

OPEXA THERAPEUTICS, INC.

FORM 424B3

(Prospectus filed pursuant to Rule 424(b)(3))

Filed 11/14/06

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

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OPEXA THERAPEUTICS

Prospectus Supplement No. 7
to Prospectus dated August 11, 2005
as amended effective June 23, 2006

Opexa Therapeutics, Inc.

2,986,767 SHARES

We are supplementing the prospectus dated August 11, 2005, as subsequently amended by Post Effective Amendment No. 3, effective June 23, 2006, to provide information contained in our:

Quarterly Report on Form 10-QSB for the third quarter ended September 30, 2006

This Prospectus Supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus dated August 11, 2005 as amended by Post Effective Amendment No. 3 effective May 25, 2006, with respect to the resale of the 2,986,767 shares of common stock, including any amendments or supplements thereto.

The number of shares stated above has been revised to reflect the one-for-ten reverse split approved by shareholders in June 2006.

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 3, 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.

The date of this Supplement is November 14, 2006

UNITED STATES SECURITIES AND
EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-QSB

☒ QUARTERLY REPORT UNDER SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT
OF 1934

For the quarterly period ended September 30, 2006

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES
EXCHANGE ACT OF 1934

Commission File Number: 000-25513

Opexa Therapeutics, Inc.
(Exact name of Issuer as specified in its charter)

(formerly PharmaFrontiers Corp.)

TEXAS
(State of Incorporation)

76-0333165
(IRS Employer Identification Number)

2635 Crescent Ridge Drive
The Woodlands, Texas 77381
(281) 272-9331
(Address and telephone number of principal executive offices)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.)
Yes ☐ No ☒

The number of shares of common stock of the registrant outstanding at November 10, 2006 was 6,696,784.

Transactional Small Business Disclosure Format (check one): Yes ☐ No ☒

OPEXA THERAPEUTICS INC.
INDEX TO FORM 10-QSB
September 30, 2006

Page No.

PART I FINANCIAL INFORMATION

Item 1. Financial Statements	
Consolidated Balance Sheets dated September 30, 2006 and December 31, 2005 (unaudited)	3
Consolidated Statements of Expenses for the Three and Nine Months Ended September 30, 2006 and 2005 and the Period from January 22, 2003 (Inception) to September 30, 2006 (unaudited)	4
Consolidated Statements of Cash Flows for the Three and Nine Months Ended September 30, 2006 and 2005 and the Period from January 22, 2003 (Inception) to September 30, 2006 (unaudited)	5
Notes to Consolidated Financial Statements (unaudited)	7
Item 2. Management's Discussion and Analysis	10
Item 3. Controls and Procedures	19

PART II OTHER INFORMATION

Item 1. Legal Proceedings	19
Item 2. Recent Sales of Unregistered Securities	19
Item 3. Defaults Upon Senior Securities	19
Item 4. Submission of Matters to a Vote of Security Holders	19
Item 5. Other Information	19
Item 6. Exhibits	19
Signatures	20

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED BALANCE SHEETS
(unaudited)

	September 30,	December 31,
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,327,320	\$ 2,560,666
Other current assets	519,221	182,524
Total current assets	17,846,541	2,743,190
Intangible assets, net of \$3,121,293 and \$1,888,891 of accumulated amortization	25,135,478	26,130,441
Property & equipment, net of \$343,635 and \$256,082 of accumulated depreciation	1,281,446	479,996
Other assets	-	388,210
Total assets	<u>\$ 44,263,465</u>	<u>\$ 29,741,837</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,070,577	\$ 689,467
Stock payable	112,440	-
Accrued expenses	202,890	240,309
Note payable	1,500,000	1,500,000
Derivative liability	7,621,785	6,761,655
Total current liabilities	<u>10,507,692</u>	<u>9,191,431</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Convertible preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.50 par value, 100,000,000 shares authorized, 6,696,784 and 2,061,955 shares issued and outstanding	3,348,351	1,030,977
Additional paid in capital	62,449,180	39,783,452
Deficit accumulated during the development stage	(32,041,758)	(20,264,023)
Total stockholders' equity	<u>33,755,773</u>	<u>20,550,406</u>
Total liabilities and stockholders' equity	<u>\$ 44,263,465</u>	<u>\$ 29,741,837</u>

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENTS OF EXPENSES
Three and Nine Months ended September 30, 2006 and 2005 and the
Period from January 22, 2003 (Inception) to September 30, 2006
(unaudited)

	Three Months Ended September 30, 2006	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005	Inception through September 30, 2006
General and administrative	\$ 1,430,507	\$ 2,324,228	\$ 5,676,221	\$ 5,789,973	\$ 6,879,734
Depreciation and amortization	462,098	438,598	1,354,873	1,302,642	3,354,901
Research and development	2,113,878	622,311	4,407,240	1,877,787	16,765,127
Loss on disposal of assets	2,015	-	2,377	-	482,309
Operating loss	(4,008,498)	(3,385,137)	(11,440,711)	(8,970,402)	(27,482,071)
Interest income	259,141	31,565	477,547	50,474	565,469
Other income	-	11,958	46,450	21,903	77,003
Gain (loss) on derivative liability	2,418,078	-	(860,130)	-	3,036,711
Interest expense	(278)	(1,385,234)	(891)	(7,323,573)	(8,238,870)
Other expense	-	-	-	(296)	-
Net loss	\$ (1,331,557)	\$ (4,726,848)	\$ (11,777,735)	\$ (16,221,894)	\$ (32,041,758)
Basic and diluted loss per share	\$ (0.20)	\$ (2.31)	\$ (2.38)	\$ (11.61)	N/A
Weighted average shares outstanding	6,696,784	2,048,283	4,950,862	1,397,332	N/A

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months ended September 30, 2006 and 2005 and the
Period from January 22, 2003 (Inception) to September 30, 2006
(unaudited)

