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

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended March 31, 2017

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from _____to _____

Commission File Number: 001-33004

Opexa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Texas	**2635 Technology Forest Blvd. The Woodlands, Texas 77381**	**76-0333165**
(State or other jurisdiction of Incorporation or organization)	(Address of principal executive offices and zip code)	(I.R.S. Employer Identification No.)

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

Indicate by check mark whether the registrant (1) has 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 such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☑ Yes ☐ No

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

Large accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 1, 2017, there were 7,657,332 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
For the Three months ended March 31, 2017

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

OPEXA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 2,822,677	$ 3,444,952
Other current assets	237,331	371,562
Total current assets	3,060,008	3,816,514
Property & equipment, net of accumulated depreciation of $0 and $3,194,029, respectively	—	50,000
Total assets	$ 3,060,008	$ 3,866,514
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 298,050	$ 377,956
Accrued expenses	428,394	625,890
Notes payable - insurance	91,871	156,642
Total current liabilities	$ 818,315	$ 1,160,488
Total liabilities	$ 818,315	$ 1,160,488
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized, 7,657,332 and 7,141,054 shares issued and outstanding	76,573	71,411
Additional paid in capital	164,410,992	163,954,215
Accumulated deficit	(162,245,872)	(161,319,600)
Total stockholders' equity	2,241,693	2,706,026
Total liabilities and stockholders' equity	$ 3,060,008	$ 3,866,514

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Revenue:		
Option revenue	$ —	$ 726,291
Research and development	206,024	1,829,062
General and administrative	719,869	987,248
Depreciation and amortization	—	72,589
Operating loss	(925,893)	(2,162,608)
Interest income (expense), net	(846)	108
Other income (expense), net	467	2,106
Net loss	$ (926,272)	$ (2,160,394)
Basic and diluted loss per share	$ (0.12)	$ (0.31)
Weighted average shares outstanding - Basic and diluted	7,597,769	6,982,909

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock				
	Shares	Par	Additional Paid in Capital	Accumulated Deficit	Total
Balances at December 31, 2016	7,141,054	$ 71,411	$ 163,954,215	$ (161,319,600)	$ 2,706,026
Shares sold for cash, net	516,278	5,162	408,500	—	413,662
Option expense	—	—	48,277	—	48,277
Net loss	—	—	—	(926,272)	(926,272)
Balances at March 31, 2017	7,657,332	$ 76,573	$ 164,410,992	$ (162,245,872)	$ 2,241,693

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (926,272)	$ (2,160,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	72,589
Option expense	48,277	153,853
Changes in:		
Other current assets	134,231	98,565
Accounts payable	(79,906)	(186,027)
Accrued expenses	(197,496)	202,531
Deferred revenue	—	(726,291)
Net cash used in operating activities	(1,021,166)	(2,545,174)
Cash flows from investing activities		
Proceeds from sale of property & equipment	50,000	(485)
Net cash provided/(used) in investing activities	50,000	(485)
Cash flows from financing activities		
Common stock sold for cash net of offering cost	413,662	—
Note payable - insurance	(64,771)	(55,144)
Payment of deferred offering costs	—	(27,512)
Net cash provided/(used) in financing activities	348,891	(82,656)
Net change in cash and cash equivalents	(622,275)	(2,628,315)
Cash and cash equivalents at beginning of period	3,444,952	12,583,764
Cash and cash equivalents at end of period	$ 2,822,677	$ 9,955,449
Cash paid for:		
Interest	$ 1,182	$ 1,371
Income taxes	—	—

NON-CASH TRANSACTIONS		
Unpaid deferred offering cost	—	8,395

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Basis of Presentation and Going Concern

The accompanying interim unaudited consolidated financial statements of Opexa Therapeutics, Inc. ("Opexa" or the "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 ("SEC") 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-K. 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 consolidated financial statements that would substantially duplicate the disclosure contained in the audited consolidated financial statements for the most recent fiscal year as reported in Form 10-K have been omitted.

The accompanying consolidated financial statements include the accounts of Opexa and its wholly owned subsidiary, Opexa Hong Kong Limited ("Opexa Hong Kong"). All intercompany balances and transactions have been eliminated in the consolidation.

Going Concern. The accompanying interim unaudited consolidated financial statements for the three months ended March 31, 2017 have been prepared assuming that the Company will continue as a going concern, meaning the Company will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of March 31, 2017, the Company had cash and cash equivalents of $2.8 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $818,315. While the Company has historically recognized revenue related to certain upfront payments received from Ares Trading SA ("Merck Serono"), a wholly owned subsidiary of Merck Serono S.A., in connection with the Option and License Agreement and an amendment thereto between Merck Serono and the Company, the Company has never generated any commercial revenues, nor does it expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. Opexa continues to incur net losses, negative operating cash flows and has an accumulated deficit of approximately $162.2 million as of March 31, 2017. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

Following the October 28, 2016 announcement that the Abili-T trial did not meet its primary or secondary endpoints, and in order to conserve cash resources while it reevaluated its programs and explored various strategic alternatives, during the fourth quarter of 2016 and first quarter of 2017 the Company implemented several reductions in workforce totaling 90% of its then 20 full-time employees. As of March 31, 2017 Opexa has two full-time employees. After further analysis of the data from the Abili-T trial, the Company has determined that it will not move forward with further studies of Tcelna in SPMS at this time and is conducting a review of its other research and development programs, including the preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. The Company is also exploring its strategic alternatives. The Company cannot fully predict its future cash needs until it completes this analysis. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company continues to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support its ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using its at-the-market offering program and cutting expenses where possible. However, in light of the disappointing Abili-T study results, there can be no assurance that the Company will be able to secure additional funds or, if such funds are available, whether the terms or conditions would be acceptable to the Company.

Note 2. Significant Accounting Polices

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.

Opexa primarily maintains cash balances on deposit in accounts at a U.S.-based financial institution. The aggregate cash balance on deposit in these accounts is insured by the Federal Deposit Insurance Corporation up to $250,000. Opexa's cash balances on deposit in these accounts may, at times, exceed the federally insured limits. Opexa has not experienced any losses in such accounts.

As of March 31, 2017, Opexa had approximately $1.8 million in a savings account. For the three months ended March 31, 2017, the savings account recognized an average market yield of 0.06%. Interest income of $336 was recognized for the three months ended March 31, 2017 in the consolidated statements of operations.

Recent Accounting Pronouncements. The Company has implemented all new accounting pronouncements that are in effect and that may impact its consolidated financial statements. Management has also considered all recent accounting pronouncements issued since the last audit of the Company's financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's financial statements.

Note 3. Other Current Assets

Other current assets consisted of the following at March 31, 2017 and December 31, 2016:

Description	March 31, 2017	December 31, 2016
Deferred offering costs	$ 49,918	$ 111,641
Prepaid expense	187,413	259,921
Total Other Current Assets	$ 237,331	$ 371,562

Deferred offering costs at March 31, 2017 and December 31, 2016 were $49,918 and $111,641 respectively. The March 31, 2017 balance includes costs incurred from third parties in connection with the March 25, 2016 implementation of a new Sales Agreement ("ATM Agreement") with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which Opexa can offer and sell shares of common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. These are included in other current assets in the consolidated balance sheets. Upon the sales of shares of common stock under the ATM Agreement, these capitalized costs will be offset against the proceeds of such sales of shares of common stock and recorded in additional paid in capital. As of March 31, 2017, $61,723 of deferred offering costs were recorded in additional paid in capital.

Prepaid expenses at March 31, 2017 and December 31, 2016 were $187,413 and $259,921 respectively. Included in the March 31, 2017 balance is $138,723 of prepaid insurance as well as the remaining balance of Opexa's NASDAQ Capital Market All-Inclusive Annual Fee of $41,250. The remaining balances are attributable to various service contracts and deposits.

