FARMERS NATIONAL BANC CORP /OH/
Form 11-K
June 29, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 11-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to __________

Commission file number 001-35296

A. Full title of the plan and the address of the plan, if different from that of the issuer named below:

Farmers National Bank 401(k) Retirement Savings Plan

B. Name of issuer of the securities held pursuant to the plan and the address of its principal executive office:

Farmers National Banc Corp.

20 South Broad Street

Canfield, Ohio 44406

FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

YEARS ENDED DECEMBER 31, 2014 AND 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

TO THE PLAN ADMINISTRATOR

FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

We have audited the accompanying statements of net assets available for benefits of the Farmers National Bank 401(k) Retirement Savings Plan (the Plan) as of December 31, 2014 and 2013, and the related statements of changes in net assets available for benefits for the years ended December 31, 2014 and 2013. These financial statements are the responsibility of the Plan s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Plan is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Plan s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the net assets available for benefits of the Plan as of December 31, 2014 and 2013, and the changes in net assets available for benefits for the years ended December 31, 2014 and 2013, in conformity with accounting principles generally accepted in the United States of America.

The supplemental information in the accompanying schedule of assets (held at end of year) as of December 31, 2014 has been subjected to audit procedures performed in conjunction with the audit of the Farmers National Bank 401(k) Retirement Savings Plan s financial statements. The supplemental information is presented for the purpose of additional analysis and is not a required part of the financial statements but include supplemental information required by the Department of Labor s Rules and Regulations for Reporting and Disclosure under the Employee Retirement Income Security Act of 1974. The supplemental information is the responsibility of the Plan s management. Our audit procedures included determining whether the supplemental information reconciles to the financial statements or the underlying accounting and other records, as applicable, and performing procedures to test the completeness and accuracy of the information presented in the supplemental information. In forming our opinion on the supplemental information in the accompanying schedule, we evaluated whether the supplemental information, including its form and content, is presented in conformity with the Department of Labor s Rules and Regulations for Reporting and Disclosure under the Employee Retirement Income Security Act of 1974. In our opinion, the supplemental information in the accompanying schedule is fairly stated in all material respects in relation to the financial statements as a whole.

SKODA MINOTTI

/s/ Skoda Minotti

Cleveland, Ohio

June 15, 2015

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

STATEMENTS OF NET ASSETS AVAILABLE FOR BENEFITS

DECEMBER 31, 2014 AND 2013

	2014	2013
INVESTMENTS, AT FAIR VALUE		
Non-interest-bearing cash	$ 27,309	$ 21,552
Registered investment companies	15,139,124	12,462,388
Farmers National Banc Corp. Common Stock	255,612	21,706
Common collective trust	725,591	703,385
	16,147,636	13,209,031
RECEIVABLES		
Notes receivable from participants	7,739	12,236
Receivable from another Plan		2,072,330
	7,739	2,084,566
	16,155,375	15,293,597
LIABILITY		
Corrective distributions payable	(34,094)	(37,634)
NET ASSETS AVAILABLE FOR BENEFITS AT FAIR VALUE	16,121,281	15,255,963
ADJUSTMENT FROM FAIR VALUE TO CONTRACT VALUE FOR INTEREST IN A COMMON COLLECTIVE TRUST RELATING TO A FULLY BENEFIT-RESPONSIVE INVESTMENT CONTRACT	(2,170)	(2,104)
NET ASSETS AVAILABLE FOR BENEFITS	$ 16,119,111	$ 15,253,859

The accompanying notes are an integral part of these financial statements.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