	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005	Inception through September 30, 2006
Cash flows from operating activities			
Net loss	\$ (11,777,735)	\$ (16,221,894)	\$ (32,041,758)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock issued for services	180,000	999,400	2,041,400
Stock issued for debt in excess of principal	-	109,070	109,070
Amortization of discount on notes payable due to warrants and beneficial conversion feature	-	5,516,638	6,313,205
Amortization of intangible assets	1,232,403	1,227,850	3,121,293
(Gain) loss on derivative liability	860,130	-	(3,036,711)
Depreciation	122,469	74,792	233,607
Debt financing costs	-	-	365,910
Option and warrant expense	3,649,583	3,908,044	8,634,545
Loss on disposition of fixed assets	2,377	-	482,309
Changes in:			
Accounts payable	381,110	(141,866)	466,277
Prepaid expenses	(387,217)	(75,618)	(514,352)
Accrued expenses	(37,419)	38,168	17,562
Other assets	-	-	(388,210)
Net cash used in operating activities	<u>(5,774,299)</u>	<u>(4,565,416)</u>	<u>(14,195,853)</u>
Cash flows from investing activities			
Purchase of licenses	(125,000)	-	(357,742)
Purchase of property & equipment	(487,567)	(77,519)	(919,474)
Net cash used in investing activities	<u>(612,567)</u>	<u>(77,519)</u>	<u>(1,277,216)</u>
Cash flows from financing activities			
Common stock sold for cash, net of offering costs	21,153,520	5,305,989	26,509,737
Common stock repurchased and canceled	-	-	(325)
Proceeds from debt	-	2,896,885	6,354,591
Repayments on notes payable	-	(58,614)	(63,614)
Net cash provided by financing activities	<u>21,153,520</u>	<u>8,144,260</u>	<u>32,800,389</u>
Net change in cash	14,766,654	3,501,325	17,327,320
Cash at beginning of period	2,560,666	851,992	-
Cash at end of period	<u>\$ 17,327,320</u>	<u>\$ 4,353,317</u>	<u>\$ 17,327,320</u>
Cash paid for:			
Income tax	\$ -	\$ -	\$ -
Interest	-	-	429

NON-CASH TRANSACTIONS

Issuance of common stock for purchase of Opexa	\$	-	\$	-	\$	23,750,000
Issuance of common stock to Sportan shareholders		-		-		147,733
Issuance of common stock for University of Chicago license		-		1,868,384		2,295,459
Issuance of common stock for accrued interest		-		525,513		525,513
Issuance of common stock for accounts payable		-		-		180,000
Conversion of notes payable to common stock		-		6,159,610		6,407,980
Conversion of accrued liabilities to common stock		-		17,176		17,176
Conversion of accounts payable to note payable		-		-		93,364
Discount on convertible notes relating to:						
- warrants		-		1,433,108		3,309,790
- beneficial conversion feature		-		831,945		1,715,973
- stock attached to notes		-		999,074		1,287,440
Fair value of derivative instrument		-		-		10,658,496
Stock payable		112,440		-		112,440

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited interim financial statements of Opexa Therapeutics, a development stage company, have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission and should be read in conjunction with the audited financial statements and notes thereto contained in Opexa's latest Annual Report filed with the SEC on Form 10-KSB/A. In the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of financial position and the results of operations for the interim periods presented have been reflected herein. The results of operations for interim periods are not necessarily indicative of the results to be expected for the full year. Notes to the financial statements that would substantially duplicate the disclosure contained in the audited financial statements for the most recent fiscal year as reported in Form 10-KSB/A, have been omitted.

In June 2006, the Company (i) changed its name to Opexa Therapeutics, Inc. from PharmaFrontiers Corp. and (ii) effected a one-for-ten reverse split, and all references to number of shares and per share amounts reflect such split as if it occurred on the first day of the first period presented.

NOTE 2 - STOCK BASED COMPENSATION

On January 1, 2006, Opexa began recording compensation expense associated with stock options and other forms of equity compensation in accordance with Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin No. 107. Prior to January 1, 2006, Opexa had accounted for stock options according to the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. Opexa adopted the modified prospective transition method provided for under SFAS No. 123R, and, consequently, have not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options recognized in the first quarter of fiscal 2006 includes the quarterly amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123.

The following table illustrates the effect on net loss and net loss per share if Opexa had applied the fair value provisions of FASB Statement No. 123 to stock-based employee compensation prior to January 1, 2006:

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005	Inception Through September 30, 2006
Net loss as reported	\$ (4,726,848)	\$ (16,221,894)	\$ (32,041,758)
Add: stock based compensation determined under intrinsic value based method	1,166,502	1,900,806	2,611,074
Less: stock based compensation determined under fair value based method	(2,388,998)	(3,303,730)	(4,417,377)
Pro forma net loss	<u>\$ (5,949,344)</u>	<u>\$ (17,624,818)</u>	<u>\$ (33,848,061)</u>
Basic and diluted			
Net loss per common share:			
As reported	\$ (2.31)	\$ (11.61)	N/A
Pro forma	\$ (2.90)	\$ (12.61)	N/A

NOTE 3 - CASH AND CASH EQUIVALENTS

Opexa considers all highly liquid investments with an original maturity of three months or less, when purchased, to be cash equivalents. Investments with maturities in excess of three months but less than one year are classified as short-term investments and are stated at fair market value.

The primary objectives for our fixed income investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Opexa's investment policy limits investments to certain types of instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

At September 30, 2006, Opexa invested \$12.9 million in in A-1/P-1 commercial paper with an average market yield of 5.39% and average time to maturity of 1.32 months. At September 30, 2006 \$4.4 million was invested in a money market account with an average yield of 5.14%. Interest income of \$259,141 and \$477,547 was recognized for the three and nine months ended September 30, 2006 in the consolidated statements of expenses.

