proportion to the series represented by a bearer global security.

Concerning the Trustee

The indenture provides that there may be more than one trustee under the indenture, each for one or more series of debt securities. If there are different trustees for different series of debt securities, each trustee will be a trustee of a trust under the indenture separate and apart from the trust administered by any other trustee under that indenture. Except as otherwise indicated in this prospectus or any prospectus supplement, any action permitted to be taken by a trustee may be taken by such trustee only on the one or more series of debt securities for which it is the trustee under the indenture. Any trustee under the indenture may resign or be removed from one or more series of debt securities. All payments of principal of, and any premium and interest on, and all registration, transfer, exchange, authentication and delivery of, the debt securities of a series will be effected by the trustee for that series at an office designated by the trustee in New York, New York.

The indenture provides that, except during the continuance of an event of default, the trustee will perform only such duties as are specifically set forth in the indenture. During the existence of an event of default, the trustee will exercise those rights and powers vested in it under the indenture and use the same degree of care and skill in its exercise as a prudent person would exercise under the circumstances in the conduct of such person’s own affairs.

If the trustee becomes a creditor of ours, the indenture places limitations on the right of the trustee to obtain payment of claims or to realize on property received in respect of any such claim as security or otherwise. The trustee may engage in other transactions. If it acquires any conflicting interest relating to any duties concerning the debt securities, however, it must eliminate the conflict or resign as trustee.

No Individual Liability of Incorporators, Stockholders, Officers or Directors

The indenture provides that no past, present or future director, officer, stockholder or employee of ours, any of our affiliates, or any successor corporation, in their capacity as such, shall have any individual liability for any of our obligations, covenants or agreements under the debt securities or the indenture.

Governing Law

The indenture and the debt securities will be governed by, and construed in accordance with, the laws of the State of New York.

D ESCRIPTION OF PREFERRED STOCK

We are authorized to issue up to 10,000,000 shares of preferred stock, no par value per share. As of November 13, 2009, no shares of preferred stock were issued and outstanding. We may issue preferred stock, in series, with such designations, powers, preferences and other rights and qualifications, limitations or restrictions as our board of directors may authorize, without further action by our stockholders, including:

- the distinctive designation of each series and the number of shares that will constitute the series;
- the voting rights, if any, of shares of the series and the terms and conditions of the voting rights;
- the dividend rate on the shares of the series, the dates on which dividends are payable, any restriction, limitation or condition upon the payment of dividends, whether dividends will be cumulative, and the dates from and after which dividends shall accumulate;
- the prices at which, and the terms and conditions on which, the shares of the series may be redeemed, if the shares are redeemable;
- the terms and conditions of a sinking or purchase fund for the purchase or redemption of shares of the series, if such a fund is provided;
- any preferential amount payable upon shares of the series in the event of the liquidation, dissolution or winding up of, or upon the distribution of any of our assets; and
- the prices or rates of conversion or exchange at which, and the terms and conditions on which, the shares of the series may be converted or exchanged into other securities, if the shares are convertible or exchangeable.

The particular terms of any series of preferred stock, and the transfer agent and registrar for that series, will be described in a prospectus supplement. All preferred stock offered, when issued, will be fully paid and nonassessable. Any material United States federal income tax consequences and other special considerations with respect to any preferred stock offered under this prospectus will also be described in the applicable prospectus supplement.

D ESCRIPTION OF DEPOSITARY SHARES

The following description of the depositary shares does not purport to be complete and is subject to and qualified in its entirety by the relevant deposit agreement and the depositary receipts with respect to the depositary shares relating to any particular series of preferred stock. You should read these documents as they, and not this description, will define your rights as a holder of depositary shares. Forms of these documents will be filed with the SEC in connection with the offering of depositary shares.