Note 4. Notes Payable

Notes payable consists of a commercial insurance premium finance agreement - promissory note with AFCO of which $78,075 and $136,038 was outstanding as of March 31, 2017 and December 31, 2016, respectively. The loan has an interest rate of 3.5% per annum and matures July 1, 2017. The second note is also a commercial insurance premium finance agreement – promissory note with AFCO of which $13,796 and $20,604 was outstanding as of March 31, 2017 and December 31, 2016, respectively. The loan has an interest rate of 3.5% per annum and matures September 1, 2017. Payments on the above notes are due and payable monthly until maturity.

Note 5. Equity

For the three months ended March 31, 2017, equity related transactions were as follows:

During January 2017, Opexa sold an aggregate of 516,278 shares of common stock under its ATM facility with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, for gross proceeds of $490,098. Proceeds net of fees and deferred offering costs were $413,662.

Note 6. Stock-Based Compensation

Stock Options

Opexa accounts for stock-based compensation, including options and nonvested shares, according to the provisions of FASB ASC 718, "Share Based Payment." During the three months ended March 31, 2017, Opexa recognized stock-based compensation expense of $48,277. Unamortized stock-based compensation expense as of March 31, 2017 amounted to $235,340.

Stock Option Activity

A summary of stock option activity for the three months ended March 31, 2017 is presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at December 31, 2016	481,947	$ 12.14	7.60	—
Exercised	—	—		
Forfeited and canceled	(187,351)	11.93		
Outstanding at March 31, 2017	294,596	$ 12.28	7.19	$ —
Exercisable at March 31, 2017	244,868	$ 13.69	6.92	$ —

Employee Options and Non-Employee Options

Option awards are granted with an exercise price equal to the market price of Opexa's stock at the date of issuance, generally have a ten-year life, and have various vesting dates that range from no vesting or partial vesting upon date of grant to full vesting on a specified date. Opexa estimates the fair value of stock options using the Black-Scholes option-pricing model and records the compensation expense ratably over the service period.

Opexa recognized stock based compensation expense of $48,277 and $153,853 during the three months ended March 31, 2017 and 2016, respectively, for grants made to employees.

In addition, during the three months ended March 31, 2017 there were 187,351 shares underlying options that were forfeited and cancelled.

There were no stock options or restricted stock awards granted during the three months ended March 31, 2017.

Warrant Activity

A summary of warrant activity for the three months ended March 31, 2017 is presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at December 31, 2016	3,596,625	$ 12.39	1.21	—
Forfeited and canceled	(127,894)	12.72		
Outstanding at March 31, 2017	3,468,731	12.38	1.00	$ —
Exercisable at March 31, 2017	3,468,731	12.38	1.00	$ —

Note 7. Licenses

License Agreement with Baylor College of Medicine

In 2001, Opexa entered into an agreement with Baylor College of Medicine for the exclusive worldwide license to a patient-specific, autologous T-cell immunotherapy for the treatment of MS, which is the initial T-cell technology on which Tcelna is based, including rights to certain patents held by Baylor. In consideration for the right and license to commercially exploit such technology, Opexa agreed to pay the following (per scenario 1 of the license agreement): (i) a 2% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products is less than or equal to $500 million; (ii) a 1% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products exceed $500 million; (iii) a 1% royalty on net sales of licensed patent pending products sold by Opexa or its affiliates; and (iv) a 1% royalty on net sales of licensed patented products or licensed patent pending products sold by any sublicensees of Opexa. Unless earlier terminated, the Baylor license agreement expires in 2025 upon expiration of the last of the licensed patent rights.

Note 8. Commitments and Contingencies

On February 1, 2017, Opexa entered into an Assignment and Assumption of Lease with KBI Biopharma, Inc. (KBI), pursuant to which Opexa assigned to KBI, and KBI assumed from Opexa, all of Opexa's remaining rights and obligations under the lease for Opexa's 10,200 square foot corporate headquarters facility located in The Woodlands, Texas. The facility was originally leased by Opexa from Dirk D. Laukien, as landlord, pursuant to a lease dated August 19, 2005 as amended by that certain First Amendment to Lease Agreement dated May 11, 2015. In light of Opexa's continuing evaluation of its strategic alternatives following the release of the data from the Abili-T clinical study, management deemed it advisable to reduce the office, R&D and manufacturing space and corresponding rent obligations. The lease had a remaining term through September 2020 and current monthly base rental payments of $16,666.67 with payment escalations to $17,500 over the remaining term. In connection with the lease assignment, Opexa also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as its laboratory supplies located at its corporate headquarters to KBI for cash consideration in the amount of $50,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition is as of March 31, 2017. Our results of operations and cash flows should be read in conjunction with our unaudited consolidated financial statements and notes thereto included elsewhere in this report and the audited financial statements and the notes thereto included in our Form 10-K for the year ended December 31, 2016.

Forward-Looking Statements

This Quarterly Report on Form 10-Q 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. Statements contained in this report, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding" and similar expressions are intended to identify forward-looking statements.

These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, costs, returns, royalties, performance and position, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, management's initiatives and strategies, and the development of Opexa's product candidates, including Tcelna (imilecleucel-T) and OPX-212, 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. These risks and uncertainties include, but are not limited to, those risks discussed in "Risk Factors," as well as, without limitation, risks associated with:

- the continued development of Tcelna for the treatment of secondary progressive multiple sclerosis "SPMS"), the continued development of OPX-212 for neuromyelitis optica ("NMO"), or any continued research or development;
- market conditions;
- our capital position;
- 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 development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna or OPX-212);
- our ability to regain or maintain compliance with NASDAQ listing standards;
- the outcome of our clinical trials;
- the efficacy of Tcelna for any particular indication, such as for relapsing remitting multiple sclerosis or SPMS, and the efficacy of OPX-212 for NMO;
- 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 and OPX-212);
- the risk of litigation regarding our intellectual property rights or the rights of third parties;
- the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we 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 SEC.

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 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC.

Overview

Unless otherwise indicated, we use "Opexa," "the Company," "we," "our" and "us" to refer to the businesses of Opexa Therapeutics, Inc.

Opexa is a biopharmaceutical company that has historically focused on developing personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica (NMO). These therapies are based on our proprietary T-cell technology. Information related to our product candidates, Tcelna® and OPX-212, is preliminary and investigative. Tcelna and OPX-212 have not been approved by the U.S. Food and Drug Administration (FDA) or other global regulatory agencies for marketing.

On October 28, 2016, we announced that our Phase IIb clinical trial ("Abili-T") of our lead product candidate, Tcelna, in patients with secondary progressive MS (SPMS) did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. Abili-T is a 183-patient, randomized, double-blind, placebo-controlled Phase IIb study that was conducted at 35 clinical trial sites in the U.S. and Canada and designed to evaluate the safety and efficacy of Tcelna (imilecleucel-T) in patients with SPMS. Patients in the Tcelna arm of the study received two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. We completed enrollment of the Abili-T study in May 2014 and un-blinded the results from the study in late October 2016.

The primary endpoint for the Abili-T study was the percentage of whole brain volume change as measured by magnetic resonance imaging ("MRI") at two years. The analysis was conducted using a mixed model of repeated measures to include data from months 6, 12 and 24, relative to baseline normalized brain volume values. The mean percentage (and standard deviation) brain volume loss at two years for placebo-treated subjects was -0.657 (0.7598), and for Tcelna-treated subjects was -0.886 (0.7519) [p=0.043]. Further analysis of the data may be conducted to evaluate the potential for pseudo-atrophy to be a primary driver in the change in whole brain atrophy for Tcelna versus placebo-treated subjects.