NOTE 4 - INTANGIBLES

In January 2006, Opexa acquired an exclusive worldwide license for the intellectual property rights and research results of an autologous T cell vaccine for rheumatoid arthritis from the Shanghai Institute for Biological Science, China Academy of Science of the People's Republic of China. In exchange for a payment of \$125,000 and an agreed running royalty from the sale of commercialized products, Opexa receives all information and data related to all clinical trials on all patient controls and patients with rheumatoid arthritis with the T cell vaccine. This includes all clinical, cell procurement and manufacturing protocols, complete patient data sheets, all laboratory materials, methods and results and manufacturing records and documents and any other data related to the intellectual property. The first payment under the license occurred in April 2006 upon the delivery of materials pursuant to the terms of the licensing agreement. Opexa amortizes this intangible asset over its life of 20 years and as of September 30, 2006 the intangible asset had an unamortized balance of \$121,874.

NOTE 5 - COMMITMENTS

In September 2006, Opexa hired PharmaNet, LLC, a contract research organization focused on managing central nervous system trials, replacing the Letter of Intent ("LOI") entered into in April 2006. PharmaNet, LLC will provide Opexa with services in connection with its Phase IIB clinical trial. An initial payment of \$400,000 was made to PharmaNet, LLC in April 2006, representing an approximate three months average of the total anticipated project cost. An additional \$235,000 payment was made in October representing an advance of pass through costs which will be credited against the final costs of the study.

NOTE 6 - EQUITY

In March 2006, 34,749 shares of common stock were issued in settlement of an outstanding accounts payable of \$180,000.

Private Placement Offering

In April 2006, Opexa closed a financing transaction in which Opexa issued 4,600,000 shares of its common stock and warrants to purchase 2,300,000 shares of Opexa's common stock for \$23,000,000 to certain institutional and accredited investors. The warrants expire in five years, and are exercisable at \$6.50 per share. Opexa has the right to call the warrants commencing on June 29, 2007, if the closing bid price per share of Opexa's common stock equals or exceeds \$13.00 for twenty consecutive trading days in which the daily average trading volume of the common stock is at least 20,000 shares. Additionally, if a resale registration statement is not effective for any period after April 13, 2007, the warrant holders may exercise their warrants on a cashless basis during the period the resale registration statement is not effective. If Opexa fails to maintain effectiveness of registration of shares underlying the warrants and shares, they are required to make certain liquidated damage payments of 1.5% of the offering per month for every month in default with a maximum of 24%. The 2,300,000 warrants had a relative fair value of \$11,729,982.

In connection with this transaction, Opexa paid commissions and fees of \$1,758,350 and issued three year warrants with a relative fair value of \$1,111,150, to purchase an aggregate of 213,720 shares of common stock at an exercise price of \$5.00 per share. These warrants are not callable and have a cashless exercise option.

As a result of this transaction, the exercise price per share of the Series B warrants was reduced to \$20.00 and the number of shares into which such warrants can be exercised increased to 603,737, and the exercise purchase per share of the Series C warrants decreased to \$30.00 and the number of shares into which such warrants can be exercised increased to 1,110,548. The change in exercise price and number of warrants was accounted for in the fair value adjustment as of September 30, 2006 for the warrant derivatives. The Series B Warrants expired on October 17, 2006 unexercised (See note 8).

NOTE 7 - OPTIONS AND WARRANTS

In February 2006, the series A warrants expired. There were no options or warrants issued during the quarter ended March 31, 2006.

During the second quarter of 2006, Opexa issued the following options:

- 372,260 options at a fair value of \$2,991,847 and a second quarter expense of \$427,151 and a third quarter expense of \$315,311 to management and employees. The options are for a term of ten years and at an exercise price ranging from \$5.80 to \$9.50. These options vest from one to three years.

During the second quarter of 2006, Opexa issued the following warrants:

- 2,300,000 warrants to investors in connection with the April 2006 Transaction. The warrants are for a term of five years and at an exercise price of \$6.50. These warrants have a relative fair value of \$11,729,982. These options vest from one to three years.
- 213,720 warrants to brokers in connection with the April 2006 Transaction. The warrants are for a term of three years and at an exercise price of \$5.00. These warrants have a relative fair value of \$1,111,150.
- 155,000 warrants at a fair value of \$1,484,000 and a second quarter expense of \$686,429 and third quarter expense of \$123,643 to consultants, directors and exiting directors. The warrants are for a term of ten years and at an exercise price ranging from \$5.20 to \$9.80. These options vest from one to three years.

During the third quarter of 2006, Opexa issued the following options:

- 16,900 options to employees at a fair value of \$134,321 and a third quarter expense of \$1,866. The options are for a term of ten years and at an exercise price ranging from \$7.09 to \$8.25. These options vest in three years.

During the third quarter of 2006, Opexa issued the following warrants:

- 1,500 warrants at a fair value of \$12,375 and a third quarter expense of \$516 to a consultant. The warrants are for a term of ten years and at an exercise price of \$8.25. This option vests in one year from the grant date.

NOTE 8 - DERIVATIVE INSTRUMENTS

In September 2006, Opexa evaluated the application of SFAS 133 and EITF 00-19 for all of its financial instruments and identified the following financial instruments as derivatives:

- (1) Series A Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005 (which expired on February 17, 2006).
- (2) Series B Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005. (which expired on October 17, 2006).
- (3) Series C Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005.

These three series of warrants are derivatives because the liquidated damage provision in the registration rights agreement covering each warrant resulted in the conclusion that it was more economic to issue registered shares than to issue unregistered shares and pay the penalty. Because issuing registered shares is outside of Opexa's control, Opexa concluded the warrants should be accounted for as derivative liabilities under SFAS 133 and EITF 00-19.