STATEMENTS OF CHANGES IN NET ASSETS AVAILABLE FOR BENEFITS

YEARS ENDED DECEMBER 31, 2014 AND 2013

	2014	2013
ADDITIONS TO NET ASSETS ATTRIBUTED TO:		
Investment income		
Net appreciation in fair value of investments	$ 427,178	$ 2,093,747
Interest and dividends	647,148	411,825
	1,074,326	2,505,572
Other income	181	41
Contributions		
Participants	1,091,359	1,007,928
Companies	336,474	341,265
Participants Rollovers		18,236
	1,427,833	1,367,429
Transfer of assets into the Plan		2,072,330
Total additions	2,502,340	5,945,372
DEDUCTIONS FROM NET ASSETS ATTRIBUTED TO:		
Benefits paid to participants	1,637,088	2,243,053
Total deductions	1,637,088	2,243,053
NET INCREASE	865,252	3,702,319
NET ASSETS AVAILABLE FOR BENEFITS:		
BEGINNING OF YEAR	15,253,859	11,551,540
END OF YEAR	$ 16,119,111	$ 15,253,859

The accompanying notes are an integral part of these financial statements.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

1. DESCRIPTION OF PLAN

The following brief description of the Farmers National Bank 401(k) Retirement Savings Plan (the Plan) provides only general information. The Plan covers eligible employees from Farmers National Bank of Canfield, Farmers Trust Company, Farmers National Insurance LLC and National Associates Inc. (collectively, the Companies). Participants should refer to the Plan document for a more complete description of the Plan s provisions.

During 2013, Farmers National Bank of Canfield acquired National Associates, Inc. Effective October 1, 2013, a participation agreement was executed to allow the employees of National Associates, Inc. to participate in the Plan. The participant account balances from the National Associates, Inc. Retirement Savings Plan were liquidated in December 2013 and received by the Plan in January 2014. These participant account balances have been recorded as a receivable from another Plan in the accompanying 2013 Statement of Net Assets Available for Benefits. Additionally, the Plan was amended during 2013 to allow for the service of the notes receivable transferred from National Associates, Inc. Retirement Savings Plan.

General

The Plan is a defined contribution plan and is subject to the provisions of the Employee Retirement Income Security Act of 1974 (ERISA), as amended.

Employees are eligible to participate in the Plan and receive employer matching and discretionary contributions when they are age 21 or older and have completed 90 days of service. Plan entry dates are January 1st, April 1st, July 1st and October 1st following the date of eligibility.

Contributions

A participant may contribute, through payroll reductions, from 1% to 100% of their compensation to the Plan on a pre-tax basis and/or Roth contributions, up to the maximum dollar amount allowed by law (plus catch-up contributions as defined by the Plan document). Participants may also make rollover contributions to the Plan from other qualified defined benefit or defined contribution plans.

The Plan permits matching contributions, discretionary contributions, qualified non-elective contributions (QNEC) and qualified matching contributions (QMAC) by the Companies. The Companies match 50% of the first 6% of compensation that the participant contributes to the Plan. The Companies do not match catch-up contributions. Employer matching contributions totaled $336,474 and $341,265 for the Plan years ended December 31, 2014 and 2013, respectively. During the years ended December 31, 2014 and 2013, the Companies did not make any discretionary contributions, QNEC, or QMAC.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

1. DESCRIPTION OF PLAN (continued)

Participant Accounts

Each participant s account is credited with the participant s contributions, the Companies allocation of discretionary employer contributions, matching contributions, and any earnings thereon, and charged with an allocation of administrative expenses. Discretionary contributions are allocated as a percentage of compensation of eligible participants for the Plan year. Allocations of the earnings and expenses are based on the participant s account balances. The benefit to which a participant is entitled is the benefit that can be provided from the participant s vested account.

Vesting

Participants are immediately vested in their contributions plus earnings thereon. Vesting in the Companies matching and discretionary contributions is based on years of continuous service according to the following schedule:

Years of Service	Vested Percentage
Less than 2 years	0%
2 years but less than 3	20%
3 years but less than 4	40%
4 years but less than 5	60%
5 years but less than 6	80%
6 years or more	100%

Forfeitures

Forfeited nonvested accounts totaled $27,308 and $21,552 at December 31, 2014 and 2013, respectively. Forfeitures may be used to reduce the Companies matching contributions to the Plan, restore participants forfeitures, be added to the Companies matching contributions or used to offset Plan expenses as defined by the Plan document. During 2014 and 2013, forfeitures of $22,843 and $19,566, respectively, were used to reduce the Companies matching contributions, and no forfeitures were reallocated to participants in the Plan.

