OPEXA THERAPEUTICS, INC.

FORM DEFA14A

(Additional Proxy Soliciting Materials (definitive))

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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
☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
☐ Definitive Proxy Statement
☒ Definitive Additional Materials
☐ Soliciting Material Pursuant to ss. 240.14a-12

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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(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

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(4) Date Filed:

OPEXA THERAPEUTICS

September 14, 2010

To Our Shareholders,

Opexa's primary goal is to advance Tovaxin ® , our flagship therapy for Multiple Sclerosis (MS), through clinical development to commercialization. For the tens of thousands of MS sufferers who face unattractive treatment options and a chronic debilitating disease, we strongly believe that the positive signals seen with Tovaxin in the clinical studies to date demonstrate convincingly that further development should continue. We continue to work tirelessly on preparing for the initiation of the next clinical trial with Tovaxin.

Although we remain a small team of ten employees, we have built up substantial expertise in cell therapy manufacturing, process development, clinical development, regulatory affairs and immunology. Cell therapy is now being recognized as an area that could contribute enormously to the treatment of many diseases over the coming decades, and Opexa has positioned itself as one of the leaders in this very important field. The team we have recently assembled, including our newly reconstituted Scientific Advisory Board, is second to none and will serve us well over Tovaxin's next stage of development and beyond. We believe our proprietary T-cell platform technology from which Tovaxin was developed holds significant promise in the treatment of other autoimmune diseases. Beyond MS, there could be possibilities to treat other debilitating diseases such as Type 1 diabetes and Rheumatoid Arthritis, among others.

Additionally, *Personalized Medicine* is an area that is getting more attention not only from the medical community but also from the regulatory authorities including the FDA. Tailoring a therapy for a specific patient is now being heralded as a means to tip the benefit/risk profile more in favor of the patient. From the beginning, we have been developing Tovaxin as a personalized vaccine and have increasingly improved the sophistication of this personalization over the years. With a disease as complex as MS and one in which every patient progresses differently, tailoring a therapy to match an individual's disease profile would appear to support a favored benefit/risk profile for MS patients. To our knowledge, no one currently is developing a personalized treatment for MS in this manner, which differentiates Tovaxin even further from the competition.

Comprehensive analyses of the efficacy and safety data related to Tovaxin have consistently demonstrated that, to date, Tovaxin appears to be one of the most promising treatments for MS in development. While we believe we have demonstrated that Tovaxin has similar or better efficacy than many of the currently marketed drugs for MS and even those in development, we have repeatedly shown that Tovaxin's safety profile appears to be superior to many of these treatments. We believe Tovaxin is well positioned in a disease area which, unfortunately, continues to demonstrate significant unmet medical need. The market potential in MS continues to grow with annual revenue figures from marketed drugs currently exceeding $9 billion, with some estimates suggesting it could climb to $15 billion in the next five years.

As stated at the outset, Opexa remains committed to the long-term development of Tovaxin. Initiating the next clinical study with Tovaxin is our primary goal. Over just the past twelve plus months, we methodically advanced on a number of critical milestones necessary for the initiation of our next clinical study. Milestones achieved during this period are:

- August 2009: *Completed transaction to sell stem cell assets to Novartis* - Generated important upfront payment and secured potential future milestones and royalties;
- September 2009: *Completed analysis and communicated Phase 2b TERMS data in which Tovaxin emerged as a leading therapy for treatment of MS* - Benefit to patients observed in key clinical endpoints: Annualized Relapse Rate (ARR) and improvement in Disability (EDSS);

- December 2009: *Completed financing to secure over $5 million* - Demonstrated support by new institutional investors, enabled advancement of regulatory activities;
- Q4 2009-Q2 2010: *Strengthened management team with critical new hires* - World class individuals recruited to manage Clinical Development, Regulatory Affairs, Process Development and R&D;
- April 2010: *Key data presented at American Academy of Neurology meeting* - Invited to present important data possibly linking Tovaxin mechanism of action to clinical efficacy;
- Q1-Q2 2010: *Strengthened patent estate* - Three key patents issued, substantially increasing asset value of Tovaxin;
- Q2 2010: *Prepayment of convertible notes* - Eliminated debt, saved one year of future interest payments and removed security interest in assets including IP; and
- Q2 2010: *Reconstituted world-class Scientific Advisory Board* - Industry leaders in the MS field joined Opexa's advisory board to advise on and help propel Tovaxin program forward.

Over the coming months, we expect to complete the internal regulatory and manufacturing support studies, further optimize the manufacturing process, continue the development of critical assays and finalize all required document reporting. We expect to meet with the FDA by the end of this year to present these results and review the complete Tovaxin manufacturing process. Additionally, refinement of the clinical protocols will continue and these will be presented to the FDA at a separate clinical meeting to follow the manufacturing review. This second meeting we hope to schedule for early next year. We fully understand that additional capital is necessary to further advance the Tovaxin clinical program. We remain engaged in discussions with potential industry partners concerning the Tovaxin opportunity.

We have and will continue to remain diligent with the management of our financial resources. We have consistently maintained a modest monthly burn rate while still advancing on the numerous objectives and activities. The management team we rebuilt over the past few months comprises strong individuals who are leading all of our development efforts.

We clearly believe there is substantial value embedded in both the Tovaxin clinical program to date and the commercial opportunity in the future. Our discussions and interactions are focused on unlocking that value.

We recognize and are grateful for all of the support from 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,

Neil K. Warma

President and Chief Executive Officer

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin ®, is a personalized cellular immunotherapy treatment that is in clinical development for multiple sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded *ex vivo* , and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin and, thereby, reduces the risk of relapse over time.

Opexa completed its 150 patient ***Tovaxin for Early Relapsing Multiple Sclerosis*** (TERMS) Phase 2b clinical study in late 2008 which was one of the first clinical studies investigating an autologous T-cell therapy in MS patients. Data from this clinical study show evidence that Relapsing Remitting MS (RRMS) patients treated with Tovaxin saw overall clinical, MRI, and immunological benefits over the placebo group, including statistical significance for decrease in the Annualized Relapse Rate (ARR), improvement in disability score (EDSS), and improvement in quality of life measures (MSQLI), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

Cautionary Statement Relating to Forward-Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

Except for historical information, the matters addressed in this letter, including statements regarding our anticipated future activities in drug development (including potential partnering arrangements) for our lead drug candidate Tovaxin, plans and expected timelines for advancing Tovaxin through clinical development, the potential therapeutic and commercial value of Tovaxin, including as to attributes (such as safety and efficacy) and indications (such as the treatment of Multiple Sclerosis, including for various segments of that patient population), the potential development of our T-cell platform technology to treat other autoimmune diseases, and our anticipated cash burn and requirements, contain predictions, estimates and other forward-looking statements. The words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including risks associated with the following: our ability to enter into and benefit from partnering arrangements for Tovaxin on reasonably satisfactory terms (if at all); 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 and our ability to raise additional capital to continue development activities; unanticipated delays, greater than expected expenses, and economic factors; the success of clinical trials for Tovaxin; our ability to develop and commercialize a marketable product; our ability to obtain required regulatory approvals and to comply with regulations of the FDA and others; our ability to obtain, maintain and protect intellectual property rights (including for Tovaxin) and 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 and our dependence on third-party manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in the reports filed with the Securities and Exchange Commission.