Secondary endpoints included percentage of subjects with confirmed disease progression of disability in one or more of the Expanded Disability Status Scale ("EDSS"), Timed 25-foot Walk ("T25FW"), or 9-Hole Peg Test ("9HPT"). For each test, the following definitions were applied: EDSS score increased from baseline by at least 1 point if baseline EDSS <6.0, or by at least 0.5 points if baseline EDSS ≥6 sustained for 12 weeks; for T25FW, time increased by at least 20% of the baseline walk sustained for six months; and for 9HPT, time increased by at least 20% of the time taken at baseline sustained for six months. After two years on study, 32.2% of placebo-treated subjects were scored as progressed, compared to 33.3% of Tcelna-treated subjects [p=0.873]. A further secondary endpoint monitored time to sustained progression of disability by EDSS confirmed over three months, but not associated with an acute relapse. 17.8% of placebo subjects versus 20.4% of Tcelna-treated subjects were scored as progressed by EDSS after two years on study. Time (in months) to sustained progression by Kaplan-Meier analysis generated values for the 25% quartile of 24.9 for placebo, versus 25.0 for Tcelna [p=0.697].

The overall summary of adverse events ("AEs") in the safety population consisting of 93 placebo subjects and 96 Tcelna-treated subjects found no difference in treatment-emergent adverse events ("TEAE") possibly, probably or definitely related to study treatment. The number of subjects with a TEAE leading to early study termination was 9 (9.7%) in the placebo treatment arm, versus 6 (6.3%) in the Tcelna treatment arm. Tcelna was considered safe and well tolerated.

An immune monitoring program was conducted on blood samples collected over time to detect Tcelna-induced immune modulation. The analysis of the differentiation and functional status of various anti-inflammatory/regulatory CD4+ T-cells showed no difference between Tcelna and placebo-treated subjects. A statistically significant increase in CD4+ T-cells displaying a Th17 (IL-17+) and Th1 (IFNg+) profile was recorded in Tcelna-treated subjects. This inflammatory response to the Tcelna product may correlate with priming of the immune response to target myelin-reactive T-cells (MRTC). A correlation analysis of immune monitoring T-cell phenotypes to MRTC bio-activity has not yet been conducted.

After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time. We are conducting a review of our other research and development programs, including our preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. We are also exploring our strategic alternatives. We cannot fully predict our future cash needs until we complete this analysis.

We implemented a reduction in workforce of 40% of our then 20 full-time employees, announced on November 2, 2016, while we reevaluated our programs and various strategic alternatives in light of the disappointing Abili-T study data. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. As of December 31, 2016, we had nine full-time employees. During January 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash. As of March 31, 2017 we had two full-time employees.

On February 1, 2017, we assigned to a third party all of our rights and obligations under the lease for our 10,200 square foot corporate headquarters facility located in The Woodlands, Texas. In light of our continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, management deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations.

To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna, including conducting clinical trials and developing manufacturing capabilities, providing general and administrative support for these operations, and protecting our intellectual property. We do not have any products approved for sale and have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. From inception, we have funded our operations primarily through the sales of equity and debt securities.

We have incurred net losses in each year since our inception. As of March 31, 2017, we had an accumulated deficit of approximately $162.2 million. Substantially all of our net losses, including those incurred during the periods presented in this report, have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We cannot predict whether and to what extent we will resume drug development activities. If we determine to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct further development. We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

If we are unable to obtain additional funding to support our current or proposed activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a substantial portion or even all of their investment.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the results of our identification and evaluation of potential strategic alternatives and the extent to which we elect to pursue drug development activities in the future.

If we are unable to seek an appropriate use for our remaining assets, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

Opexa was incorporated in Texas in March 1991. Our principal executive offices are located at 2635 Technology Forest Blvd., The Woodlands, Texas 77381, and our telephone number is (281) 775-0600.

License Agreement with Baylor College of Medicine

In 2001, we entered into an agreement with Baylor College of Medicine for the exclusive worldwide license to a patient-specific, autologous T-cell immunotherapy for the treatment of MS, which is the initial T-cell technology on which Tcelna is based, including rights to certain patents held by Baylor. In consideration for the right and license to commercially exploit such technology, we agreed to pay the following (per scenario 1 of the license agreement): (i) a 2% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products is less than or equal to $500 million; (ii) a 1% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products exceed $500 million; (iii) a 1% royalty on net sales of licensed patent pending products sold by Opexa or its affiliates; and (iv) a 1% royalty on net sales of licensed patented products or licensed patent pending products sold by any sublicensees of Opexa. Unless earlier terminated, the Baylor license agreement expires in 2025 upon expiration of the last of the licensed patent rights.

Critical Accounting Policies

General. Our discussion and analysis of our financial condition and results of operations is based on our unaudited, consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect our most significant judgments and estimates used in preparation of our unaudited, consolidated financial statements.

Stock-Based Compensation. We adopted the provisions of FASB ASC 718 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. 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.

We estimated volatility by considering historical stock volatility. We have opted to use the simplified method for estimating expected term of options as equal to the midpoint between the vesting period and the contractual term.

Research and Development. The costs of materials and equipment or facilities that are acquired or constructed for research and development activities and that have alternative future uses are capitalized as tangible assets when acquired or constructed. The cost of such materials consumed in research and development activities and the depreciation of such equipment or facilities used in those activities are research and development costs. However, the costs of materials, equipment, or facilities acquired or constructed for research and development activities that have no alternative future uses are considered research and development costs and are expensed at the time the costs are incurred.

Results of Operations and Financial Condition

Comparison of the Three Months Ended March 31, 2017 with the Three Months Ended March 31, 2016.

Revenue. Revenues of $0 and $726,291 for the three months ended March 31, 2017 and 2016, respectively, included $0 and $307,686, respectively, related to the $5 million payment from Merck Serono in connection with the Merck Serono Agreement. Revenues for the three months ended March 31, 2017 and 2016 also include $0 and $418,605, respectively, related to the $3 million payment from Merck Serono in connection with the Merck Serono Amendment (see Revenue Recognition).

Research and Development Expenses. Research and development expenses were $206,024 for the three months ended March 31, 2017, compared with $1,829,062 for the three months ended March 31, 2016. The decrease in expenses is primarily due to cost reductions in connection with the winding down of the clinical trial of Tcelna in SPMS, including our site expenses as well as additional expense reduction due to a pause in NMO study development cost. Additionally, expenses were further reduced due to the workforce reductions over the past year. The reduction in expense was slightly offset by the severance accrual for our former Chief Scientific Officer.

General and Administrative Expenses. General and administrative expenses were $719,869 for the three months ended March 31, 2017, compared with $987,248 for the three months ended March 31, 2016. The decrease in expenses is primarily due to the workforce reduction over the past year as well as a reduction in rent and property taxes. These reductions were slightly offset by an increase in professional services and no reallocation of general and administrative expenses to research and development.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the three months ended March 31, 2017 were $0, compared with $72,589 for the three months ended March 31, 2016. The decrease in depreciation is due to the sale of certain furniture, fixtures, laboratory and manufacturing equipment in connection with the assignment of our facilities lease to a third party.

Interest Income, Net. Net interest expense was $846 for the three months ended March 31, 2017, compared to net income of $108 for the three months ended March 31, 2016.

Other Income and Expense, Net . Other Income and Expense, net was net income of $467 for the three months ended March 31, 2017, compared to net income of $2,106 for the three months ended March 31, 2016. The decrease is due to a reduction in the number of Canadian clinical sites still treating patients and the related realized gain in currency fluctuation between the US dollar and the Canadian dollar for payments made to clinical sites located in Canada.