Investment Options

Upon enrollment in the Plan, participants may direct contributions to their accounts into various investment options offered by the Plan.

Payment of Benefits

On termination of service due to death, disability, retirement, or separation of service, a participant may elect to receive installment payments or a lump-sum amount equal to the value of the participant s vested interest in his or her account. Participants may also elect to receive periodic payments through a life annuity equal to the value of the participant s vested interest in his or her account. Upon proven financial hardship, participants may elect to receive a distribution equal to the value of their deferral contributions.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

The accompanying financial statements are prepared on the accrual basis of accounting.

Investment contracts held by a defined contribution plan are required to be reported at fair value. However, contract value is the relevant measurement attribute for that portion of the net assets available for benefits of a defined contribution plan attributable to fully benefit-responsive investment contracts because contract value is the amount participants would receive if they were to initiate permitted transactions under the terms of the Plan. The Plan invests in an investment contract through a common collective trust. Contract value, as reported to the Plan by EMJAY Corporation, the custodian of the Plan, represents contributions made under the contract, plus earnings, less participant withdrawals, wrapper fees, and administrative expenses. The Statements of Net Assets Available for Benefits present the fair values of the common collective trust as well as the adjustments from fair value to contract value. The Statements of Changes in Net Assets Available for Benefits are prepared on a contract value basis.

Investment Valuation and Income Recognition

Investments are reported at fair value. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. See Note 4 for a discussion of fair value measurements.

Purchases and sales of securities are recorded on a trade-date basis. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date. Net appreciation includes the Plan s gains and losses on the investments purchased and sold, as well as held during the year.

Payment of Benefits

Benefits are recorded when paid.

Administrative Expenses

The Plan allows administrative expenses to be paid either by the Plan or the Companies, at the discretion of the Companies. During the years ended December 31, 2014 and 2013, administrative expenses were paid by the Companies.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Subsequent Events

The Companies evaluated subsequent events through June 15, 2015, the date these financial statements were available to be issued. There were no other material subsequent events that required recognition or additional disclosure in these financial statements.

Notes Receivable from Participants

Notes receivable from participants are measured at their unpaid principal balance plus any accrued but unpaid interest. Delinquent notes receivable are reclassified as distributions based upon the terms of the Plan document. Interest income of $181 and $41 for 2014 and 2013 respectively, has been recorded as other income in the accompanying Statements of Changes in Net Assets Available for Benefits.

3. INVESTMENTS

The following table presents the fair value of investments at December 31, 2014 and 2013. Individual investments that represent 5% or more of the Plan s net assets are separately identified.

	2014	2013
Non-interest-bearing cash	$ 27,309	$ 21,552
Registered investment companies		
American Funds AMCAP Fund	2,106,631	1,718,695
Federated Government Obligations Fund	804,438	786,997
Federated Total Return Bond Fund	1,832,812	1,353,181
Goldman Sachs Mid Cap Value Fund	820,043	588,812
Oppenheimer International Growth Fund	1,403,537	1,436,357
Vanguard 500 Index Fund	3,082,832	2,374,438
Vanguard Small Cap Index Fund	1,913,940	1,713,209
Other registered investment companies	3,174,891	2,490,699
	15,139,124	12,462,388
Common collective trust		
Federated Capital Preservation Fund*	723,421	701,281

Farmers National Banc Corp. Common Stock	255,612	21,706
	$ 16,145,466	$ 13,206,927

* This amount represents contract value for this investment

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

3. INVESTMENTS (continued)

The Plan s registered investment companies and Farmers National Banc Corp. Common Stock (including gains and losses on investments purchased and sold, as well as held during the year) appreciated in value by $427,178 and $2,093,747 during the years ended December 31, 2014 and 2013, respectively.

