

OPEXA THERAPEUTICS, INC.

FORM POS AM

(Post-Effective Amendment to Registration Statement)

Filed 09/25/09

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**POST-EFFECTIVE AMENDMENT NO. 1
TO
FORM SB-2
ON
FORM S-3 /A**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

OPEXA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Texas
(State or Other Jurisdiction of
Incorporation or Organization)

76-0333165
(I.R.S. Employer Identification Number)

**2635 N. Crescent Ridge Drive
The Woodlands, Texas 77381
(281) 272-9331**

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

**Neil K. Warma
2635 N. Crescent Ridge Drive
The Woodlands, Texas 77381
(281) 272-9331**

(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent for Service)

**Copy to :
Michael C. Blaney
Vinson & Elkins L.L.P.
1001 Fannin, Suite 2300
Houston, TX 77002
(713) 758-2222**

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box: ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(Do not check if smaller reporting company)

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

EXPLANATORY NOTE

This Post-Effective Amendment No. 1 to Form SB-2 on Form S-3 /A (this “Post-Effective Amendment”) is being filed to update our registration statement on Form SB-2 (Registration No. 333-147167) (the “Registration Statement”), which was previously declared effective by the Securities and Exchange Commission on February 13, 2008, to incorporate by reference certain filings we have made under the Securities Exchange Act of 1934, as amended. No additional securities are being registered under this Post-Effective Amendment. We consummated the sale of 3,500,000 shares of common stock and 3,500,000 Series E Warrants on February 13, 2008. Subsequently the underwriter exercised its over allotment option and we sold an additional 525,000 Series E Warrants. Pursuant to this Registration Statement we are continuing to offer shares of common stock issuable upon exercise of all of the Series E Warrants. All applicable registration fees were paid at the time of the original filing of the Registration Statement.

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

SUBJECT TO COMPLETION, DATED SEPTEMBER 25 , 2009

PROSPECTUS



OPEXA THERAPEUTICS

Opexa Therapeutics, Inc.

3,500,000 Shares of Common Stock
4,025,000 Series E Warrants to Purchase One Share of Common Stock
4,025,000 Shares of Common Stock Issuable Upon Exercise of the Series E Warrants

We are offering 3,500,000 shares of common stock and Series E Warrants to purchase 4,025,000 shares of common stock at an exercise price of \$2.00. We are offering the common stock and warrants separately and not as a combined unit. This prospectus also covers the offer and sale of 4,025,000 shares of our common stock issuable upon exercise of the Series E Warrants.

Our common stock is currently traded on the NASDAQ Capital Market under the symbol "OPXA." The Series E Warrants are currently traded on the NASDAQ Capital Market under the symbol "OPXAW." On September 23 , 2009, the reported closing price per share of our common stock was \$3.89 and the reported closing price of the Series E Warrants was \$1.54 .

The aggregate market value of our outstanding voting common stock on September 17, 2009 was \$39.3 million. We do not have any non-voting stock outstanding. During the twelve months prior to the date of this prospectus, we have offered \$8.05 million of securities pursuant to General Instruction I.B.6.

Investing in our common stock involves a high degree of risk. You should read carefully this entire prospectus, including the section captioned "Risk Factors" beginning on page 5, before making a decision to purchase our stock.

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

This prospectus is dated , 2009.

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You should rely only on the information contained in or incorporated by reference into this prospectus. We have not authorized any dealer or other person to provide you with additional or different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which it relates and is not an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make an offer or solicitation in that jurisdiction. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process or continuous offering process. Under this shelf registration process, we may, from time to time, sell the securities described in this prospectus in one or more offerings. This prospectus provides you with a description of the securities that may be offered by us. Each time we sell securities, we are required to provide you with this prospectus and, in certain cases, a prospectus supplement containing specific information about us and the terms of the offering. Any prospectus supplement may add, update, or change information in this prospectus. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the information in that prospectus supplement.

Additional information, including our financial statements and the notes thereto, is incorporated in this prospectus by reference to our reports filed with the SEC. Please read “Incorporation of Certain Information by Reference” and “Where You Can Find More Information.” You are urged to read this prospectus carefully, including the information set forth under “Risk Factors,” and our SEC reports in their entirety before investing in our securities.

Unless the context requires otherwise or unless otherwise noted, all references in this prospectus or any accompanying prospectus supplement to “Opexa,” “Company,” “our,” “us” or “we” are to Opexa Therapeutics, Inc. and its subsidiaries.