Net Loss. We had a net loss for the three months ended March 31, 2017 of $926,272, or $0.12 loss per share (basic and diluted), compared with a net loss of approximately $2.2 million or $0.31 loss per share (basic and diluted) for the three months ended March 31, 2016. The decrease in net loss from March 31, 2016 to March 31, 2017 is due to the cost reduction efforts taken over the last year. The reduction in both general and administrative expenses as well as research and development expenses, was offset by the completed term for revenue recognition of the Option and License Agreement with Merck Serono in December 2016.

Liquidity and Capital Resources

Historically, we have financed our operations primarily through the sale of debt and equity securities. The report of our independent auditors in respect of the 2016 fiscal year expressed substantial doubt about our ability to continue as a going concern. Specifically, it noted our recurring losses, negative operating cash flows and accumulated deficit. The accompanying unaudited consolidated financial statements for the three months ended March 31, 2017 have been prepared assuming that Opexa will continue as a going concern, meaning Opexa will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of March 31, 2017, we had cash and cash equivalents of $2.8 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $818,315. While we have historically recognized revenue related to certain upfront payments received from Ares Trading SA (“Merck Serono”), a wholly owned subsidiary of Merck Serono S.A., in connection with the Option and License Agreement and an amendment thereto, we have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts.

We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities through at least the second quarter of 2017. However, if our projections prove to be inaccurate, or if we encounter additional costs to wind down the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing further research and development, we would need to raise additional capital to continue our operations.

On March 25, 2016, we entered into a new Sales Agreement with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an “at the market” offering. We registered up to 1,000,000 shares of common stock for potential sale under the new ATM facility. During January 2017, we sold an aggregate of 516,278 shares of common stock for gross proceeds of $490,098, with the average share price ranging from $0.90 to $0.97. Proceeds net of fees and deferred offering cost were $413,662. We will need to keep current our shelf registration statement and the offering prospectus relating to the ATM facility in order to use the program to sell shares of common stock in the future.

If we determine to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct further development. Given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, in light of the Abili-T study results, there can be no assurance that we will be able to secure additional funds or, if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current or proposed activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a substantial portion or even all of their investment.

We do not maintain any external lines of credit or have any sources of debt or equity capital committed for funding, other than our ATM facility. Should we need any additional capital in the future beyond the ATM facility, management will be reliant upon "best efforts" debt or equity financings. As our prospects for funding, if any, develop, we will assess our business plan and make adjustments accordingly. Although we have successfully funded our operations to date by attracting additional investors in our equity and debt securities, given the disappointing results of our Abili-T study, there is no assurance that our capital raising efforts will be able to attract additional capital necessary for future operations.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

For the three months ended March 31, 2017, there were no accounting standards or interpretations issued that are expected to have a material impact on our financial position, operations or cash flows.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms, and that information is accumulated and communicated to our management, including our principal executive (whom we refer to in this periodic report as our Certifying Officer), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officer, the effectiveness of our disclosure controls and procedures as of March 31, 2017, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of March 31, 2017, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should consider the following risk factors, as well as other information contained or incorporated by reference in this report, before deciding to invest in our securities. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof 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, the market price of our securities could decline and you could lose all or part of your investment in our securities.

Risks Related to Our Business

Our business to date has been almost entirely dependent on the development of Tcelna, which recently failed to show a treatment effect in the Phase IIb clinical trial known as the Abili-T study. We are continuing to assess the viability of our other research and development programs and conduct a review of strategic alternatives, and it is possible that we may ultimately decide not to pursue any further drug development of Tcelna or our other programs. Although we have decreased our cash burn substantially, our cash needs over the next few months may be unpredictable.

On October 28, 2016, we announced that the Phase IIb Abili-T clinical trial designed to evaluate the efficacy and safety of Tcelna (imilecleucel-T) in patients with SPMS did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. We had previously devoted substantially all of our research, development, clinical efforts and financial resources toward the development of Tcelna. We implemented a reduction in workforce of 40% of our then 20 full-time employees, announced on November 2, 2016, while we reevaluated our programs and various strategic alternatives in light of the disappointing Abili-T study data. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. In January 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash. As of March 31, 2017 we had two full-time employees. After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time. We are conducting a review of our other research and development programs, including our preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. We are also exploring our strategic alternatives. We cannot fully predict whether or to what extent we will resume drug development activities, and we cannot predict our future cash needs until we complete this analysis and while we are evaluating strategic alternatives.

If we decide to continue one or more of our development programs, we will be required to raise additional capital, and our ability to obtain funding in light of the disappointing results of the Abili-T study is likely to be challenging. If sufficient capital is not available, we may not be able to continue our operations, which may require us to suspend or terminate any ongoing development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

As of March 31, 2017, we had cash and cash equivalents of $2.8 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $818,315. Our operating cash burn rate during the three months ended March 31, 2017 was approximately $324,000 per month, which was mainly general and administrative expenses.

We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities through at least the second quarter of 2017. However, if our projections prove to be inaccurate, or if we encounter additional costs to wind down the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing further research and development, we would need to raise additional capital to continue our operations.

If we decide to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct additional clinical trials of Tcelna or any other product candidates. Given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, in light of the Abili-T study results, there can be no assurance that we will be able to secure additional funds or, if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a substantial portion or even all of their investment.

If we are not successful in attracting another partner, we may not be able to complete development of or commercialize any product candidate. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations. In such event, our shareholders may lose a substantial portion or even all of their investment.

We do not maintain any external lines of credit or have any sources of debt or equity capital committed for funding, other than our ATM facility. Should we need any additional capital in the future beyond these sources, management will be reliant upon "best efforts" debt or equity financings. We can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- 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.

If we raise additional funds by issuing equity securities, shareholders may experience substantial dilution. Debt financing, if available, may involve restrictive covenants that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our shareholders. There is no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations.

There is substantial doubt as to our ability to continue as a going concern, which may make it more difficult for us to raise capital.

The report of our independent auditors in respect of the 2016 fiscal year expressed substantial doubt about our ability to continue as a going concern. Specifically, it noted our recurring losses, negative operating cash flows and accumulated deficit. Our consolidated financial statements as of March 31, 2017 and for the three-month period then ended were prepared assuming that we will continue as a going concern, meaning that we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. While we have historically recognized revenue related to the $5 million and $3 million payments from Merck Serono received in February 2013 and March 2015 in connection with the Option and License Agreement and the Amendment over the exclusive option period based on the expected completion term of the Abili-T clinical trial, we have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. As of March 31, 2017, we had cash and cash equivalents of $2.8 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $818,315.

On October 28, 2016, we announced that the Abili-T trial did not meet its primary or secondary endpoints, and, in order to conserve cash resources while we reevaluated our programs and explored various strategic alternatives, during the fourth quarter of 2016 and the first quarter of 2017 we implemented several reductions in workforce totaling 90% of our then 20 full-time employees. As of March 31, 2017 we had two full time employees. After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time, and we are conducting a review of our other research and development programs. We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities at least through the second quarter of 2017.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. In the absence of significant additional funding to support our operations, there is substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Additionally, in light of the disappointing Abili-T study results, there can be no assurance that we will be able to secure additional funds, or if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a substantial portion or even all of their investment.

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

We have not generated any profits since our entry into the biotechnology business and we have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future. We have not received, and we do not expect to receive for at least the next several years, any revenues from the commercialization of any potential products. We do not currently have any sources of revenues and may not have any in the foreseeable future.

The employment agreement with our President and Chief Executive Officer may require us to pay severance benefits if he is terminated under specified circumstances, including in connection with a change of control of us, which could harm our financial condition or results.