4. FAIR VALUE MEASUREMENTS

GAAP establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. It applies to fair value measurements already recognized or permitted by existing standards. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs used in valuation models (Level 3 measurements).

The three levels of the fair value hierarchy under GAAP are described as follows:

Level 1	Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Plan has the ability to access.
Level 2	Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in inactive markets. Level 2 inputs include those other than quoted prices that are observable for the asset or liability. Level 2 inputs are derived principally from, or are corroborated by, observable market data by correlation or other means. If the asset or liability has a specified term, the Level 2 input must be observable for substantially the full term of the asset or liability.
Level 3	Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset s or liability s fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used should maximize the use of observable inputs and minimize the use of unobservable inputs.

Following is a description of the valuation methodologies used for assets measured at fair value. There have been no changes in the methodologies used at December 31, 2014 and 2013.

Non-interest-bearing cash Valued at cost, which equals fair value.

Registered investment companies and common stock Valued at the closing price reported on the active market on which the individual securities are traded.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

4. FAIR VALUE MEASUREMENTS (continued)

Common collective trust Valued at fair value and includes a variety of investment contracts such as traditional and separate account guaranteed investment contracts (GICs) issued by insurance companies and other investment products (synthetic GICs) with similar characteristics.

The preceding methods described may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, although the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different fair value measurement at the reporting date.

The following table sets forth by level, within the fair value hierarchy, the Plan s assets at fair value as of December 31, 2014:

	Level 1	Level 2	Total
Non-interest-bearing cash	$ 27,309	$	$ 27,309
Registered investment companies			
Fixed income funds	18,292		18,292
Corporate bond funds	64,562		64,562
Government bond funds	1,981,813		1,981,813
International funds	1,629,173		1,629,173
Large-cap funds	5,852,573		5,852,573
Money market funds	805,450		805,450
Small and mid-cap funds	3,345,236		3,345,236
Target date funds	1,349,990		1,349,990
Real estate funds	92,035		92,035
Common stock			
Farmers National Banc Corp.	255,612		255,612
Common collective trust			
Short-term fixed income fund		725,591	725,591
Total assets at fair value	$ 15,422,045	$ 725,591	$ 16,147,636

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

4. FAIR VALUE MEASUREMENTS (continued)

The following table sets forth by level, within the fair value hierarchy, the Plan s assets at fair value as of December 31, 2013:

	Level 1	Level 2	Total
Non-interest-bearing cash	$ 21,552	$	$ 21,552
Registered investment companies			
Fixed income funds	54,955		54,955
Corporate bond funds	12,467		12,467
Government bond funds	1,495,966		1,495,966
International funds	1,663,870		1,663,870
Large-cap funds	4,650,825		4,650,825
Money market funds	788,131		788,131
Small and mid-cap funds	2,836,295		2,836,295
Target date funds	933,652		933,652
Real estate funds	26,227		26,227
Common stock			
Farmers National Banc Corp.	21,706		21,706
Common collective trust			
Short-term fixed income fund		703,385	703,385
Total assets at fair value	$ 12,505,646	$ 703,385	$ 13,209,031

5. GUARANTEED INVESTMENT CONTRACT

The Plan is invested in the Federated Capital Preservation Fund (the Fund), a fully benefit-responsive investment contract through Federated Investors, Inc. The Fund invests primarily in stable value products, such as traditional GICs, separate account GICs, and synthetic GICs.

Certain events limit the ability of the Plan to transact at contract value, allow the issuer to terminate the contract, or require the Plan sponsor to settle at an amount different than the contract value. Such events include the following: (1) mergers, (2) mass layoffs, (3) Plan terminations, (4) implementation of early retirement incentive programs, or (5) other events within the control of the Fund or Plan sponsor resulting in a material and adverse financial impact on the issuer s obligations under the GICs. The Plan s management has no knowledge that the occurrence of any such event, which would limit the Plan s ability to transact at contract value with participants, is probable.