General

If we elect to offer fractional interests in shares of preferred stock, we will provide for the issuance by a depositary to the public of receipts for depositary shares. Each depositary share will represent fractional interests of preferred stock. We will deposit the shares of preferred stock underlying the depositary shares under a deposit agreement between us and a bank or trust company selected by us. The bank or trust company must have its principal office in the United States and a combined capital and surplus of at least \$50 million. The depositary receipts will evidence the depositary shares issued under the deposit agreement.

The deposit agreement will contain terms applicable to the holders of depositary shares in addition to the terms stated in the depositary receipts. Each owner of depositary shares will be entitled to all the rights and preferences of the preferred stock underlying the depositary shares in proportion to the applicable fractional interest in the underlying shares of preferred stock. The depositary will issue the depositary receipts to individuals

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purchasing the fractional interests in shares of the related preferred stock according to the terms of the offering described in a prospectus supplement.

Dividends and Other Distributions

The depositary will distribute all cash dividends or other cash distributions received for the preferred stock to the entitled record holders of depositary shares in proportion to the number of depositary shares that the holder owns on the relevant record date. The depositary will distribute only an amount that can be distributed without attributing to any holder of depositary shares a fraction of one cent. The depositary will add the undistributed balance to and treat it as part of the next sum received by the depositary for distribution to holders of depositary shares.

If there is a non-cash distribution, the depositary will distribute property received by it to the entitled record holders of depositary shares, in proportion, insofar as possible, to the number of depositary shares owned by the holders, unless the depositary determines, after consultation with us, that it is not feasible to make such distribution. If this occurs, the depositary may, with our approval, sell such property and distribute the net proceeds from the sale to the holders. The deposit agreement also will contain provisions relating to how any subscription or similar rights that we may offer to holders of the preferred stock will be available to the holders of the depositary shares.

Conversion, Exchange, Redemption and Liquidation

If any series of preferred stock underlying the depositary shares may be converted or exchanged, each record holder of depositary receipts will have the right or obligation to convert or exchange the depositary shares represented by the depositary receipts.

The terms on which the depositary shares relating to the preferred stock of any series may be redeemed, and any amounts distributable upon our liquidation, dissolution or winding up, will be described in the relevant prospectus supplement.

Voting

When the depositary receives notice of a meeting at which the holders of the preferred stock are entitled to vote, the depositary will mail the particulars of the meeting to the record holders of the depositary shares. Each record holder of depositary shares on the record date may instruct the depositary on how to vote the shares of preferred stock underlying the holder's depositary shares. The depositary will try, if practical, to vote the number of shares of preferred stock underlying the depositary shares according to the instructions. We will agree to take all reasonable action requested by the depositary to enable it to vote as instructed.

Amendments

We and the depositary may agree to amend the deposit agreement and the depositary receipt evidencing the depositary shares. Any amendment that (a) imposes or increases certain fees, taxes or other charges payable by the holders of the depositary shares as described in the deposit agreement or that (b) otherwise prejudices any substantial existing right of holders of depositary shares, will not take effect until 30 days after the depositary has mailed notice of the amendment to the record holders of depositary shares. Any holder of depositary shares that continues to hold its shares at the end of the 30-day period will be deemed to have agreed to the amendment.

Termination

We may direct the depositary to terminate the deposit agreement by mailing a notice of termination to holders of depositary shares at least 30 days prior to termination. In addition, a deposit agreement will automatically terminate if:

- the depositary has redeemed all related outstanding depositary shares, or

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- we have liquidated, terminated or wound up our business and the depositary has distributed the preferred stock of the relevant series to the holders of the related depositary shares.

Payment of Fees and Expenses

We will pay all fees, charges and expenses of the depositary, including the initial deposit of the preferred stock and any redemption of the preferred stock. Holders of depositary shares will pay transfer and other taxes and governmental charges and any other charges as are stated in the deposit agreement for their accounts.

Resignation and Removal of Depositary

At any time, the depositary may resign by delivering notice to us, and we may remove the depositary. Resignations or removals will take effect upon the appointment of a successor depositary and its acceptance of the appointment. The successor depositary must be appointed within 60 days after delivery of the notice of resignation or removal and must be a bank or trust company having its principal office in the United States and having a combined capital and surplus of at least \$50 million.