The employment agreement with our President and Chief Executive Officer contains change of control and severance provisions providing for the payment of severance and other benefits, including accelerated vesting of stock options, in the event of a termination of employment under specified circumstances, including in connection with a change of control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of severance benefits could harm our financial condition and results of operation. In addition, these potential severance payments and benefits may discourage or prevent third parties from seeking a business combination with us.

Our business is at an early stage of development. To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna.

Our business is at an early stage of development. We do not have any products on the market. We have only one product candidate, Tcelna, which has progressed to the stage of being studied in human clinical trials in the United States. To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna, including conducting clinical trials and developing manufacturing capabilities, providing general and administrative support for these operations and protecting our intellectual property. The disappointing results of our Abili-T trial have resulted, at a minimum, in a development delay of at least a few years. If we decide to continue the development of one or more of our programs, we will need to commence and complete additional clinical trials, manage clinical and manufacturing activities, and obtain necessary regulatory approvals from the FDA in the United States and from foreign regulatory authorities in other jurisdictions. Additionally, our second pipeline candidate, OPX-212 has been in preclinical development for the treatment of NMO. Any of our potential products will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, obtain regulatory approvals, enter clinical trials (or any development activities) for any product candidates, or commercialize any products. Any of our potential products may prove to have undesirable or 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 to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

The Abili-T trial results cast doubt about the probative value of our results in earlier clinical trials of Tcelna.

Trial designs and results from previous trials are not necessarily predictive of our future clinical trial designs or results. For example, although the results of prior clinical trials of Tcelna for the treatment of MS included evidence of efficacy, the Abili-T trial for the treatment of patients with SPMS failed to meet either its primary or secondary endpoints.

There is a high failure rate for drug candidates proceeding through clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

We will need regulatory approvals for any product candidate prior to introduction to the market, which will require successful testing in clinical trials. Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement. Any product candidate may fail to achieve necessary safety and efficacy endpoints during clinical trials in which case we will be unable to generate revenue from the commercialization and sale of our products.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous FDA requirements, and must otherwise comply with federal, state and local requirements and policies of the medical institutions where they are conducted. The clinical trial process is also time-consuming. Failure can occur at any stage of the trials, and problems could be encountered that would cause us to be unable to initiate a trial, or to abandon or repeat a clinical trial.

The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

- FDA or IRB objection to proposed protocols;
- discussions or disagreement with the FDA over the adequacy of trial design to potentially demonstrate effectiveness, and subsequent design modifications;
- unforeseen safety issues;
- determination of dosing issues, epitope profiles, and related adjustments;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- product quality problems (e.g., sterility or purity);
- challenges to patient monitoring, retention and data collection during or after treatment (e.g., patients' failure to return for follow-up visits or to complete the trial, detection of epitope profiles in subsequent visits, etc.); and
- failure of medical investigators to follow our clinical protocols.

In addition, we or the FDA (based on its authority over clinical studies) may delay a proposed investigation or suspend clinical trials in progress at any time if it appears that the study may pose significant risks to the study participants or other serious deficiencies are identified. Prior to approval of any product candidate, the FDA must determine that the data demonstrate safety and effectiveness. The large majority of drug candidates that begin human clinical trials fail to demonstrate the desired safety and efficacy characteristics.

Furthermore, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols, or otherwise modify our intended course of clinical development, to reflect these changes. This, too, may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even if regulatory approval is obtained for any product candidate, any such approval may be subject to limitations on the indicated uses for which it may be marketed. Our ability to generate revenues from the commercialization and sale of any potential products, whether directly or through any development arrangement, will be limited by any failure to obtain or limitation on necessary regulatory approvals.

As a result of the disappointing data from the Abili-T trial and the reductions in our workforce during 2016 and early 2017, our workforce has been reduced substantially. If we are unable to retain our remaining employees, or rebuild our workforce if we decide to continue one or more of our development programs, our business will be seriously jeopardized. It will be difficult to grow or operate our business with the limited number of employees we currently have.

On November 2, 2016, we announced a reduction of 40% of our then full-time workforce of 20 employees as a result of the disappointing data from the Abili-T study. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. During January 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash, leaving us at this point with only two full-time employees. Our Chief Development Officer resigned in November 2016 after announcement of the Abili-T trial results and the employment of our Chief Scientific Officer was terminated as part of the January 2017 reduction. We have only one officer remaining, who serves as our President, Chief Executive Officer and Acting Chief Financial Officer.

Our exploration of strategic alternatives and cash conservation activities may yield unintended consequences, such as attrition beyond our planned reductions in workforce and reduced employee morale which may cause our remaining employees to seek alternate employment. In such event, we may be unable on a timely basis to hire suitable replacements to operate our business effectively. The loss of the services of any of our employees could have a material adverse effect on our business and results of operations. Our restructuring initiatives have caused disruption in our business operations, and we may not be able to effectively realize the savings anticipated by any restructuring initiative and reductions-in-force. Additionally, there may be future changes in our workforce, including as a result of changes that may occur in our operations or operating plan, or other reasons or events. There may also be possible changes in the amount of charges and cash payments associated with any workforce reduction, including the possibility that we may incur unanticipated charges or make cash payments that are not contemplated.

Additionally, if we ultimately decide to pursue one or more of our development programs, we will need to rebuild our workforce and management team. We may be unable on a timely basis to hire and train suitable new employees to continue to operate our business and further any such development programs. It will be difficult to grow or operate our business with the small number of employees we currently have.

Funding from our ATM facility may be limited or be insufficient to fund our operations or to implement our strategy.

We will need to keep current our shelf registration statement and the offering prospectus relating to ATM facility with Brinson Patrick (now a division of IFS Securities, Inc.) in order to use the program to sell shares of our common stock. The number of shares and price at which we may be able to sell shares under our ATM facility may be limited due to market conditions and other factors beyond our control.

We may make changes to discretionary R&D investments that may have an impact on costs.

We conducted an immune monitoring program on blood samples collected over time to detect Tcelna-induced immune modulation. While certain data has been analyzed to date, a correlation analysis of immune monitoring T-cell phenotypes to MRTC bio-activity has not been conducted. Expenses associated with the immune monitoring program are incurred at our discretion and are not required to satisfy any FDA-mandated criteria. Consequently, we may make changes to the parameters that are being analyzed, or we may elect not to proceed with certain analyses, and these changes may result in either increased or decreased expenses for any such study.

We may also incur discretionary expenses related to preclinical, Phase I, Phase II and/or Phase III development programs, manufacturing scale-up/automation and technology transfer, research on additional indications and business development activities. There is no assurance that any such future expenses would be recovered by us.

We would need to rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize any product candidate.

Although we have participated in the design and management of our past clinical trials, we do not have the ability to conduct clinical trials directly for any product candidate. We would need to rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct any clinical trials and to perform data collection and analysis.

Any clinical trials we may conduct could be delayed, suspended or terminated if:

- any third party upon whom we rely does not successfully carry out its contractual duties or regulatory obligations or meet expected deadlines;
- licenses needed from third parties for manufacturing in order to conduct Phase III trials or to conduct commercial manufacturing, if applicable, are not obtained;
- any such third party needs to be replaced; or
- the quality or accuracy of the data obtained by the third party is compromised due to its failure to adhere to clinical protocols or regulatory requirements or for other reasons.

Failure to perform by any third party upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of any product candidate. While we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.

We have focused on MS as the first disease to be pursued off our T-cell platform technology, and in 2014, we initiated development activities for OPX-212, our drug candidate for NMO, as the second disease we are pursuing. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. While preclinical development and manufacturing activities have been conducted for OPX-212 in NMO, such work is modest compared to the effort that has been committed to Tcelna for the lead MS indication. However, inasmuch as the Abili-T study of Tcelna in SPMS did not meet either its primary or secondary endpoints, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time and are assessing whether to continue our development activities. Our business over the long term is substantially dependent on our ability to develop, license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to expand our existing platform or identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

Moreover, any product candidate acquisition that we do complete will involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new potential markets or technologies;
- inability to generate sufficient funding to offset acquisition costs; and
- delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

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 diligently to pursue development of commercial products under the licensed patents. If applicable, we may also need to seek additional licenses to move into Phase III trials or the commercial stage of operations. These licenses may require increased payments to the licensors. 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 adversely affected.