Average Yields for the Years Ended December 31:

	2014	2013
Based on actual earnings (underlying investment return)	1.64%	1.21%
Based on interest rate credited to participants	1.76%	1.23%

Distributions to the Funds unit holders are declared daily from the net investment income and automatically reinvested in the Funds on a monthly basis, when paid.

FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

6. TAX STATUS
The Companies adopted a Prototype Non-Standardized Profit Sharing Plan, which received a favorable opinion letter from the Internal Revenue Service (IRS) on March 31, 2008, which stated that the Plan, as then designed, was in compliance with the applicable requirements of the Internal Revenue Code (IRC). The Plan has been amended since receiving the determination letter, however the Plan sponsor believes the Plan as currently designed, is being operated in compliance with the applicable requirements of the IRC. Therefore, no provision for income taxes has been included in the Plan s financial statements.

GAAP requires Plan management to evaluate tax positions taken by the Plan and recognize a tax liability (or asset) if the Plan has taken an uncertain position that more likely than not would not be sustained upon examination by the IRS. The Plan s management has analyzed the tax positions taken by the Plan, and has concluded that as of December 31, 2014, there are no uncertain positions taken or expected to be taken that would require recognition of a liability (or asset) or disclosure in the financial statements. The Plan is subject to routine audits by taxing jurisdictions; however, there are currently no audits for any tax periods in progress. The Plan s management believes it is no longer subject to income tax examinations for years prior to the year ended December 31, 2011.

7. PLAN TERMINATION
Although they have not expressed any intent to do so, the Companies have the right under the Plan to discontinue contributions at any time and to terminate the Plan, subject to the provisions of ERISA. In the event of Plan termination, participants will become 100% vested in their accounts.

8. PARTY-IN-INTEREST TRANSACTIONS
Certain Plan investments are shares of registered investment companies and a common collective trust managed by Federated Investors, Inc. (Federated). Federated is related to the Record Keeper of the Plan, Great West, and is related to EMJAY Corporation, the custodian. Since these parties are related, these transactions are considered party-in-interest transactions.

During 2014, the Plan purchased 27,385 shares and sold 84 shares of Farmers National Banc Corp. Common Stock. The Plan holds 30,612 shares of Farmers National Banc Corp. Common Stock at December 31, 2014 with a cost basis of $228,785. During 2013, the Plan purchased 3,336 shares and sold 24 shares of Farmers National Banc Corp. Common Stock. The Plan held 3,312 shares of Farmers National Banc Corp. Common Stock at December 31, 2013 with a cost basis of $14,488. During the years ended December 31, 2014 and 2013, the plan recorded dividend income on Company common stock of $2,766 and $111, respectively. During the years ended December 31, 2014 and 2013, the plan recorded appreciation on Company common stock of $26,164 and $684, respectively.

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

9. CORRECTIVE DISTRIBUTIONS PAYABLE

In order to pass the 2014 and 2013 Actual Deferral Percentage (ADP) Test, the Plan s management elected to refund excess elective deferrals and earnings thereon to certain highly-compensated employees. The calculated amount for 2014 was $34,094 and was distributed on various dates in 2015. The calculated amount for 2013 was $37,634 and was distributed on March 14, 2014. These amounts have been included as a corrective distributions payable in the accompanying Statements of Net Assets Available for Benefits at December 31, 2014 and 2013.

10. RISKS AND UNCERTAINTIES

The Plan invests in various investment securities which are exposed to various risks such as interest rate, market and credit risks. Due to the level of risk associated with certain investment securities, it is at least reasonably possible that changes in the values of investment securities will occur in the near term and that such changes could materially affect participants account balances and the amounts reported in the Statements of Net Assets Available for Benefits.

