

OPEXA THERAPEUTICS, INC.

FORM DEFA14A

(Additional Proxy Soliciting Materials (definitive))

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**UNITED STATES
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Washington, D.C. 20549**

SCHEDULE 14A

**Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934**

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ Definitive Proxy Statement

☒ Definitive Additional Materials

☐ Soliciting Material Pursuant to ss. 240.14a-12

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Opexa Therapeutics, Inc.

(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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☒ No fee required.

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To Our Shareholders,

2008 was a year of progress and challenges for Opexa. The difficult conditions that prevailed in the global economy weighed heavily, and we continue to see this pattern persist well into 2009. Nonetheless, since our last shareholder's meeting, Opexa has achieved several critical milestones which have strengthened not only our resolve but also our competitive position. Steady progress has been achieved through a determined focus on monthly goals and cash conservation. Critical milestones that were achieved these past twelve months which formed the basis of our recovery and growth include:

- Completing the first-in-class TERMS trial in Multiple Sclerosis (MS);
- Analyzing the TERMS data which has resulted in Tovaxin[®] emerging as what appears to be a safe and effective treatment for MS and one of the most promising potential therapies in development for MS;
- Closing a private offering of convertible notes which demonstrated support by existing investors, directors and officers;
- Monetizing an asset that had generated little perceived value for the Company by securing an agreement with Novartis Pharmaceuticals for our stem cell technology for an upfront cash payment of \$3 million, an additional \$1 million as a technology transfer fee, in a deal with total potential payments of \$50 million; and
- Regaining compliance with the NASDAQ Capital Market listing requirements and eliminating the going concern reference in our ongoing SEC filings.

I joined Opexa as the CEO in June 2008 with the primary objectives being to complete the landmark TERMS clinical study and increase the awareness of the Company in the investor community. In September 2008, we completed what was and remains a first-in-class clinical trial for the treatment of MS with our lead product, Tovaxin. We reported the top line data in September 2008 and while we were encouraged by the data, an unfortunate imbalance in the patient populations affected the outcome such that the primary endpoint was not achieved. This led to some negative press and also resulted in a significant decline in our stock price as several large institutional shareholders largely liquidated their holdings. We made the difficult decision in last year's fourth quarter to close the open label extension trial that followed the TERMS trial, and to significantly downsize our corporate staff and operations. We remained encouraged, however, by the continued data analysis of the TERMS trial as we were observing some positive results related to Tovaxin. By the end of the year our analysis had shown that Tovaxin was setting new benchmarks in safety and appeared to be possibly as effective as the best drug currently on the market for MS.

We entered 2009 with an enterprise value below \$5 million and a stock price below \$0.20. Believing that there remained significant inherent value in the fundamental assets of the Company, we mapped a path to recovery and rebuilding shareholder value based on our belief in Tovaxin and in the potential of our second platform technology – the adult stem cell program.

We initiated partnering discussions on both the Tovaxin and stem cell programs. With Tovaxin, we have focused on large and mid-tier pharmaceutical and biotechnology companies that were either (i) very strong in MS and, therefore, interested in supporting and strengthening their franchise or (ii) strong in neurology and interested in expanding into MS with a novel and promising therapy. In parallel to these discussions, we continued to analyze the TERMS data and continued to uncover significant promise in Tovaxin. Our most recent communication related to Tovaxin data was quite encouraging and demonstrated the following attributes in a well defined patient population comprised of patients having at least one relapse in the twelve months prior to treatment ($ARR \geq 1$):

- A superb safety profile: no adverse events related to Tovaxin treatment have been reported;
- 42% reduction in Annualized Relapse Rate (ARR) in Tovaxin patients as compared to placebo patients;

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- An ARR of 0.20, which is at the lowest range of any ARR for currently marketed drugs;
 - Over 83% of Tovaxin patients remained relapse free at the end of the 52 week trial; and
 - 73% of Tovaxin patients 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.

These results were greeted positively by the investment community and form the basis for our continuing discussions with prospective strategic partners. In parallel with such discussions, we continue to prepare and plan for the next clinical study with Tovaxin.

We were fortunate earlier this year to get a vote of confidence from several of our existing investors and closed a financing in the form of a private offering of secured convertible notes. This provided the Company with additional runway to continue our partnering discussions.

Additionally, less than three months later in August 2009, we executed an agreement with Novartis Pharmaceuticals whereby Novartis acquired our stem cell technology in a transaction with total potential payments that could exceed \$50 million (not including royalties). The upfront and near term payments totaling \$4 million are being directed toward planning and preparation for the further development of Tovaxin. It was also important for us to secure potential future payments in the form of clinical and sales milestones and royalties. This will allow us to benefit both in the near term and, potentially, through the future success of products developed from this novel technology. In addition to generating non-dilutive capital for the Company and strengthening our balance sheet, the Novartis transaction allowed us to generate value from an early stage asset.

We remain committed to the further clinical development of Tovaxin and believe that this therapy could potentially yield enormous benefits to patients suffering from multiple sclerosis. Our discussions with potential partners for Tovaxin are ongoing, but such dialogue and negotiations require a significant level of due diligence and a substantial amount of time.

We believe that cell therapy is a technology that can have profound effects in medicine and disease treatment in the next decade and beyond. Even though somewhat in its infancy, progress is being demonstrated across numerous fronts. Opexa, being at the leading edge of many of these efforts, is focused on developing Tovaxin, an autologous cell therapy product that is not only tailored to each individual patient but also to each patient's specific disease state. Opexa's determination to bring personalized therapies to patients in this way could yield significant benefits to MS sufferers and to patients with other autoimmune disorders if, as we believe, Opexa's platform technology can be applied across other autoimmune disorders.

On a final note, David McWilliams, Opexa's previous CEO and a member of the Board of Directors, has informed the Board that he will not stand for re-election at this year's annual meeting. I would like to take this opportunity, on behalf of Opexa's Board, to thank David for all his contributions and efforts over the past several years to position Opexa as a successful cell therapy company and for ensuring a smooth transition for me upon joining the Company last year.

Even though 2008 proved to be a challenging year, we managed to push through some difficult times to re-emerge stronger in 2009 and competitively positioned to move into 2010 and beyond.

We appreciate the support of our shareholders, and on behalf of all of us at Opexa Therapeutics, we look forward to your continued support and to reporting to you on the further progress of our programs.

Sincerely,

A handwritten signature in black ink, appearing to read "Neil K. Warma", with a long horizontal flourish extending to the right.

Neil K. Warma
President and Chief Executive Officer