PROSPECTUS SUMMARY

The following summary does not contain all the information that may be important to you and is qualified in its entirety by more detailed information appearing elsewhere in, or incorporated by reference into, this prospectus. You should read the entire prospectus, paying particular attention to the risks referred to under the heading “Risk Factors,” request from us all additional public information that you wish to review relating to us and complete your own examination of us before making an investment decision.

Our Business

We are a biopharmaceutical company developing autologous cellular therapies with the potential to treat major illnesses, including multiple sclerosis (MS). This therapy is 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, Tovaxin®, is an individualized T-cell therapeutic vaccine licensed from Baylor College of Medicine, which is in clinical development for the treatment for MS.

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 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 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 patients with an annualized relapse rate of one or greater at study entry (ARR≥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≥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.

Other Opportunities

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

Principal Executive Offices

Our principal executive offices are located at 2635 N. Crescent Ridge Drive, The Woodlands, Texas 77381.

THE OFFERING

Securities Offered:	3,500,000 shares of our common stock; 4,025,000 Series E Warrants to purchase a share of our common stock; and 4,025,000 shares of common stock issuable upon exercise of the Series E Warrants.
Series E Warrant Terms:	Exercisable upon issuance and until the five year anniversary of the issuance, at an initial exercise price per share equal to \$2.00. Warrants may be redeemed, in whole and not in part, at a price of \$.01 per warrant upon 30 days advance notice, if the last sales price of the common stock equals or exceeds 200% of the then exercise price for 20 consecutive days.
Shares of common stock to be outstanding after this offering:	12,737,926 shares
Warrants and options to be outstanding after this offering:	12,868,699 warrants and options
Common Stock NASDAQ Capital Market Symbol:	OPXA.
Warrant NASDAQ Capital Market Symbol:	OPXAW.
Over-Allotment Option:	525,000 shares and 525,000 Series E Warrants.
Use of Proceeds:	We intend to use the net proceeds of this offering to conduct our clinical studies, fund research and development projects and corporate purposes, including working capital needs. Pending these uses, the net proceeds will be invested in an interest-bearing money market account with a financial institution.
Risk Factors:	See “Risk Factors” for a discussion of the factors you should carefully consider before deciding to invest in our common stock.

The number of shares of our common stock to be outstanding after this offering is based on 12,737,926 shares of common stock outstanding as of September 25, 2009, and excludes:

- 1,736,634 shares of common stock issuable upon the exercise of outstanding options issued pursuant to our current stock option plan;
- 1,110,548 shares issuable upon the exercise of our Series C Warrants;
- 2,300,000 shares issuable upon the exercise of warrants issued in April, 2006;
- 4,025,000 shares of common stock issuable upon the exercise of Series E Warrants offered under this prospectus;
- 1,530,902 shares of common stock issuable upon the exercise of our Series F Warrants;
- 1,414,140 shares of common stock issuable upon the exercise of our Series G Warrants;
- 2,604,000 shares of common stock issuable upon conversion of our 10% Convertible Promissory Notes issued April 14, 2009 and May 14, 2009;
- 51,475 shares issuable upon exercise of other warrants and options issued to brokers in connection with various offerings; and
- 700,000 shares of common stock that have been reserved for issuance upon exercise of the underwriters’ warrants, as described in the “Underwriting” section of this prospectus.

The number of our warrants and options to be outstanding after this offering is based on 11,132,065 warrants and broker options and 1,736,634 options outstanding as of September 25, 2009 but excluding our 10% Convertible Promissory Notes. Each warrant is exercisable for one share of common stock. The exercise prices of our outstanding warrants and options range from \$0.18 to \$40.00, with a weighted average exercise price of \$5.31.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in or incorporated by reference into this prospectus, as well as other written and oral statements made or incorporated by reference from time to time by us and our representatives in other reports, filings with the SEC, press releases, conferences, or otherwise, may be deemed to be forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Although we believe that the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to have been correct. When used in this prospectus, the words “anticipate,” “believe,” “estimate,” “expect,” “may,” and similar expressions, as they relate to us and our management, identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are made subject to certain risks and uncertainties that could cause actual results to differ materially from those stated. Risks and uncertainties that could cause or contribute to such differences include, without limitation, those discussed in the section entitled “Risk Factors” included in this prospectus and elsewhere in or incorporated by reference into this prospectus, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2009 and June 30, 2009, our subsequent SEC filings and those factors summarized below:

- our need of additional capital;
- our history of operating losses;
- the early stage of development of our products;
- government regulation of our product candidates;
- our ability to meet our obligations under our license agreement;
- our lack of sufficient facilities to manufacture our future T-cell therapies;
- our ability to obtain patents and other proprietary rights;
- the reception of our product candidates by the health care community; and
- the limited market for our securities.