As a result, Opexa reports the value of these derivatives as current liabilities in its balance sheet and report changes in the value of these derivatives as non-operating gains or losses in its statements of operations. The value of the derivatives is required to be remeasured on a quarterly basis, and is based on the Black Scholes Pricing Model.

Variables used in the Black-Scholes option-pricing model include (1) 4.62% risk-free interest rate, (2) expected warrant life is the actual remaining life of the warrants as of each period end, (3) expected volatility is 486% and (4) zero expected dividends.

The impact of the application of SFAS 133 and EITF 00-19 on the balance sheets and statements of operations as of December 31, 2005 and for the three months and nine months ended September 30, 2006 and from inception through September 30, 2006 is as follows:

	As of 12/31/2005	As of 9/30/2006	Gain(Loss) Three months ended 9/30/2006	Gain(Loss) Nine months ended 9/30/2006	Gain(Loss) Inception Through 9/30/2006
Series A Warrants	\$ -	\$ -	\$ -	\$ -	\$ 332,440.00
Series B Warrants	264,957	-	5,398	264,957	905,840
Series C Warrants	6,496,698	7,621,785	2,412,680	(1,125,087)	1,798,430
Totals	<u>\$ 6,761,655</u>	<u>\$ 7,621,785</u>	<u>\$ 2,418,078</u>	<u>\$ (860,130)</u>	<u>\$ 3,036,710</u>

The warrants from the April 2006 financing were determined to qualify for equity treatment under SFAS 133 and EITF 00-19. Nothing in the warrant agreement required cash settlement or allowed for the possibility of cash settlement including the impact of the liquidated damages penalty under the registration rights agreement. It was determined as of the issue date and September 30, 2006 that it was more economic to issue unregistered shares and pay the penalty than to issue registered shares. These warrants will be reevaluated at each balance sheet date to determine whether equity classification is still appropriate.

NOTE 9 - SUBSEQUENT EVENTS

The Series B Warrant issued to investors in connection with the bridge note exchange and private placement offerings in June and July of 2005 expired on October 17, 2006.

In October 2006, Opexa amended that certain Amended and Restated License Agreement, dated December 30, 2004, with the University of Chicago with respect to certain payment obligations of Opexa, as follows: (i) an October 30, 2006 \$1,500,000 cash payment obligation was extended until April 30, 2007; and (ii) the obligation to issue 21,623 shares of Opexa's common stock issuable was extended until April 30, 2007, with \$112,440 accrued at September 30, 2006.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and the related footnotes thereto.

Forward-Looking Statements

Some of the statements contained in this report discuss future expectations, contain projections of results of operations or financial condition, or state other "forward-looking" information. The words "believe," "intend," "plan," "expect," "anticipate," "estimate," "project," "goal" and similar expressions identify such statement was made. These statements are subject to known and unknown risks, uncertainties, and other factors that could cause the actual results to differ materially from those contemplated by the statements. The forward-looking information is based on various factors and is derived using numerous assumptions. Factors that might cause or contribute to such a discrepancy include, but are not limited to the risks discussed in this and our other SEC filings. We do not promise to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements. Future events and actual results could differ materially from those expressed in, contemplated by, or underlying such forward-looking statements.

The following discussion and analysis of our financial condition is as of September 30, 2006. Our results of operations and cash flows should be read in conjunction with our unaudited financial statements and notes thereto included elsewhere in this report and the audited financial statements and the notes thereto included in our Form 10-KSB/A for the year ended December 31, 2005.

Business Overview

Opexa is a biotechnology company engaged in developing autologous personalized cellular therapies. Autologous therapies use cells or other materials from the patient's own body to create treatments for the patient, thus preventing rejection complications that result when "foreign" or "non-self" cells are introduced into a patient. Our strategy is to develop and commercialize cell therapies to treat several major illnesses, including multiple sclerosis (MS), rheumatoid arthritis (RA) and diabetes. These therapies are based on our proprietary T-cell vaccination (TCV) and stem cell technologies.

The Company has an exclusive license from Baylor College of Medicine to an individualized T-cell therapy that is in FDA Phase IIb clinical trials to evaluate its safety and effectiveness in treating multiple sclerosis. Our multiple sclerosis cell therapy, Tovaxin™, is a T-cell-based therapeutic vaccine that offers a unique and personalized approach to treating the disease. Tovaxin™ consists of modified autoreactive T-cells. Multiple sclerosis is a result of a person's own T-cells attacking the myelin sheath that coats the nerve cells of the central nervous system. These T-cells, that attack a person's own body, are referred to as "autoreactive" T-cells. In our treatment the T-cells are taken from the patient, modified and returned to the patient. The modified T-cells cause an immune response directed at the autoreactive T-cells in the patient's body.

We also hold exclusive worldwide license for the intellectual property rights and research results of an autologous T-cell vaccine for RA from the Shanghai Institutes for Biological Sciences (SIBS), Chinese Academy of Sciences of the People's Republic of China.

Opexa's RA T-cell vaccination (TCV) technology is conceptually similar to Tovaxin. RA is an autoimmune T-cell-mediated disease in which pathogenic T-cells trigger an inflammatory autoimmune response of the synovial joints of the wrists, shoulders, knees, ankles and feet which causes pain, stiffness, and swelling around the joints. The RA TCV technology allows the isolation of these pathogenic T-cells from synovial fluid drawn from a patient. We expand and modify these T-cells in our laboratory. The modified T-cells are injected subcutaneously into patients thereby inducing an immune response directed at the pathogenic T-cells in the patient's body. This immune response reduces the level of pathogenic T-cells and potentially allows the reduction of joint swelling in RA patients. Human trials that have been conducted in China show minimal side-effects and promising efficacy measured as a reduction of joint swelling following the T-cell vaccination.

