

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/13/12 for the Period Ending 08/13/12

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (date of earliest event reported): August 13, 2012

OPEXA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of incorporation)

001-33004
(Commission File Number)

76-0333165
(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas
(Address of principal executive offices)

77381
(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On August 13, 2012, Opexa Therapeutics, Inc. (the “ **Company** ”) filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and announced its results of operations in a press release. A copy of the press release announcing the results is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2 to Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

Item 3.01. Notice of Delisting or Failure to Satisfy Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed, on February 10, 2012, the Company received a letter from the listing qualifications department staff of the NASDAQ Stock Market notifying the Company that for the last 30 consecutive business days the bid price of the Company’s common stock had closed below \$1.00 per share, the minimum closing bid price required by the continued listing requirements of NASDAQ listing rule 5550(a)(2). The Company was initially provided 180 calendar days, or until August 8, 2012, to regain compliance with the minimum bid price rule.

On August 1, 2012, the Company requested an additional 180-day grace period to regain compliance with NASDAQ’s minimum bid price requirement because the Company’s stock has continued to trade below the \$1.00 minimum closing bid price. NASDAQ staff granted the Company’s extension request on August 9, 2012, and the Company now has until February 4, 2013 to achieve compliance with this listing standard (*i.e.*, by the Company’s common stock maintaining a closing bid price of \$1.00 per share or more for a minimum of ten consecutive business days during the additional grace period, or such longer period of time as the NASDAQ staff may require).

While the Company intends to actively monitor the closing bid price of its common stock and consider available alternatives, including implementing a reverse stock split, if necessary, there can be no assurance that the Company will be able to regain compliance. In the event the Company is unable to regain compliance by February 4, 2013, or if it does not meet the other listing standards, NASDAQ staff could provide notice that the Company’s common stock will become subject to delisting, and in such event, the Company may request a hearing before the NASDAQ Listing Qualifications Panel.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

David E. Jorden, age 50, has been appointed as Acting Chief Financial Officer of the Company effective August 15, 2012, with a term of office to serve at the discretion of the Board of Directors. Mr. Jorden has served as a director of the Company since August 2008, as Chair and member of the Board's Audit Committee and as a member of the Governance and Nominating Committee. Concurrent with assuming his new role as Acting Chief Financial Officer, Mr. Jorden will step down as Chair and member of the Board's Audit Committee and as a member of the Governance and Nominating Committee, but will continue to serve as a director. As Acting Chief Financial Officer, Mr. Jorden will serve as the Company's principal financial and accounting officer, to succeed in that position the Company's President and Chief Executive Officer, Neil K. Warma, who previously held the additional title of Acting Chief Financial Officer.

Mr. Jorden currently also serves as Executive Chairman for Cytomedix, Inc., a publicly-traded regenerative therapies company commercializing and developing innovative platelet and adult stem cell technologies for wound and tissue repair, and has held that position since February 2012, previously serving as an executive board member since October 2008. Prior to Cytomedix, Mr. Jorden served as vice president with Morgan Stanley in its Private Wealth Management group where he was responsible for equity portfolio management for high net worth individuals since 2003. From March 2000 to September 2002, Mr. Jorden served as vice president and chief financial officer of Genometrix, Inc., a private genomics/life sciences company focused on high-throughput microarray applications. Mr. Jorden was a principal with Fayed Sarofim & Co. prior to joining Genometrix. He currently serves as a director of Cytomedix, Inc. and PLx Pharma, Inc., a private specialty pharmaceutical company developing GI safer formulations of proven non-steroidal anti-inflammatory drugs. Mr. Jorden is a Chartered Financial Analyst and Certified Public Accountant. He has extensive experience in various aspects of corporate finance and accounting for public companies, including capital formation and deployment.

Mr. Jorden will receive compensation of \$100,000 per annum for his service as a non-employee officer of the Company. Additionally, he will receive a nonqualified stock option to purchase up to 75,000 shares of the Company's common stock under the Company's 2010 Stock Incentive Plan (the "**Plan**"), such option to have a 10-year term and an exercise price equal to the closing market price of the Company's common stock on the NASDAQ Capital Market on August 15, 2012. The option will vest as follows: (i) one-third upon grant; (ii) one-third at December 31, 2012; and (iii) the remaining one-third on the earlier of June 30, 2013 or such time as the Company appoints a permanent chief financial officer. The option vesting is subject to continued service as an officer and certain other terms and conditions of the Plan and the Company's standard award agreement.

Item 8.01 Other Events.

As disclosed in Item 5.02 above, concurrent with assuming his new role of Acting Chief Financial Officer on August 15, 2012, Mr. Jorden will step down as Chair and member of the Board's Audit Committee and as a member of the Governance and Nominating Committee. Director Gail J. Maderis, who is an independent Board member with the requisite attributes of an "audit committee financial expert," will join the Audit Committee. Director Scott B. Seaman, who currently serves as a member of the Audit Committee, will be the Chair of the Audit Committee. Director Michael S. Richman will join the Governance and Nominating Committee as a member.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished as a part of this Form 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on August 13, 2012.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: August 13, 2012

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on August 13, 2012.