Other factors besides those described in this prospectus, any prospectus supplement or the documents we incorporate by reference herein could also affect our actual results. These forward-looking statements are largely based on our expectations and beliefs concerning future events, which reflect estimates and assumptions made by our management. These estimates and assumptions reflect our best judgment based on currently known market conditions and other factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control.

Although we believe our estimates and assumptions to be reasonable, they are inherently uncertain and involve a number of risks and uncertainties that are beyond our control. Our assumptions about future events may prove to be inaccurate. We caution you that the forward-looking statements contained in this prospectus are not guarantees of future performance, and we cannot assure you that those statements will be realized or the forward-looking events and circumstances will occur. All forward-looking statements speak only as of the date of this prospectus. We do not intend to publicly update or revise any forward-looking statements as a result of new information, future events or otherwise, except as required by law. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

RISK FACTORS

Your investment in the shares of our common stock and Series E Warrants involves significant risks. You should carefully consider the important factors set forth in the documents incorporated by reference in this prospectus and any accompanying prospectus supplement, including the risk factors incorporated herein by reference from our Annual Report on Form 10-K for the year ended December 31, 2008 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2009 and June 30, 2009, before investing in our common stock. Any of these risks could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the price of our common stock and the value of your investment in us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$6.4 million (or \$7.4 million if the underwriter exercises its over-allotment option in full) after deducting underwriting discounts and commissions and estimated offering expenses that we will pay, assuming no proceeds from warrants being issued.

Previously, we used some of the net proceeds of our sales of common stock and the associated warrants in this offering to (1) complete the Tovaxin Phase IIb clinical study, (2) initiate the second year open label extension study being offered to patients who complete the Phase IIb study and (3) fund working capital and for other general corporate purposes. We intend to use the net proceeds received from the sale of common stock upon exercise of the warrants, if any, to (1) fund the further development of Tovaxin, our lead therapy for the treatment of MS and (2) fund working capital and for other general corporate purposes. We expect the proceeds will fund our operations into 2011. We will be required to raise additional capital to fund the clinical development of Tovaxin and/or curtail certain activities related to the Tovaxin clinical programs. Pending these uses, the net proceeds will be invested in an interest-bearing money market account with a financial institution.

UNDERWRITING

In accordance with the terms and conditions contained in the underwriting agreement, we have agreed to sell to each of the underwriters named below for which MDB Capital Group LLC is acting as the representative, severally, and not jointly, and each has agreed to purchase from us on a firm commitment basis the number of the shares of our common stock and of the Series E Warrants offered in this offering set forth opposite their respective names below:

Underwriters	Number of Shares	Number of Warrants
MDB Capital Group LLC	2,250,000	2,587,500
GunnAllen Financial, Inc.	1,250,000	1,437,500
Total	<u>3,500,000</u>	<u>4,025,000</u>

A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus forms a part.

We have been advised by the representative of the underwriters that the underwriters propose to offer shares of our common stock and Series E Warrants directly to the public at the public offering prices set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering prices less a selling concession not in excess of \$0.14 per share and \$0.0105 per common stock purchase warrant.

The underwriting agreement provides that the underwriters' obligations to purchase shares of our common stock and Series E Warrants are subject to conditions contained in the underwriting agreement. The underwriters are obligated to purchase and pay for all of the common stock and Series E Warrants offered by this prospectus, other than those covered by the over-allotment option, if any of these securities are purchased

No action has been taken by us or the underwriters that would permit a public offering of the shares of our common stock and Series E Warrants included in this offering in any jurisdiction where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus and any other offering material or advertisements in connection with the offer and sales of any of our common stock and warrants be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of our common stock and Series E Warrants and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy any of our common stock or Series E Warrants included in this offering in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount to be paid to the underwriters by us.