11. RECONCILIATION TO THE FORM 5500

The following is a reconciliation of net assets available for benefits per the financial statements at December 31, 2014 and 2013 to the Form 5500:

	2014	2013
Net assets available for benefits per the financial statements	$ 16,119,111	$ 15,253,859
Plus: Adjustment from contract value to fair value for interest in a common collective trust relating to fully benefit-responsive investment contracts	2,170	2,104
Net assets available for benefits per the Form 5500	$ 16,121,281	$ 15,255,963

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FARMERS NATIONAL BANK 401(k) RETIREMENT SAVINGS PLAN

NOTES TO THE FINANCIAL STATEMENTS

11. RECONCILIATION TO THE FORM 5500 (continued)

The following is a reconciliation of investment income per the financial statements for the years ended December 0%" ALIGN="CENTER">

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The fair value measurements of the Company s cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

		Fair Value Measurements at Reporting Date Using		
	September 30, 2015	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds	$ 16,830	$ 16,830	$	$
U.S. Government Agency Securities	17,024		17,024	
FDIC certificates of deposit	23,010		23,010	
Certificates of deposit	104,500		104,500	
Commercial paper	4,476		4,476	
Corporate Bonds/Notes	38,894		38,894	
	$ 204,734	$ 16,830	$ 187,904	$

		Fair Value Measurements at Reporting Date Using		
	December 31, 2014	**Quoted Prices in Active**	**Significant Other Observable**	**Significant Unobservable Inputs**

		Markets for Identical Assets (Level 1)	Inputs (Level 2)	(Level 3)
Money market funds	$ 8,495	$ 8,495	$	$
U.S. Government Agency Securities	4,313		4,313	
FDIC certificates of deposit	16,360		16,360	
Certificates of deposit	41,000		41,000	
Commercial paper	9,744		9,744	
Corporate Bonds/Notes	35,903		35,903	
	$ 115,815	$ 8,495	$ 107,320	$

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at September 30, 2015 and December 31, 2014. Management believes that the risks associated with its financial instruments are minimal as the counterparties are various corporations, financial institutions and government agencies of high credit standing.

Concentration of Credit Risk

Cash equivalents and certificates of deposits are held with major financial institutions in the United States. Certificates of deposit held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Accounts Receivable

Accounts receivable that management has the intent and ability to collect are reported in the balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of September 30, 2015 and December 31, 2014, as the Company has a history of collecting on all of its accounts, including government agencies and collaborations funding its research.

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Property and Equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over estimated useful lives ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the term of the related lease. Expenditures for maintenance and repairs are charged to operations as incurred.

When indicators of possible impairment are identified, the Company evaluates the recoverability of the carrying value of its long-lived assets based on the criteria established in ASC Topic 360, *Property, Plant and Equipment*. The Company considers historical performance and anticipated future results in its evaluation of potential impairment. The Company evaluates the carrying value of those assets in relation to the operating performance of the business and undiscounted cash flows expected to result from the use of those assets. Impairment losses are recognized when carrying value exceeds the undiscounted cash flows, in which case management must determine the fair value of the underlying asset. No such impairment losses have been recognized to date.

Revenue Recognition

Revenue is recognized when all terms and conditions of the agreements have been met, including that persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. The Company is reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. The Company records the amount of reimbursement as revenues on a gross basis in accordance with ASC Topic 605-45, *Revenue Recognition/Principal Agent Considerations*. The Company is the primary obligor with respect to purchasing goods and services from third-party suppliers, is obligated to compensate the service provider for the work performed, and has discretion in selecting the supplier. Provisions for estimated losses on research grant projects and any other contracts are made in the period such losses are determined.

The Company has entered into arrangements involving the delivery of more than one element. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For the Company, this determination is generally based on whether the deliverable has stand-alone value to the customer. The Company adopted this accounting standard on a prospective basis for all Multiple-Deliverable Revenue Arrangements (MDRAs), entered into on or after January 1, 2011, and for any MDRAs that were entered into prior to January 1, 2011, but materially modified on or after that date.