We also have an exclusive license to a stem cell technology in which adult multipotent stem cells are derived from monocytes obtained from the patient's own blood. We are initially pursuing indications in Type I diabetes with our stem cell therapy and are conducting animal studies.

The Company's stem cell technology isolates novel multipotent stem cells derived from peripheral blood monocytes. *In vitro* experiments with monocyte-derived stem cells (MDSC) have shown their capacity to differentiate into a wide variety of cell types including pancreatic β cells. We have demonstrated that these pancreatic islets clusters derived from MDSCs are composed of all three pancreatic cells types (α , β and δ), these clusters are responsive to glucose and mimics the normal pulsatile pattern observed in human islets. The importance of these stem cells is the ability to easily isolate them from an individual's circulating monocytes, expand them and administer them back into the same patient. This autologous approach provides a method to overcome any rejection issues and the need for immunosuppressant drugs which are often associated with current transplantations. This technology may lead to the formation of an unlimited source of β cells suitable for an autologous cell therapy for the treatment of Type I diabetes mellitus.

Organizational History

We were incorporated in Texas in 1991 and in May 2004, we entered the biopharmaceutical business by acquiring an entity that held rights to treatments using adult multipotent stem cells derived from adult human peripheral blood, and in connection therewith we changed our name to PharmaFrontiers Corp. From an accounting standpoint, the subsidiary is deemed the acquirer in a reverse merger whereby the parent is deemed the survivor of the reorganization/reverse merger. As such, our financial statements are those of the subsidiary. In November 2004, we acquired Opexa Pharmaceuticals, Inc. which holds rights to technology to diagnose and treat multiple sclerosis through modified autoreactive T-cells. In June 2006 we changed our name to Opexa Therapeutics, Inc. from PharmaFrontiers Corp.

Critical Accounting Policies

General

The consolidated financial statements and notes to the consolidated financial statements contain information that is pertinent to this management's discussion and analysis. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of any contingent assets and liabilities. Management believes these accounting policies involve judgment due to the sensitivity of the methods, assumptions and estimates necessary in determining the related asset and liability amounts. Management believes it has exercised proper judgment in determining these estimates based on the facts and circumstances available to it at the time the estimates were made. The significant accounting policies are described in our financial statements.

Long-lived assets

Long-lived assets (i.e., intangible assets) are reviewed for impairment whenever events or changes in circumstances indicate that the net book value of the asset may not be recoverable. An impairment loss is recognized if the sum of the expected future cash flows (undiscounted and before interest) from the use of the asset is less than the net book value of the asset. Generally, the amount of the impairment loss is measured as the difference between the net book value of the asset and the estimated fair value of the related asset. Management does not believe any assets have been impaired at September 30, 2006.

Intellectual Property

As of September 30, 2006, we had \$25,135,478 of intellectual property, accumulated amortization of \$3,121,293, \$23,991,167 of which resulted from the acquisition of Opexa, \$4,028,204 which pertained to the consideration paid or accrued to date to the University of Chicago for the worldwide license to technology developed at Argonne National Laboratory, \$112,400 stock payable to the University of Chicago accrued at September 30, 2006 for 21,623 shares, and \$125,000 paid to the Shanghai Institute for Biological Science, China Academy of Science of the People's Republic of China whereby it acquired an exclusive worldwide license for the intellectual property rights and research results of an autologous T cell vaccine for rheumatoid arthritis. Of the \$23,991,167 of acquired intangible assets, the full amount is assigned to an inseparable group of patents and licenses that cannot function independently by themselves. The weighted average useful life of the intangible group as of September 30, 2006 is approximately 16 years. The weighted average useful life of the University of Chicago license as of September 30, 2006 is 17 years.

Accounting for Derivative Instruments

Statement of Financial Accounting Standard No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, requires all derivatives to be recorded on the balance sheet at fair value. These derivatives are separately valued and accounted for on our balance sheet. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

The pricing model we use for determining fair values of our derivatives is the Black Scholes Pricing Model. Valuations derived from this model are subject to ongoing internal and external verification and review. The model uses market-sourced inputs such as interest rates, exchange rates and stock price volatilities. Selection of these inputs involves management's judgment and may impact net income.

In September 2000, the Emerging Issues Task Force issued EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in, a Company's Own Stock, which requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required. In accordance with EITF 00-19, in June 2006, we determined that certain outstanding warrants to purchase our common stock should be separately accounted for as liabilities.

We have evaluated the provisions of the registration rights agreement that require us to pay registration delay payments in combination with the financial instrument and concluded that the combined instrument meets the definition of a derivative under SFAS 133.

The EITF recently deliberated the impact of liquidated damages clauses in registration rights agreements and the effect on accounting and classification of instruments subject to the scope of EITF 00-19 in EITF 05-04 *The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to Issue No. 00-19*. The EITF has not reached a consensus on this issue and has deferred deliberation until the FASB addresses certain questions which could impact a conclusion on this issue. Specifically, EITF 05-04 presents alternative views on whether the liquidated damages provisions in registration rights agreements should be combined with or treated separately from the associated financial instrument. As discussed above, we view the registration rights agreement and the financial instrument as one combined freestanding instrument. If the EITF were to adopt the view that the registration rights agreement should be viewed as a separate instrument from the financial instrument, we may have to account for additional derivatives.

We determined certain warrants to purchase our common stock are derivatives that we are required to account for as liabilities in our financial statements. As a result, we report the value of these derivatives as current liabilities on our balance sheet and we report changes in the value of these derivatives as non-operating gains or losses on our statement of expenses. The value of the derivatives is required to be remeasured on a quarterly basis, and is largely based on the market value of our common stock. Due to the nature of the required calculations and the large number of shares of our common stock involved in such calculations, changes in our common stock price may result in significant changes in the value of the derivatives and resulting gains and losses on our statement of expenses. The aggregate balance sheet amount shown for these derivative liabilities increased from \$6,761,655 on December 31, 2005 to \$7,621,785 on September 30, 2006, resulting in a loss of \$860,130 in the statements of expenses for the nine months ended September 30, 2006.