We no longer lease a research and manufacturing facility in which to conduct development or manufacture product candidates for our programs or clinical trial activities or, if any such clinical trials were to be successful, commercial applications.

Through January 2017, we conducted our research and development in a 10,200 square foot facility in The Woodlands, Texas, which included an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. On February 1, 2017, we assigned the facility lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. In connection with the lease assignment, we also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as our laboratory supplies located at our corporate headquarters to the third party for cash consideration. In light of the continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, we deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations. As a result, we are currently using temporary office space in the same facility but no longer have the capacity for any research and development or for any manufacturing operations. If we decide to continue to pursue development of any of our product candidates, we would need to locate and obtain a new facility, arrange for R&D and manufacturing staff, contract with corporate collaborators or other third parties to assist with future drug production and commercialization, or defer to a collaborative partner or third party to address these needs.

In the event that we decide to again establish a R&D or manufacturing facility, we would require substantial additional funds and would 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 an R&D or manufacturing facility, and we may not be able to build a facility that both meets regulatory requirements and is sufficient for our needs.

We may arrange with third parties for the manufacture of our future products, if any. 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 cGMP 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.

Problems with our manufacturing process or with a manufacturing facility (whether ours or a third party's) could result in the failure to produce, or a delay in producing, adequate supplies of any of our product candidates. A number of factors could cause interruptions or delays, including equipment malfunctions or failures, destruction or damage to a manufacturing facility due to natural disasters or otherwise, contamination of materials, changes in regulatory requirements or standards that require modifications to our manufacturing process, action by a regulatory agency or by a manufacturer (whether us or a third party) that results in the halting or slowdown of production due to regulatory issues, any third-party manufacturer going out of business or failing to produce as contractually required, or other similar factors.

Difficulties, delays or interruptions in the manufacture and supply of any of our product candidates could require us to stop treating patients in our clinical development of such product candidate and/or require a halt to or suspension of, or otherwise adversely affect, a clinical trial, thus increasing our costs and damaging our reputation. If a product candidate is approved, difficulties, delays or interruptions in the manufacture and supply of such product candidate could cause a delay in or even halt or suspend the commercialization of such product candidate, potentially causing a partial or complete loss of revenue or market share.

Tcelna was manufactured using our proprietary ImmPath® technology for the production of an autologous T-cell immunotherapy utilizing a patient's own blood. Our manufacturing process may raise development issues that may not be resolvable, regulatory issues that could delay or prevent approval, or personnel issues that may prevent the further development or commercialization, if approved, of any product candidate.

Tcelna was based on our novel T-cell immunotherapy platform, ImmPath, which produces an autologous T-cell immunotherapy utilizing a patient's own blood. OPX-212 may be similarly produced. The manufacture of living T-cell products requires specialized facilities, equipment and personnel which are different than the resources required for manufacturing chemical or biologic compounds. Scaling-out the manufacture of living cell products to meet demands for commercialization will require substantial amounts of such specialized facilities, equipment and personnel, especially where the products are personalized and must be made for each patient individually. Because our manufacturing processes are complex, require facilities and personnel that are not widely available in the industry, involve equipment and training with long lead times, and the establishment of new manufacturing facilities is subject to a potentially lengthy regulatory approval process, alternative qualified production capacity may not be available on a timely basis or on reasonably terms, if at all. In addition, not many consultants or advisors in the industry have relevant experience and can provide guidance or assistance because active immune therapies are fundamentally a new category of product in two major ways: (i) the product consists of living T-cells, not chemical or biologic compounds; and (ii) the product is personalized. There can be no assurance that manufacturing problems will not arise in the future which we may not be able to resolve or which may cause significant delays in development or, if any product candidate is approved, commercialization.

Regulatory approval of product candidates that are manufactured using novel manufacturing processes such as ours can be more expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to a lack of experience with them. FDA approval of personalized immunotherapy products has been limited to date. This lack of experience and precedent may lengthen the regulatory review process, require that additional studies or clinical trials be conducted, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization, or lead to significant post-approval limitations or restrictions.

In addition, the novel nature of product candidates also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

If any product we may eventually have is not accepted by the market or if users of any such product are unable to obtain adequate coverage of and reimbursement for such product from government and other third-party payors, our revenues and profitability will suffer.

Our ability to successfully commercialize any product we may eventually have, to the extent applicable, and/or our ability to receive any revenue will depend in significant part on the extent to which appropriate coverage of and reimbursement for such product and any related treatments are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider any product cost-effective or provide coverage of and reimbursement for such product, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that any product is less safe, less clinically effective, or less cost-effective than existing products, and third-party payors may not approve such product for coverage and reimbursement. If adequate coverage of and reimbursement for any product from third-party payors cannot be obtained, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of any such product would cause sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of any such product profitable.

In addition, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for any product we may eventually have. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, the use of formularies. The market for any product depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

Any product candidate, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

Even if a product candidate is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, and our profitability and growth, will depend on a number of factors, including:

- demonstration of efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of sales and marketing strategies for the product and competition for such product;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC and The NASDAQ Stock Market (NASDAQ). Changes in the laws and regulations affecting public companies, including the provisions of SOX and rules adopted by the SEC and by NASDAQ, have resulted in, and will continue to result in, increased costs to us as we respond to their requirements. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to conclude an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may determine that our internal control over financial reporting was not effective. We currently have a very limited workforce, and it may be difficult to adhere to appropriate internal controls over financial reporting or disclosure controls with such limited staffing. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting, especially in light of the fact that we currently have a very limited workforce. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Under the corporate governance standards of NASDAQ, a majority of our Board of Directors and each member of our Audit and Compensation Committees must be an independent director. If any vacancies on our Board or our Audit or Compensation Committees occur that need to be filled by independent directors, we may encounter difficulty in attracting qualified persons to serve on our Board and, in particular, our Audit Committee. If we fail to attract and retain the required number of independent directors, we may be subject to SEC enforcement proceedings and delisting of our common stock from the NASDAQ Capital Market.

Any acquisitions that we make could disrupt our business and harm our financial condition.

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies on a global geographic footprint. We may also consider joint ventures, licensing and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management's time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies, or with acquiring products outside of the United States. Any cash acquisition we pursue would potentially divert the cash we have on our balance sheet from our present clinical development programs. Any stock acquisitions would dilute our shareholders' ownership. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present agreements with respect to any acquisitions or collaborative projects.

We plan to do business internationally, which may prove to be difficult and fraught with economic, regulatory and political issues.

We may acquire or in-license foreign companies or technologies or commercialize our T-cell or stem cell platform in countries where the business, economic and political climates are very different from those of the United States. We may not be aware of some of these issues and it may be difficult for a U.S. company to overcome these issues and ultimately become profitable. Certain foreign countries may favor businesses that are owned by nationals of those countries as opposed to foreign-owned business operating locally. As a small company, we may not have the resources to engage in the negotiation and time-consuming work needed to overcome some of these potential issues.

Risks Related to Our Intellectual Property

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, such as Tcelna.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make or use our potential products, such as Tcelna, 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 any affected product candidate 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 patent protection and other proprietary rights, our operations will be significantly harmed.

Our ability to compete effectively is dependent 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 pending patent applications for our technology will result in the issuance of patents, or if any issued 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 18 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 owned or licensed intellectual property rights were the first to make the inventions at issue or that any patent applications at issue were the first to be filed for such inventions. There can be no assurance that patents will issue from pending 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.

Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on a third party payor to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we may not maintain direct control over the payment of all such annuities, we cannot assure you that our third party payor will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, we or our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of product candidates, such as Tcelna, involves complex legal and factual questions. To the extent that it would be necessary or advantageous for any of our licensors to cooperate or lead in the enforcement of our licensed intellectual property rights, we cannot control the amount or timing of resources such licensors devote on our behalf or the priority they place on enforcing such rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them, or our underlying licenses.

We cannot be certain that any of the patents issued to us or to our licensors will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates such as Tcelna;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights (owned or licensed) is uncertain. For example:

- we or our licensor might not have been the first to make the inventions covered by pending patent applications or issued patents owned by, or licensed to, us;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of the technologies owned by, or licensed to, us;
- it is possible that none of the pending patent applications owned by, or licensed to, us will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws; or
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

We rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

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, T-cells, and other technologies potentially relevant to or required by our product candidates such as Tcelna. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware of a number of patent applications and patents claiming use of modified cells to treat disease, disorder or injury.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, such as Tcelna, or their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. If our product candidates, such as Tcelna, or their methods of manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to Tcelna or OPX-212. Consequently, no assurance can be given that third-party patents containing claims covering Tcelna or OPX-212, their methods of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potentially treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or
- significant cost and expense, as well as distraction of our management from our business.

As a result, we could be prevented from commercializing current or future product candidates.

Risks Related to Our Industry

We are subject to stringent regulation of our product candidates, which could delay development and commercialization.

We, our third-party contractors and suppliers, and our product candidates are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. No product candidate of ours has been approved, and we may never receive FDA approval for any product candidate. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce our ability to generate revenues.

In addition, both before and after regulatory approval, we and our product candidates are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us and our product candidates. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs resulted in the enactment of legislation addressing drug safety issues, the FDA Amendments Act of 2007. This legislation provides the FDA with expanded authority over drug products after approval and the FDA's exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Approval by the FDA does not automatically lead to the approval of authorities outside of the United States and, similarly, approval by other regulatory authorities outside the United States will not automatically lead to FDA approval. In addition, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our product candidates may not be approved for all indications that we request, which would limit uses and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which any potential product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

We may need to change our business practices to comply with health care fraud and abuse regulations, and our failure to comply with such laws could adversely affect our business, financial condition and results of operations.

If we are successful in achieving approval to market one or more of our product candidates, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

Beginning August 1, 2013, the Physician Payments Sunshine Act (the "Sunshine Act"), which is part of the Patient Protection and Affordable Care Act, requires manufacturers of drugs, medical devices, biologicals or medical supplies that participate in U.S. federal health care programs to track and then report certain payments and items of value given to U.S. physicians and U.S. teaching hospitals (defined as "Covered Recipients"). The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services by the 90th day of each subsequent year.

If our operations are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.

Competition in the pharmaceutical industry, particularly the market for MS products, is intense, and we expect such competition to continue to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies. These companies have significantly greater capital resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing than we currently do. However, smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. In addition to the competitors with existing products that have been approved, many of our 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 further product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

Our competitors may also develop alternative therapies that could further limit the market for any products that we may develop.

Rapid technological change could make our products obsolete.

Biopharmaceutical technologies have undergone rapid and significant change, and we expect that they will continue to do so. As a result, there is significant risk that our product candidates may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates are rendered obsolete by advancements in biopharmaceutical technologies, our future prospects will suffer.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products.

In the event that any of our product candidates becomes an approved product and is commercialized, consumers may make product liability claims directly against us and/or our partners, and our partners or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We have insurance that covers clinical trial activities. We believe our insurance coverage as of the date hereof is reasonably adequate at this time. However, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if any product candidate is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our products.

Government controls and health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of any product candidate to other available therapies. If reimbursement of any product candidate is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability in such country. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for any product candidate covered by a Part D prescription drug plan will likely be lower than the prices that might otherwise be obtained outside of the Medicare Part D prescription drug plan. Moreover, while Medicare Part D applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any product candidate. Among policy-makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: the demand for any product candidate; the ability to set a price that we believe is fair for any product candidate; our ability to generate revenues and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

Risks Related to Our Securities

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

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

Our stock may be delisted from NASDAQ, which could affect its market price and liquidity.

We are required to meet certain qualitative and financial tests (including a minimum bid price for our common stock of $1.00 per share and a minimum stockholders' equity of $2.5 million), as well as certain corporate governance standards, to maintain the listing of our common stock on the NASDAQ Capital Market. While we are exercising diligent efforts to maintain the listing of our common stock and warrants on NASDAQ, there can be no assurance that we will be able to do so, and our securities could be delisted.

For example, as a consequence of our announcement on October 28, 2016 that the Abili-T trial did not meet either its primary or secondary endpoints, our stock has traded below $1.00 per share at times. On April 10, 2017, we received a staff deficiency letter from NASDAQ indicating that our common stock failed to comply with the minimum bid price requirement because it closed below the $1.00 minimum closing bid price for 30 consecutive business days. The notice further stated that we will be provided a period of 180 calendar days to regain compliance. If our common stock maintains a closing bid price of $1.00 per share or more for a minimum of 10 consecutive business days (or such longer period of time as the NASDAQ staff may require in some circumstances, but generally not more than 20 consecutive business days) before October 9, 2017, we will achieve compliance with this listing standard. If our common stock does not achieve compliance with the minimum bid price by October 9, 2017, we may be eligible for an additional 180-day grace period to regain compliance if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide timely notice of our intention to cure the deficiency during the second grace period by effecting a reverse stock split, if necessary. However, if it appears to the NASDAQ staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, NASDAQ could provide notice that our stock will become subject to delisting. We are actively monitoring the closing bid price of our common stock and evaluating available options to resolve this deficiency and regain compliance with the minimum bid price rule.

Additionally, our stockholders' equity as of March 31, 2017 was $2,241,693, which is below the NASDAQ minimum continued listing requirement of $2.5 million. It is also possible that we could fail to satisfy another NASDAQ requirement for continued listing of our stock, such as the market value or number of publicly held shares or number of shareholders, or a corporate governance requirement. In addition to the minimum bid price deficiency notice we received on April 10, 2017, we may receive additional future notices from NASDAQ that we have failed to meet its requirements including for minimum stockholders' equity, and proceedings to delist our stock could be commenced. In such event, NASDAQ rules permit us to appeal any delisting determination to a NASDAQ Hearings Panel. If we are unable to maintain or regain compliance in a timely manner or if we do not meet the other listing standards and our common stock is delisted, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital or enter into a potential strategic transaction.

Our share price is volatile, and you may not be able to resell our shares at a profit or at all.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the disappointing results recently announced on October 28, 2016 for the Abili-T clinical study of Tcelna in SPMS;
- announcements of significant changes in our business or operations, including the decision not to pursue one or more of our drug development programs or the decision to implement restructurings such as reductions in our workforce;
- the development status of any drug candidates, such as Tcelna, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- our inability to obtain additional funding;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques;
- regulatory developments in the United States and in foreign countries; or
- dilutive effects of sales of shares of common stock by us or our shareholders, and sales of common stock acquired upon exercise or conversion by the holders of warrants, options or convertible notes.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

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. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. Moreover, following the announcement on October 28, 2016 of disappointing results of the Abili-T study, our stock price decreased substantially, which may portend securities class action litigation against us. If 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.

Our "blank check" preferred stock could be issued to prevent a business combination not desired by management or our majority shareholders.