	Without Over-Allotment	With Over-Allotment
Underwriting discount to be paid to the underwriters by us for the common stock	\$ 700,000	\$ 805,000
Underwriting discount to be paid to the underwriters by us for the Series E Warrants	\$ 52,500	\$ 60,375

We have agreed to pay to the underwriters a non-accountable expense allowance equal to 1% of the gross proceeds from the sale of the shares of common stock and Series E Warrants offered by us (excluding the over-allotment). We have also agreed to pay all expenses in connection with qualifying the shares offered hereby under the laws of the states designated by the underwriters. We estimate the expenses payable by us for this offering to be \$827,750, including the underwriting discount, or \$951,913 if the underwriters' over-allotment option is exercised in full.

Over-Allotment Option

We have granted to the underwriters an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to an additional 525,000 shares of our common stock and 525,000 Series E Warrants at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. The representative may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of our common stock or Series E Warrants are purchased pursuant to the over-allotment option, the underwriters will offer these additional shares and Series E Warrants on the same terms as those on which the other shares and Series E Warrants are being offered hereby.

Determination of Offering Price

The public offering prices of the common stock and Series E Warrants were negotiated between us and the representative of the underwriters, based on the trading prior to the offering, among other things. Other factors considered in determining the price of the securities include the history and prospects of the company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-Up Agreements

We will agree, for a period of 180 days from the date of this prospectus, subject to certain exceptions, not, to offer, sell, contract to sell, pledge or otherwise dispose of, enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) or file (or participate in the filing of) a registration statement with the Securities and Exchange Commission, or the SEC, in respect of, any shares of capital stock of the Company or any securities convertible into, or exercisable or exchangeable for such capital stock, for the Company's account, without the prior written consent of MDB Capital Group LLC. Certain of our executive officers and directors will agree to substantially similar terms for a period of 180 days pursuant to individual lock-up agreements. The foregoing restrictions on sales will not apply to our ability to sell securities to the underwriter pursuant to the underwriting agreement. In addition, the foregoing restrictions will not apply to our ability to issue our common stock pursuant to our existing stock option and employee stock purchase plans or under outstanding securities convertible into or exercisable for common stock.

Indemnification

We will agree to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in over-allotment, stabilizing transactions, syndicate covering transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Over-allotment involves sales by the underwriter of shares and warrants in excess of the number of shares and warrants the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares and warrants over-allotted by an underwriter is not greater than the number of shares and warrants that it may purchase in the over-allotment option. In a naked short position, the number of shares and warrants involved is greater than the number of shares and warrants in the over-allotment option. The underwriter may close out any short position by either exercising its over-allotment option and/or purchasing shares and warrants in the open market.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Syndicate covering transactions involve purchases of the common stock and warrants in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares and warrants to close out the short position, the underwriter will consider, among other things, the price of shares and warrants available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If an underwriter sells more shares and warrants than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares and warrants in the open market. A naked short position is more likely to be created if an underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit an underwriter to reclaim a selling concession from a syndicate member when the shares and warrants originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock and warrants or preventing or retarding a decline in the market price of the common stock or warrants. As a result, the price of the common stock or warrants may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ Capital Market, in the case of the common stock or of the warrants, or otherwise and, if commenced, may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock or warrants. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Passive Market Making

In connection with the offering, the underwriters and selling group members may engage in passive market making transactions in the common stock and Series E Warrants on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act during the period before the commencement of offers or sales of common stock and Series E Warrants and extending through the completion of distribution. A passive market maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market maker's bid, that bid must be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares and Series E Warrants for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations.

Other than the prospectus in electronic format, the information on an underwriter's or a selling group member's website and any information contained in any other website maintained by the underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

Underwriter's Warrants

We have agreed to issue to the underwriters warrants to purchase up to a total each of 350,000 shares of common stock and of 350,000 Series E Warrants. The warrants will be exercisable at an exercise price of \$2.40 per share and \$0.18 per warrant. The underwriters' warrants and the shares and Series E Warrants underlying the warrants may not be sold, transferred, assigned, pledged or hypothecated for a period of one year from the date of this prospectus, except to officers of the underwriters and members of the selling group and/or their officers and partners. The exercise prices and number of shares and Series E Warrants issuable upon exercise of the underwriters' warrants may be adjusted in certain circumstances including in the event of a stock dividend, or our recapitalization, reorganization, merger or consolidation.