Results of Operations and Financial Condition

Three Months Ended September 30, 2006 Compared with the Three Months Ended September 30, 2005

Net Sales. We recorded no sales for the three months ended September 30, 2006 and 2005.

General and Administrative Expenses. Our general and administrative expenses decreased during the three months ended September 30, 2006, to \$1,430,507 as compared to \$2,324,228 from the same period in 2005. The decrease in general and administrative expenses is due primarily to the decrease in stock-based compensation expense. In January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," ("SFAS 123R") which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors including stock options and restricted stock based on estimated fair values. We elected to adopt the modified prospective transition method as provided by SFAS 123R and, accordingly, prior year results have not be restated. Stock-based compensation expense recognized under SFAS 123R for the three months ended September 30, 2006 was \$819,867.

Research and Development Expenses. Research and development expense increased to \$2,113,878 for the three months ended September 30, 2006, compared to \$622,311 for the same period in 2005. The increase is primarily related to the initiation of the Tovaxin Phase IIB clinical trial and a higher allocation of facilities and overhead costs to research and development due to increased development activities.

Interest Expense. Interest expense was \$278 for the three months ended September 30, 2006 compared to \$1,385,234 for the same period in 2005. Interest expense during 2005 was due to notes payable that were outstanding during the second quarter of 2005 which were subsequently converted into equity in June 2005, resulting in acceleration of the amortization of the discount related to the notes.

Interest Income. Interest income was \$259,141 for the three months ended September 30, 2006 compared to \$31,565 for the same period in 2005. The increase was due to the investment of the cash proceeds from the April 2006 offering in cash equivalent investments .

Gain (loss) on derivative instruments liabilities, net. We recognized a gain on derivative instruments of \$2,418,078 for the three months ended September 30, 2006. This gain is a result of the net unrealized (non-cash) change in the fair value of our derivative instrument liabilities related to certain warrants.

Net loss. We had a net loss for the three months ended September 30, 2006, of \$1,331,557, or \$.20 per share (basic and diluted), compared with a net loss of \$4,726,848, or \$.23 per share (basic and diluted), for the same period in 2005. The decrease in net loss is primarily due to the decrease in stock-based compensation expense and interest expense and the gain on derivative instruments.

Nine Months Ended September 30, 2006 Compared with the Nine Months Ended September 30, 2005

Net Sales. We recorded no sales for the nine months ended September 30, 2006 and 2005.

General and Administrative Expenses. Our general and administrative expenses decreased during the nine months ended September 30, 2006, to \$5,676,221 as compared to \$5,789,973 from the same period in 2005. The decrease in general and administrative expenses is due primarily to the decrease in stock-based compensation expense. In January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment," ("SFAS 123R") which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors including stock options and restricted stock based on estimated fair values. We elected to adopt the modified prospective transition method as provided by SFAS 123R and, accordingly, prior year results have not be restated. Stock-based compensation expense recognized under SFAS 123R for the nine months ended September 30, 2006 was \$3,649,583.

Research and Development Expenses. Research and development expense increased to \$4,407,240 for the nine months ended September 30, 2006, compared to \$1,877,787 for the same period in 2005. The increase is primarily related to the initiation of the Phase IIB clinical trial and a higher allocation of facilities and overhead costs to research and development due to increased development activities.

Interest Expense. Interest expense was \$891 for the nine months ended September 30, 2006 compared to \$7,323,573 for the same period in 2005. Interest expense during 2005 was due to notes payable that were outstanding during 2005 which were subsequently converted into equity in June 2005, resulting in acceleration of the amortization of the discount related to the notes.

Interest Income. Interest income was \$477,547 for the nine months ended September 30, 2006 compared to \$50,474 for the same period in 2005. The increase was due to the investment of the cash proceeds from the April 2006 offering in cash equivalent investments.

Gain (loss) on derivative instruments liabilities, net. We recognized a loss on derivative instruments of \$860,130 for the nine months ended September 30, 2006. This loss is a result of the net unrealized (non-cash) change in the fair value of our derivative instrument liabilities related to certain warrants.

Net loss. We had a net loss for the nine months ended September 30, 2006, of \$11,777,735, or \$2.38 per share (basic and diluted), compared with a net loss of \$16,221,894, or \$11.61 per share (basic and diluted), for the same period in 2005. The decrease in net loss is primarily due to the decrease in stock-based compensation expense and interest expense and the gain on derivative instruments.

Recent Financing

In April 2006, we sold 4,600,000 common shares and warrants to purchase 2,300,000 common shares for \$23,000,000 to certain institutional and accredited investors. The warrants expire in five years and are exercisable at \$6.50 per share. We have the right to call the warrants commencing on June 29, 2007, if the closing bid price per share of our common stock equals or exceeds \$13.00 for twenty consecutive trading days in which the daily average trading volume of the common stock is at least 20,000 shares. Additionally, if a resale registration statement is not effective for any period after April 13, 2007, then the warrant holders may exercise their warrants on a cashless basis during the period the resale registration statement is not effective. If we fail to maintain effectiveness of registration of shares underlying the warrants and shares, we are required to make certain liquidated damage payments of 1.5% of the offering per month for every month in default with a maximum of 24% of the aggregate amount invested.

Liquidity and Capital Resources

Changes in cash flow. Cash used in operations for the nine month period ended September 30, 2006 increased from \$4,565,416 for the same period in 2005 to \$5,884,956. The increase in cash used in operations is primarily due to the increased research and development expenditures for the Tovaxin Phase IIb trial. Cash used in investing activities for the nine month period ended September 30, 2006 increased from \$77,519 in the same period of 2005 to \$501,910. The increase was due to the license payment made to Shanghai Institute related to the license obtained during the period for its Rheumatoid Arthritis T-cell technology and the purchase of laboratory equipment. Cash provided from financing activities for the nine month period ended September 30, 2006 was \$21,153,520 as compared to \$8,144,260 for the same period of 2005. The increase was due to proceeds from the April 2006 equity financing.