Opexa Therapeutics Reports Second Quarter 2012 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 13, 2012--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company developing Tcelna™, a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the quarter ended June 30, 2012 and provided an overview of recent corporate developments.

Recent highlights include:

- Closed a financing of \$4.1 million in gross proceeds through a private offering consisting of convertible secured notes and warrants to purchase shares of common stock;
- Rebranded our lead MS drug therapy with the new name Tcelna™, reflecting the optimization of the overall manufacturing process and clinical trial design of our MS program;
- Submitted the Chemistry, Manufacturing and Control (“CMC”) update to the FDA for final review;
- Advanced preparations and final contract negotiations with key clinical trial sites across North America to support the Phase IIb clinical trial; and
- Appointed current Board Member David E. Jorden as Acting Chief Financial Officer effective August 15, 2012.

“The first half of the year was focused on advancing preparations for our Phase IIb clinical trial in patients with Secondary Progressive MS, including securing additional capital to enable the initiation of the trial,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “We advanced well in these two key priorities having submitted the complete manufacturing CMC package to the FDA and having closed a financing which raised just over \$4 million. The most important task we face in the near term is to initiate the clinical trial and begin to treat patients who so desperately need new safe and effective treatments. SPMS patients currently have very limited treatment options so we are excited to be preparing to initiate the trial with what we believe to be one of the safest and potentially most efficacious therapies for this disease.”

“We have been diligently working to identify and secure leading clinical trial sites across the U.S. and Canada that we believe provide a strong base of SPMS patients for recruitment and enrollment in the trial,” continued Mr. Warma. “Contract negotiations with these sites are going well and we anticipate that the U.S.-based sites could be in a position to begin recruiting patients this quarter. The Canadian regulatory approvals should be finalized later in the quarter allowing us to expand enrollment in the clinical study at that time.”

“Today we also announced that David Jorden, one of Opexa’s board members, will be appointed to the position of Acting CFO to assist with the execution of the critical financing activities envisioned over the coming months and beyond. David has been an extremely active and supportive board member over the past four years and I look forward to working even more closely with him in this new capacity,” commented Mr. Warma. “With the recently announced closing of a convertible secured note financing, the Opexa team is focused on 1) the timely initiation and execution of the planned Phase IIb clinical trial, 2) continuing to advance ongoing discussions with potential strategic partners, and 3) appropriately resourcing the Company from a capital standpoint to be able to fully support ongoing clinical development, either through additional capital raises, a strategic partnership or both. The entire Opexa team is dedicated to successfully advancing Tcelna back into the clinic as a truly novel therapy for the long-term benefit of MS patients.”

“I am extremely pleased to join Neil and the other outstanding members of the Opexa senior management team at this important and exciting time in Opexa’s corporate development,” said Mr. Jorden. “Success across the indicated corporate objectives offers the opportunity to build substantial shareholder value in this Company and I am looking forward to further deepening my involvement with Opexa and executing on these priorities.”

“As of June 30, 2012, our cash and cash equivalents totaled approximately \$1.6 million. Our monthly burn rate for the first half of 2012 was approximately \$925,000, inclusive of increased cash expenditures to support preparations for the initiation of the planned Phase IIb clinical study in North America,” continued Mr. Warma. “As previously announced, on July 25, 2012, we closed a financing of \$4.1 million in gross proceeds through a private offering. At the current burn rate, and including the additional net proceeds from this financing, we should have sufficient capital through November 2012 to initiate the Phase IIb clinical study and enroll a portion of the overall patients. Moving forward, we are continuing to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to complete the Phase IIb study and to support ongoing operations during the pendency of such study.”

Additionally, Opexa today announced that on August 9, 2012, the Company received notice that the listing qualifications department staff of the NASDAQ Stock Market has granted the Company an extension of an additional 180 days to regain compliance with the listing standard for the minimum bid price rule contained in Listing Rule 5550(a)(2) which will allow the continued listing of the Company’s securities on The NASDAQ Capital Market. As previously announced, in February 2012, Opexa received a staff deficiency letter from NASDAQ notifying the Company that for the preceding 30 consecutive business days, the bid price of the Company’s common stock had closed below the minimum closing bid price of \$1.00 per share. To regain compliance, the closing bid price of the Company’s common stock must be at least \$1.00 per share for a minimum of ten consecutive business days (or such longer period of time as the NASDAQ staff may require) before February 4, 2013.

While the Company intends to actively monitor the closing bid price of its common stock and consider available alternatives, including implementing a reverse stock split, if necessary, there can be no assurance that the Company will be able to regain compliance. In the event the Company is unable to regain compliance in a timely manner or if it does not meet the other listing standards, NASDAQ staff could provide notice that the Company’s common stock will become subject to delisting, and in such event, the Company may request a hearing before the NASDAQ Listing Qualifications Panel. Such request would stay any delisting determination by the staff and the Company’s securities would remain listed on NASDAQ pending a formal determination by the Panel.