Relationships

In October 2005, we engaged MDB Capital Group LLC as placement agent for a private financing. In connection with the financing completed April 2006, MDB Capital Group LLC acquired 200,000 shares of the Company's common stock and a Warrant to purchase 100,000 shares of the Company's common stock, and received \$1,723,300 for its services and a three year warrant to purchase 208,330 shares of our common stock at \$5.00 per share.

The underwriter's compensation in connection with this offering is limited to the fees and expenses described above under "Commissions and Expenses" and to its warrants as described above under "Underwriter's Warrants."

We have no other arrangements with any of the underwriters following completion of this offering. The underwriters may, however, from time to time, engage in transactions with or perform services for us in the ordinary course of its business.

LEGAL MATTERS

The validity of the common stock offered by this prospectus was passed upon for us by Vinson & Elkins L.L.P., Houston, Texas.

EXPERTS

The consolidated financial statements for the years ended December 31, 2008, December 31, 2007 and December 31, 2006 included in this prospectus have been audited by Malone & Bailey, PC, independent registered public accounting firm, as stated in their report appearing herein.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We incorporate by reference information into this prospectus, which means that we disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information contained expressly in this prospectus. Any information that we file under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, and that is deemed "filed," with the SEC will automatically update and supersede this information. You should rely only on the information contained in or incorporated by reference in this prospectus and in any applicable prospectus supplement. In the event the information set forth in a prospectus supplement differs in any way from the information set forth in this prospectus, you should rely on the information set forth in the prospectus supplement. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the document. Our business, financial condition, results of operations and prospects may have changed since that date.

The following documents we filed with the SEC pursuant to the Exchange Act are specifically incorporated herein by reference:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, as amended by our Form 10-K/A filed on May 18, 2009 ;
- Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2009;
- Our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2009;
- Our Current Reports on Form 8-K filed with the Commission on 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 and September 10, 2009; and
- The description of our shares of common stock contained in our Registration Statement on Form 8-A filed with the SEC on August 30, 2006.

You may request a copy of these filings at no cost by writing or telephoning us at the following address and telephone number:

Opexa Therapeutics, Inc.
Investor Relations
2635 N. Crescent Ridge Drive
The Woodlands, Texas 77381
(281) 272-9331

We also maintain a website at <http://www.opexatherapeutics.com>. However, the information on our website is not part of this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the SEC. In addition, we have filed with the SEC a Post-Effective Amendment No.1 to Form SB-2 on Form S-3 under the Securities Act with respect to the common stock offered hereby. This prospectus constitutes a part of the registration statement, and it does not contain all of the information in the registration statement, as certain portions have been omitted in accordance with the rules and regulations of the SEC. For further information with respect to our company and this offering, we refer you to the registration statement and exhibits filed as part of it.

You may inspect the documents we file with the SEC, without charge, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any portion of such documents from the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, upon payment of the prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also access such material electronically by means of the SEC's home page on the Internet at <http://www.sec.gov>.

Certain information about us may also be obtained from our website at <http://www.opexatherapeutics.com>. Information on our website does not constitute a part of this prospectus.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All amounts are estimates except the Securities and Exchange Commission ("SEC") registration fee.

SEC Registration Fee	\$	1,346 *
FINRA Filing Fee	\$	4,884 *
Nasdaq Listing Fee		5,000 *
Printing Costs	\$	100,000
Legal Fees and Expenses	\$	200,000
Accounting Fees and Expenses	\$	80,000
Transfer Agent and Registrar Fees	\$	5,000
Miscellaneous	\$	25,000
Total	\$	<u>421,230</u>

* Previously paid

Item 15. Indemnification of Directors and Officers.

Opexa Therapeutics, Inc. (the "Company") has the authority under Articles 2.02a(16) and 2.02-1 of the Texas Business Corporation Act ("TBCA") to indemnify its directors and officers to the extent provided for in such statute. The TBCA provides, in part, that a corporation may indemnify a director or officer or other person who was, is or is threatened to be made a named defendant or respondent in a proceeding because such person is or was a director, officer, employee or agent of the corporation, if it is determined that such person: (1) conducted himself in good faith; (2) reasonably believed, in the case of conduct in his official capacity as a director or officer of the corporation, that his conduct was in the corporation's best interest and, in all other cases, that his conduct was at least not opposed to the corporation's best interests; and (3) in the case of any criminal proceeding, had no reasonable cause to believe that his conduct was unlawful.