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of September 30, 2006, we had cash of \$17,327,320. Our current burn rate is approximately \$1 million per month excluding capital expenditures. As a result of the April 2006 financing, we believe have sufficient working capital to fund operations through the third quarter of 2007. Thereafter, we will need to raise additional capital to fund our working capital needs during fiscal 2007. We do not have any material commitments from investors or any credit facilities available with financial institutions or any other third parties. Therefore, we expect that we will need to engage in best efforts sales of our securities to raise needed working capital. There is no assurance that we will be successful in any funding effort. The failure to raise such funds may necessitate the curtailment of operations in fiscal 2007.

Off-Balance Sheet Arrangements

As of September 30, 2006, we had no off-balance sheet arrangements.

Recent Accounting Pronouncements

Effective January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" which establishes accounting for equity instruments exchanged for employee service. We utilize the Black-Scholes option pricing model to estimate the fair value of employee stock based compensation at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Further, as required under SFAS 123R, we now estimate forfeitures for options granted, which are not expected to vest. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances.

For the period ended September 30, 2006, there were no other changes to our critical accounting policies as identified in our annual report of Form 10-KSB/A for the year ended December 31, 2005.

Risks Related to Our Business and Our Common Stock

The following factors affect our business and the industry in which we operate. The risks and uncertainties described below are not the only ones that we face. Additional risks and uncertainties not presently known or that we currently consider immaterial may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected.

Our business is at an early stage of development .

Our business is at an early stage of development. We do not have any products in late-stage clinical trials or on the market. We are still in the early stages of identifying and conducting research on potential products. Only one of our products has progressed to the stage of being studied in human clinical trials. Our potential products will require significant research and development and preclinical and clinical testing prior to regulatory approval in the United States and other countries. We may not be able to develop any products, to obtain regulatory approvals, to enter clinical trials for any of our product candidates, or to commercialize any products. Our product candidates may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits, or achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We have a history of operating losses and do not expect to be profitable in the near future .

We have not generated any profits since our entry into the biotechnology business and have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future and, as we increase our research and development activities, we expect our operating losses to increase significantly. We do not have any sources of revenues and may not have any in the foreseeable future.

We will need additional capital to conduct our operations and develop our products and our ability to obtain the necessary funding is uncertain.

We need to obtain significant additional capital resources from sources including equity and/or debt financings, license arrangements, grants and/or collaborative research arrangements in order to develop products and continue the Company's business. We believe that we have sufficient working capital to finance operations through the third quarter of 2007. Thereafter, we will need to raise additional working capital in fiscal 2007. Our current burn rate is approximately \$1 million per month excluding capital expenditures. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs in 2007 and beyond;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

Additional financing through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our stockholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize by itself. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse affect on our financial condition or business prospects.

Our financial statements include substantial non-operating gains or losses resulting from required quarterly revaluation under GAAP of our outstanding derivative instruments.

Generally accepted accounting principles in the United States require that we report the value of certain derivative instruments we have issued as current liabilities on our balance sheet and report changes in the value of these derivatives as non-operating gains or losses on our statement of operations. The value of the derivatives is required to be recalculated (and resulting non-operating gains or losses reflected in our statement of operations and resulting adjustments to the associated liability amounts reflected on our balance sheet) on a quarterly basis, and is based on the market value of our common stock. Due to the nature of the required calculations and the large number of shares of our common stock involved in such calculations, changes in our common stock price may result in significant changes in the value of the derivatives and resulting gains and losses on our statement of operations.

Clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials.

We are dependent upon our management team and a small number of employees.

Our business strategy is dependent upon the skills and knowledge of our management team. We believe that the special knowledge of these individuals gives us a competitive advantage. If any critical employee leaves, we may be unable on a timely basis to hire suitable replacements to operate our business. We also operate with a very small number of employees and thus have little or no backup capability for their activities. The loss of the services of any member of our management team or the loss of a number of other employees could have a material adverse effect on our business.

We are dependent on contract research organizations and other contractors for clinical testing and for certain research and development activities, thus the timing and adequacy of our clinical trials and such research activities are, to a certain extent, beyond our control.

The nature of clinical trials and our business strategy requires us to rely on contract research organizations, independent clinical investigators and other third party service providers to assist us with clinical testing and certain research and development activities. As a result, our success is dependent upon the success of these outside parties in performing their responsibilities. Although we believe our contractors are economically motivated to perform on their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise applied to these activities by our contractors. If our contractors do not perform their activities in an adequate or timely manner, the development and commercialization of our drug candidates could be delayed.

Our current research and manufacturing facility is not large enough to manufacture future stem cell and T-cell therapies.

We conduct our research and development in a 10,000 square foot facility in The Woodlands, Texas, which includes a 1,200 square foot suite of three rooms for the future manufacture of stem cell and T-cell therapies through Phase III trials. Our current facility is not large enough to conduct future commercial-scale manufacturing operations. We will need to expand further our manufacturing staff and facility, obtain a new facility or contract with corporate collaborators or other third parties to assist with future drug production.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We do not have funds available for building a manufacturing facility, and we may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our commercial-scale manufacturing.

We may arrange with third parties for the manufacture of our future products. However, our third-party sourcing strategy may not result in a cost-effective means for manufacturing our future products. If we employ third-party manufacturers, we will not control many aspects of the manufacturing process, including compliance by these third parties with the FDA's current Good Manufacturing Practices and other regulatory requirements. We further may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, stem cells, T-cells, and other technologies potentially relevant to or required by our expected products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed applications relating to stem cells. We are also aware of a number of patent applications and patents claiming use of stem cells and other modified cells to treat disease, disorder or injury.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make and use our potential products and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop some products commercially. There can be no assurance that we will not be obliged to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

If we are unable to obtain future patents and other proprietary rights our operations will be significantly harmed .