Reports

The depositary will forward to the holders of depositary shares all reports and communications from us that are delivered to the depositary and that we are required by law, the rules of an applicable securities exchange or our restated certificate of incorporation to furnish to the holders of the preferred stock. Neither we nor the depositary will be liable if the depositary is prevented or delayed by law or any circumstances beyond its control in performing its obligations under the deposit agreement. The deposit agreement limits our obligations and the depositary's obligations to performance in good faith of the duties stated in the deposit agreement. Neither we nor the depositary will be obligated to prosecute or defend any legal proceeding connected with any depositary shares or preferred stock unless the holders of depositary shares requesting us to do so furnish us with satisfactory indemnity. In performing our obligations, we and the depositary may rely upon the written advice of our counsel or accountants, on any information that competent people provide to us and on documents that we believe are genuine.

DESCRIPTION OF COMMON STOCK

Common Stock

This section describes the general terms and provisions of the shares of our common stock, par value \$0.01 per share. This description is only a summary. Our amended and restated articles of incorporation 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 amended and restated articles of incorporation 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."

General . We are authorized to issue up to 100,000,000 shares of common stock. As of November 11, 2009, there were 12,918,222 shares of common stock issued and outstanding.

Voting Rights . Each share of common stock is entitled to one vote per share for the election of directors and on all other matters submitted to a vote of stockholders. There are no cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in the election of directors can elect all of the directors standing for election, if they so choose.

Dividends . Subject to the rights of holders of the any other securities subsequently issued, holders of the common stock are entitled to receive dividends when and as declared by our Board of Directors out of funds legally available. We have not paid any dividends since our inception and have no intention to pay any dividends in the foreseeable future. Any future dividends would be subject to the discretion of the Board of Directors and would depend on, among other things, our future earnings, the operating and financial condition, our capital requirements, and general business conditions.

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Other Rights . Common stockholders do not have preemptive rights or other rights to subscribe for additional shares, and the common stock is not subject to conversion or redemption. 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. In the event of liquidation, the holders of common stock will share equally in any balance of corporate assets available for distribution to them.

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.

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of debt securities, preferred stock, common stock, depositary shares, or any combination thereof. We may issue warrants independently or together with any other securities offered by any prospectus supplement and may be attached to or separate from the other offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into by us with a warrant agent. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. Further terms of the warrants and the applicable warrant agreements will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement relating to any particular issue of warrants will describe the terms of the warrants, including, as applicable, the following:

- the title of the warrants;
- the aggregate number of the warrants;
- the price or prices at which the warrants will be issued;
- the designation, terms and number of shares of debt securities, preferred stock or common stock purchasable upon exercise of the warrants;
- the designation and terms of the offered securities, if any, with which the warrants are issued and the number of the warrants issued with each offered security;
- the date, if any, on and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;
- the price at which each share of debt securities, preferred stock or common stock purchasable upon exercise of the warrants may be purchased;
- the date on which the right to exercise the warrants shall commence and the date on which that right shall expire;
- the minimum or maximum amount of the warrants which may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- a discussion of certain federal income tax considerations; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

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We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

PLAN OF DISTRIBUTION

Pursuant to General Instruction I.B.6. of Form S-3, we are permitted to utilize the registration statement of which this prospectus forms a part to sell a maximum amount of securities equal to one-third of the aggregate market value of the outstanding voting and non-voting common equity held by our non-affiliates in any 12-month period. We may, from time to time, offer the securities registered hereby up to this maximum amount.

We may sell the securities offered by this prospectus to one or more underwriters or dealers for public offering and sale by them or to investors directly or through agents. The accompanying prospectus supplement will set forth the terms of the offering and the method of distribution and will identify any firms acting as underwriters, dealers or agents in connection with the offering, including:

- the name or names of any underwriters, dealers or agents;
- the purchase price of the securities and the proceeds to us from the sale;
- any underwriting discounts and other items constituting compensation to underwriters, dealers or agents;
- any public offering price;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities offered in the prospectus supplement may be listed.