A corporation may indemnify a person under the TBCA against judgments, penalties, including excise and similar taxes, fines, settlement, unreasonable expenses actually incurred by the person in connection with the proceeding. If the person is found liable to the corporation or is found liable on the basis that personal benefit was improperly received by the person, the indemnification is limited to reasonable expenses actually incurred by the person in connection with the proceeding, and shall not be made in respect of any proceeding in which the person shall have been found liable for willful or intentional misconduct in the performance of his duty to the corporation. The corporation may also pay or reimburse expenses incurred by a person in connection with his appearance as a witness or other participation in a proceeding at a time when he is not a named defendant or respondent in the proceeding.

The Company's Articles of Incorporation provide that none of its directors shall be personally liable to the Company or its shareholders for monetary damages for an act or omission in such director's capacity as a director; provided, however, that the liability of such director is not limited to the extent that such director is found liable for (1) a breach of the director's duty of loyalty to the Company or its shareholders, (2) an act or omission not in good faith that constitutes a breach of duty of the director to the Company or an act or omission that involves intentional misconduct or a knowing violation of the law, (3) a transaction from which the director received an improper benefit, whether or not the benefit resulted from an action taken within the scope of the director's office, or (4) an act or omission for which the liability of the director is expressly provided by an applicable statute.

The Company believes that these provisions will assist it in attracting and retaining qualified individuals to serve as executive officers and directors. The inclusion of these provisions in the Company's Articles of Incorporation may have the effect of reducing the likelihood of derivative litigation against the Company's directors and may discourage or deter shareholders or management from bringing a lawsuit against directors for breach of their duty of care, even though such an action, if successful, might otherwise have benefited us or our shareholders.

The Company's Articles of Incorporation and By-laws provide that the Company may indemnify its officers, directors, agents and any other persons to the fullest extent permitted by the TBCA.

Additionally, under their employment agreements with Opexa Therapeutics Inc. Mr. Warma and Ms. Rill are entitled to indemnification in their capacity as officers of the Company to the fullest extent permitted by the TBCA.

Item 16. Exhibits

<u>Exhibit Number</u>	<u>Description</u>
1.1† —	Form of Underwriting Agreement (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) (File No. 333-147167), filed on December 20, 2007).
4.1† —	Form of Common Stock Certificate (incorporated by reference to Exhibit 2.3 to the Company's Registration Statement on Form 10-SB (File No. 000-25513), initially filed March 8, 1999).
4.2† —	Form of Series E Warrant (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) (File No. 333-147167), filed on December 20, 2007).
4.3† —	Form of Warrant Agent Agreement for Series E Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) (File No. 333-147167), filed on December 20, 2007).
4.4† —	Form of Underwriters' Warrant Agreement (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) (File No. 333-147167), filed on December 20, 2007).
4.5† —	Form of Underwriters' Warrant to Acquire Warrants Agreement (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) (File No. 333-147167), filed on December 20, 2007).
5.1† —	Opinion of Vinson & Elkins L.L.P. (incorporated by reference to Exhibit 5.1 to the Company's Registration Statement on Form SB-2 (File No. 333-147167)).
23.1 † —	Consent of Malone & Bailey, PC.
23.4† —	Consent of Vinson & Elkins L.L.P. (contained in Exhibit 5.1).
24.1 † —	Powers of Attorney (included on the signature page hereto).

† Previously filed.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

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

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended ("Securities Act");

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

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

provided, however, that paragraphs (a)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement;

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser:
 - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; and
- (5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Exchange Act; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.
- (d) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (e) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
 - (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, in the City of The Woodlands, State of Texas, on the 25th day of September, 2009.

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Name: Neil K. Warma
President, Chief Executive Officer
and Acting Chief Financial Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Neil K. Warma</u> Neil K. Warma	President, Chief Executive Officer, Acting Chief Financial Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	September 25 , 2009
<u>*</u> David Hung	Director	September 25 , 2009
<u>*</u> David E. Jorden	Director	September 25 , 2009
<u>*</u> David B. McWilliams	Director	September 25 , 2009
<u>*</u> Michael S. Richman	Director	September 25 , 2009
<u>*</u> Scott B. Seaman	Director	September 25 , 2009

* By: /s/ Neil K. Warma
Neil K. Warma

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