Our ability to compete effectively is dependent in part upon obtaining patent protection relating to our technologies. The patent positions of pharmaceutical and biotechnology companies, including ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced before or after the patent is issued. Consequently, we do not know whether the patent applications for our technology will result in the issuance of patents, or if any future patents will provide significant protection or commercial advantage or will be circumvented by others. Since patent applications are secret until the applications are published (usually eighteen months after the earliest effective filing date), and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that the inventors of our licensed patents were the first to make the inventions covered by the patent applications or that the licensed patent applications were the first to be filed for such inventions. There can be no assurance that patents will issue from the patent applications or, if issued, that such patents will be of commercial benefit to us, afford us adequate protection from competing products, or not be challenged or declared invalid.

Our competition includes fully integrated biopharmaceutical and pharmaceutical companies that have significant advantages over us .

The markets for therapeutic stem cell products, multiple sclerosis products, and rheumatoid arthritis are highly competitive. We expect that our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies. These companies are developing stem cell-based products and they have significantly greater capital resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing than we currently do. Many of these potential competitors are further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.

Our business depends on licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform could be severely adversely affected.

Restrictive and extensive government regulation could slow or hinder our production of a cellular product .

The research and development of stem cell therapies is subject to and restricted by extensive regulation by governmental authorities in the United States and other countries. The process of obtaining U.S. Food and Drug Administration, or FDA, and other necessary regulatory approvals is lengthy, expensive and uncertain. We may fail to obtain the necessary approvals to continue our research and development, which would hinder our ability to manufacture or market any future product.

To be successful, our product candidates must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products .

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide to not accept and utilize these products. The product candidates that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our developed products will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our product candidates;
- our ability to create products that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payers.

If the health care community does not accept our products for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

There is currently a limited market for our common stock, and any trading market that exists in our common stock may be highly illiquid and may not reflect the underlying value of the Company's net assets or business prospects .

Although our common stock is currently traded on the Nasdaq Global Market, there is currently a limited market for our common stock and there can be no assurance that an improved market will ever develop. Investors are cautioned not to rely on the possibility that an active trading market may develop.

As our share price is volatile, we may be or become the target of securities litigation, which is costly and time-consuming to defend .

In the past, following periods of market volatility in the price of a company's securities or the reporting of unfavorable news, security holders have often instituted class action litigation. If the market value of our common stock experiences adverse fluctuations and we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer.

Future sales of our common stock in the public market could lower our stock price .

We may sell additional shares of common stock in subsequent public or private offerings. We may also issue additional shares of common stock to finance future acquisitions. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of shares of our common stock will have on the market price of our common stock. Sales of substantial amounts of our common stock, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock.

We presently do not intend to pay cash dividends on our common stock .

We currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of the our business. Therefore, prospective investors who anticipate the need for immediate income by way of cash dividends from their investment should not purchase the shares offered in this offering.

ITEM 3. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 (Exchange Act) Rules 13a-15(e) and 15d-15(e) as of September 30, 2006, have concluded that our disclosure controls and procedures are effective in providing reasonable assurance that information required to be disclosed by us in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

(b) Changes in Internal Control Over Financial Reporting.

Our management, with the participation of the principal executive officer and principal financial officer, has concluded there were no significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS .

None.

ITEM 3 DEFAULTS UPON SENIOR SECURITIES .

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS .

None.

ITEM 5. OTHER INFORMATION .

None.

ITEM 6. EXHIBITS .

Exhibit 31.1 Chief Executive Officer Certification Pursuant to Section 13a-14 of the Securities Exchange Act (1)

Exhibit 31.2 Chief Financial Officer Certification Pursuant to Section 13a-14 of the Securities Exchange Act (1)

Exhibit 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002 (1)

Exhibit 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002 (1)

(1) Filed herewith.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Opexa Therapeutics, Inc.

By: /s/ David B. McWilliams

David B. McWilliams, CEO

By: /s/ Lynne Hohlfeld

Lynne Hohlfeld, CFO

Date: November 13, 2006

**CHIEF EXECUTIVE OFFICER CERTIFICATION
PURSUANT TO SECTION 13A-14 OF THE SECURITIES EXCHANGE ACT**

I, David B. McWilliams, certify as Chief Executive Officer of Opexa Therapeutics, Inc. that:

1. I have reviewed this quarterly report on Form 10-QSB of Opexa Therapeutics, Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ David B. McWilliams
David B. McWilliams, CEO

Date: November 13, 2006

**CHIEF FINANCIAL OFFICER CERTIFICATION
PURSUANT TO SECTION 13A-14 OF THE SECURITIES EXCHANGE ACT**

I, Lynne Hohlfeld, certify as Chief Financial Officer of Opexa Therapeutics, Inc. that:

1. I have reviewed this quarterly report on Form 10-QSB of Opexa Therapeutics, Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Lynne Hohlfeld
Lynne Hohlfeld, CFO

Date: November 13, 2006

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, the undersigned Officer of Opexa Therapeutics, Inc. (the “Company”), hereby certifies, to such officer’s knowledge, that the Company’s Quarterly Report on Form 10-QSB for the quarter ended September 30, 2006 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ David B. McWilliams
David B. McWilliams, CEO

Date: November 13, 2006

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. Section 1350, the undersigned Officer of Opexa Therapeutics, Inc. (the "Company"), hereby certifies, to such officer's knowledge, that the Company's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Lynne Hohlfeld
Lynne Hohlfeld, CFO

Date: November 13, 2006