Second Quarter Financial Results

Opexa reported no commercial revenues in the three and six months ended June 30, 2012 or in the comparable prior-year periods.

Research and development expenses were \$1,558,208 and \$3,048,305 for the three and six months ended June 30, 2012, respectively, compared with \$854,208 and \$1,539,369 for the three and six months ended June 30, 2011, respectively. The increase for the three and six months ended June 30, 2012 compared to the three and six months ended June 30, 2011 was primarily due to an increase in the procurement and use of laboratory reagents and supplies and increases in employee personnel costs, professional service fees, facilities costs and non-cash stock compensation expense.

General and administrative expenses for the three and six months ended June 30, 2012 were \$529,566 and \$1,345,762, respectively, compared with \$560,834 and \$1,152,892 for the three and six months ended June 30, 2011, respectively. The decrease for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 was primarily due to decreases in business development expenses and non-cash stock compensation expense, and was partially offset by increases in compensation expense to employees, facilities costs and investor outreach expenses. The increase for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was primarily due to increases in employee personnel costs, facilities costs and investor outreach expenses, and was partially offset by decreases in business development and non-cash stock compensation expense.

Depreciation and amortization expense for the three and six months ended June 30, 2012 was \$76,496 and \$143,851, respectively, compared with \$70,732 and \$100,366 for the three and six months ended June 30, 2011, respectively. The increase in expense is primarily due to increases in depreciation for facility build-out costs, and increases in depreciation for laboratory, manufacturing and information technology equipment acquired during 2011 and 2012.

Interest expense for the three and six months ended June 30, 2012 was \$486 and \$973, respectively, compared with \$870 and \$2,005 for the three and six months ended June 30, 2011, respectively.

Opexa reported a net loss for the three months ended June 30, 2012 of \$2.16 million, or (\$0.09) per share, and a net loss for the six months ended June 30, 2012 of \$4.54 million, or (\$0.20) per share. For the same three month and six month periods ending June 30, 2011, Opexa reported a net loss of \$1.49 million, or (\$0.06) per share, and \$2.79 million, or (\$0.13) per share, respectively.

Cash and cash equivalents were \$1,570,148 as of June 30, 2012 compared to \$9,876,675 as of June 30, 2011.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading therapy, Tcelna™, is a personalized cellular immunotherapy treatment that is in late stage clinical development for MS. Tcelna 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.

For more information visit the Opexa Therapeutics website at www.opexatherapeutics.com.

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

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "expects," "believes," "hope," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing" and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements regarding the development of the Company's product candidate, Tcelna, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: our capital position, the rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes (including a secured interest in all of our assets), the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tcelna, on reasonably satisfactory terms (if at all), our dependence (if partnered) on the resources and abilities of any partner for the further development of Tcelna, our ability to compete with larger, better financed pharmaceutical and biotechnology companies, new approaches to the treatment of our targeted diseases, our expectation of incurring continued losses, our uncertainty of developing a marketable product, our ability to raise additional capital to continue our treatment development programs and to undertake and complete any further clinical studies for Tcelna, the success of our clinical trials, the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS, our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna), the risk of litigation regarding our intellectual property rights, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that the Company may license or transfer, our limited manufacturing capabilities, our dependence on third-party manufacturers, our ability to hire and retain skilled personnel, our volatile stock price, and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data (unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research and development	\$ 1,558,208	\$ 854,208	\$ 3,048,305	\$ 1,539,369
General and administrative	529,566	560,834	1,345,762	1,152,892
Depreciation and amortization	76,496	70,732	143,851	100,366
Operating loss	(2,164,270)	(1,485,774)	(4,537,918)	(2,792,627)
Interest income	59	260	195	471
Interest expense	(486)	(870)	(973)	(2,005)
Net loss	<u>\$ (2,164,697)</u>	<u>\$ (1,486,384)</u>	<u>\$ (4,538,696)</u>	<u>\$ (2,794,161)</u>
Basic and diluted loss per share	\$ (0.09)	\$ (0.06)	\$ (0.20)	\$ (0.13)
Weighted average shares outstanding	23,048,488	23,048,488	23,048,488	22,007,955

OPEXA THERAPEUTICS, INC.
(a development stage company)

Selected Balance Sheet Data (unaudited):

	June 30, 2012	Dec. 31, 2011
Cash and cash equivalents	\$ 1,570,148	\$ 7,109,215
Other current assets	953,440	124,773
Fixed assets, net	1,385,919	1,029,236
Other long term assets	27,076	-
Total assets	3,936,583	8,263,224
Total current liabilities	908,466	1,067,860
Total long term liabilities	-	-
Total stockholders' equity	3,028,117	7,195,364

CONTACT:
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