Only those underwriters identified in such prospectus supplement are deemed to be underwriters in connection with the securities offered in the prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, or at prices determined as the applicable prospectus supplement specifies. The securities may be sold through a rights offering, forward contracts or similar arrangements. In connection with the sale of the securities, underwriters, dealers or agents may be deemed to have received compensation from us in the form of underwriting discounts or commissions and also may receive commissions from securities purchasers for whom they may act as agent. Underwriters may sell the securities to or through dealers, and the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agent. Some of the underwriters, dealers or agents who participate in the securities distribution may engage in other transactions with, and perform other services for, us or our subsidiaries in the ordinary course of business.

We will provide in the applicable prospectus supplement information regarding any underwriting discounts or other compensation that we pay to underwriters or agents in connection with the securities offering, and any discounts, concessions or commissions which underwriters allow to dealers. Underwriters, dealers and agents participating in the securities distribution may be deemed to be underwriters, and any discounts and commissions they receive and any profit they realize on the resale of the securities may be deemed to be underwriting discounts and commissions under the Securities Act of 1933. Underwriters and their controlling persons, dealers and agents may be entitled, under agreements entered into with us, to indemnification against and contribution toward specific civil liabilities, including liabilities under the Securities Act.

The securities may or may not be listed on a national securities exchange. In connection with an offering, the underwriters may purchase and sell securities in the open market. These transactions may include short sales,

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stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of securities than they are required to purchase in an offering. Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of the securities while an offering is in progress. The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the underwriters have repurchased securities sold by or for the account of that underwriter in stabilizing or short-covering transactions. These activities by the underwriters may stabilize, maintain or otherwise affect the market price of the securities. As a result, the price of the securities may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time.

L EGAL MATTERS

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

E XPERTS

The financial statements of Opexa as of December 31, 2008 and 2007 and for the year ended December 31, 2008, 2007 and 2006 incorporated in this prospectus by reference to Opexa's Annual Report on Form 10-K for the year ended December 31, 2008, as amended, have been audited by Malone & Bailey, PC, an independent registered public accounting firm, and are incorporated in reliance upon their report dated April 14, 2009, given upon such firm's authority as experts in auditing and accounting.

W HERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC under the Securities Act of 1933. 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 address of that site on the world wide web is <http://www.sec.gov>. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

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, 2008, as amended by our Form 10-K/A filed on May 18, 2009;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2009, June 30, 2009 and September 30, 2009;
- our Current Reports on Form 8-K filed January 20, 2009, February 23, 2009, March 5, 2009, March 17, 2009, April 16, 2009, April 24, 2009, May 15, 2009, June 9, 2009, August 7, 2009, August 10, 2009, August 13, 2009, September 10, 2009, November 4, 2009, November 5, 2009 and November 13, 2009; and

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- 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 also incorporate by reference all additional documents that we file with the SEC under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part and the effectiveness of the registration statement, as well as between the date of this prospectus and the termination of any offering of securities offered by this prospectus. 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.

You may request a copy of any or all of the documents incorporated by reference but not delivered with this prospectus, at no cost, by writing or telephoning us at the following address and number: Investor Relations, Opexa Therapeutics, Inc., 2635 N. Crescent Ridge Drive, The Woodlands, Texas 77381, telephone (281) 272-9331. We will not, however, send exhibits to those documents, unless the exhibits are specifically incorporated by reference in those documents. We also maintain a website at <http://www.opexatherapeutics.com>. However, the information on our website is not part of this prospectus.

* * *

[_____] Shares of Common Stock



OPEXA THERAPEUTICS

PROSPECTUS SUPPLEMENT

Sole Book-Running Manager

L AZARD C APITAL M ARKETS

February __, 2011