Our charter authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined by our Board of Directors without shareholder approval. Our preferred stock could be utilized as a method of discouraging, delaying, or preventing a change in our control and as a method of preventing shareholders from receiving a premium for their shares in connection with a change of control.

Future sales of our securities could cause dilution, and the sale of such securities, or the perception that such sales may occur, could cause the price of our stock to fall.

On March 25, 2016, we entered into a new Sales Agreement with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering. We registered up to 1,000,000 shares of common stock for potential sale under the new ATM facility. From August 17, 2016 through December 31, 2016, we sold an aggregate of 66,184 shares of our common stock under our ATM facility. We generated gross and net proceeds, including amortization of deferred offering costs, of $293,345 and $276,912, respectively, with the average share price ranging from $4.12 to $4.73 per share. During January 2017, we further sold an aggregate of 516,278 shares of common stock for gross and net proceeds of $490,098 and $413,662 respectively, with the average share price ranging from $0.90 to $0.97. We will need to keep current our shelf registration statement and the offering prospectus relating to the ATM facility in order to use the program to sell shares of common stock in the future.

Sales of additional shares of our common stock, as well as securities convertible into or exercisable for common stock, could result in substantial dilution to our shareholders and cause the market price of our common stock to decline. An aggregate of 7,657,332 shares of common stock were outstanding as of March 31, 2017. As of such date, another (i) 244,868 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,468,736 shares of common stock were issuable upon the exercise of outstanding warrants. A substantial majority of the outstanding shares of our common stock and warrants (as well as a substantial majority of the shares of common stock issuable upon exercise of outstanding options and warrants) are freely tradable without restriction or further registration under the Securities Act of 1933.

We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. We may need to raise additional capital in order to initiate or complete additional development activities for Tcelna in MS and for OPX-212 in NMO, or to pursue additional disease indications for our T-cell technology, and this may require us to issue a substantial amount of securities (including common stock as well as securities convertible into or exercisable for common stock). There can be no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations. Moreover, we cannot predict the size of future issuances of our common stock, as well as securities convertible into or exercisable for common stock, or the effect, if any, that future issuances and sales of our securities will have on the market price of our common stock. Sales of substantial amounts of our common stock, as well as securities convertible into or exercisable for common stock, including shares issued in connection with an acquisition or securing funds to complete our clinical trial plans, or the perception that such sales could occur, may result in substantial dilution and 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 our business.

Our shareholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 150,000,000 shares of our common stock and to issue and designate the rights of, without shareholder approval, up to 10,000,000 shares of preferred stock. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by other investors, and dilution to our shareholders could result. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors.

We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

Our management has significant flexibility in using our current available cash.

In addition to general corporate purposes (including working capital, research and development, business development and operational purposes), we currently intend to use our available cash to continue to assess the viability of pursuing one or more of our research and development programs, including our preclinical program for OPX-212 in NMO, and to explore our strategic alternatives. We cannot fully predict our future cash needs until we complete this analysis. However, after further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time.

Depending on future developments and circumstances, we may use some of our available cash for other purposes which may have the potential to decrease our cash runway. Notwithstanding our current intentions regarding use of our available cash, our management will have significant flexibility with respect to such use. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount and timing of cash used in our operations and our research and development efforts. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

An active trading market may never develop for our Series M warrants, which may limit the ability to resell the warrants.

There is no established trading market for the Series M warrants we issued in April 2015. While the warrants have been listed for trading on NASDAQ under the symbol "OPXAW," there can be no assurance that that a market will develop for the warrants. Even if a market for the warrants does develop, the price of the warrants may fluctuate and liquidity may be limited. If a market for the warrants does not develop, then holders of the warrants may be unable to resell the warrants or be able to sell them only at an unfavorable price. Future trading prices of the warrants will depend on many factors, including our operating performance and financial condition, our ability to continue the effectiveness of the registration statement covering the warrants and the common stock issuable upon exercise of the warrants, the interest of securities dealers in making a market and the market for similar securities.

The market price of our common stock may not exceed the exercise price of the Series M warrants.

The Series M warrants issued in April 2015 will expire on April 9, 2018. The warrants entitle the holders to purchase shares of common stock at an exercise price of $12.00 per share through their expiration. There can be no assurance that the market price of our common stock will exceed the exercise price of the warrants at any or all times prior to their expiration. Any warrants not exercised by their expiration date will expire worthless and we will be under no further obligation to the warrant holder.

The Series M warrants may be redeemed on short notice. This may have an adverse impact on their price.

We may redeem the Series M warrants for $0.01 per warrant if the closing price of our common stock has equaled or exceeded $20.00 per share, subject to adjustment, for 10 consecutive trading days. If we give notice of redemption, holders will be forced to sell or exercise their warrants or accept the redemption price. The notice of redemption could come at a time when it is not advisable or possible to exercise the warrants. As a result, holders would be unable to benefit from owning the warrants being redeemed.

Our ability to use net operating loss carryovers to reduce future tax payments may be limited.

As of December 31, 2016, we had net operating loss carryforwards (NOLs) for federal income tax purposes of approximately $74 million. These NOLs are generally carried forward to reduce taxable income in future years. If unused, the NOLs will begin to expire December 31, 2024. However, our ability to utilize the NOLs is subject to the rules under Section 382 of the Internal Revenue code.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs"), to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders (generally 5% shareholders, applying certain look-through and aggregation rules) increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards. This annual limitation is generally equal to the product of the value of our stock on the date of the ownership change, multiplied by the long-term tax-exempt rate published monthly by the Internal Revenue Service. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL carryforwards.

The rules of Section 382 are complex and subject to varying interpretations. As a result of our numerous capital raises, which have included the issuance of various classes of convertible securities and warrants, uncertainty exists as to whether we may have undergone an ownership change in the past. Based on our recent stock prices, we believe any ownership change would severely limit our ability to utilize the NOLs. Limitations imposed on our ability to utilize NOL carryforward amounts could cause U.S. federal income taxes to be paid earlier than if such limitations were not in effect and could cause such NOL carryforward amounts to expire unused, in each case reducing or eliminating the expected benefit to us. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOL carryforward amounts before they expire. If any of these events occur, we may not derive some or all of the benefits from our NOL carryforward amounts. Presently, impairment tests have not been conducted to verify NOL preservation. Accordingly, no assurance can be given that our NOLs will be fully available.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Through January 2017, we leased a 10,200 square foot facility located on three acres at 2635 Technology Forest Boulevard in The Woodlands, Texas. This location provided space for research and development and manufacturing capacity for clinical trials; a specialized Flow Cytometry and Microscopy lab; support of clinical trials with 800 square feet of cGMP manufacturing suites; Quality Systems management with a Quality Control Laboratory, Regulatory Affairs, and Quality Assurance; as well as administrative support space. Approximately 2,500 square feet of space remained available for future build-out. We leased the facility for a term ending in September 2020 with two options for an additional five years each at the then prevailing market rate.

On February 1, 2017, we assigned the facility lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. In connection with the lease assignment, we also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as our laboratory supplies located at our corporate headquarters to the third party for cash consideration. In light of the continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, we deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations. As a result, we are currently using temporary office space in the same facility but do not have any long-term arrangements.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 6. Exhibits

Exhibit No.	Description
10.1	Assignment and Assumption of Lease, dated February 1, 2017, by and between Opexa Therapeutics, Inc. and KBI Biopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 1, 2017).
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

* Filed herewith.

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.

OPEXA THERAPEUTICS, INC.

Date: May 12, 2017

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

EXHIBIT INDEX

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* Filed herewith.

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Neil K. Warma, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opexa Therapeutics, Inc.;

2. Based on my knowledge, this 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 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 report;

4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. 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

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth 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(s) 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 the 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.

Date: May 12, 2017

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2017 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President, Chief Executive Officer and Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2017

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