The Company adopted ASC Topic 605-28, *Milestone Method*. Under this guidance, the Company recognizes revenue contingent upon the achievement of a substantive milestone in its entirety in the period the milestone is achieved. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;

- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort on the Company s part is involved in achieving the milestone;

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and

a reasonable amount of time passes between the up-front license payment and the first milestone payment, as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore, the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable. In addition, the determination that one such payment was not a substantive milestone could prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable.

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Research and Development

Except for payments made in advance of services, which at the commencement of a clinical trial are generally significant, the Company expenses its research and development costs as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs primarily consist of the costs of clinical trials and salaries and related expenses for personnel and resources. Other research and development expenses include pre-clinical analytical testing, outside services, providers, materials and consulting fees.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and its respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities.

The Company accounts for uncertain tax positions pursuant to ASC Topic 740 (previously included in FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109).* Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Comprehensive Income (Loss)

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are incurred. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. In accordance with accounting guidance, the Company presents the impact of any unrealized gains or (losses) on its investment securities in a separate statement of comprehensive income (loss) for each period.

Share-Based Compensation

Share-based payments are accounted for in accordance with the provisions of ASC Topic 718, *Compensation Stock Compensation*. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes-Merton option-pricing model (the Black-Scholes model). The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. For awards that contain a performance-based vesting condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized in the statements of operations for the three and nine months ended September 30, 2015 and 2014 is based on share-based awards ultimately expected to vest, and this amount has therefore been reduced for estimated forfeitures. ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated based on the Company s historical experience and have not been material.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities and other factors due to the limited historical information of the Company s common stock. The expected life of stock options is the period of time for which the stock options are expected to be outstanding. Given the limited historical exercise data, the expected life is determined using the simplified method, which is defined as the midpoint between the vesting date and the end of the contractual term.

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The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

Prior to January 1, 2014, given that there was no active market for the Company s common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in the Company s business development and performance, the price per share of its convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For stock options granted in 2014 and 2015, the exercise price was determined by using the closing market price of the Company s common stock on the date of grant.

Under ASC Topic 718, the cumulative amount of compensation cost recognized for instruments classified as equity that ordinarily would result in a future tax deduction under existing tax law shall be considered to be a deductible difference in applying ASC Topic 740, *Income Taxes*. The deductible temporary difference is based on the compensation cost recognized for financial reporting purposes; however, these provisions currently do not impact the Company, as all the deferred tax assets have a full valuation allowance.

Since the Company had net operating loss carryforwards as of September 30, 2015 and 2014, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to non-employees are accounted for under the provisions of ASC Topic 718 and ASC Topic 505-50, *Equity/Equity-Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed and are marked to market during the service period.

Loss Per Share

Basic net loss per common share is determined by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company s stock option grants.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from operations for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2015	**2014**	**2015**	**2014**
Stock options	1,746,502	1,043,834	1,742,555	1,043,834

3. Property and Equipment

Property and equipment consist of the following:

	September 30, 2015	December 31, 2014
Computer equipment	**$ 39,589**	$ 39,160
Furniture and fixtures	**234,431**	35,958
Scientific equipment	**2,821,330**	2,207,848
	3,095,350	2,282,966
Less accumulated depreciation	**(2,309,806)**	(2,228,413)
	$ 785,544	$ 54,553

Depreciation expense for the nine months ended September 30, 2015 and 2014 was $92,594 and $19,156 respectively.

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4. Share-Based Compensation

The Company sponsors the Intra-Cellular Therapies, Inc. 2013 Equity Incentive Plan (the 2013 Plan) to provide for the granting of stock-based awards, such as stock options, restricted common stock, restricted stock units and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. In August 2013, the Company assumed in the Merger the ITI 2003 Equity Incentive Plan, as amended (the 2003 Plan), which expired by its terms in July 2013. As of September 30, 2015, there were options to purchase 2,876,069 shares of common stock outstanding under 2013 Plan. Effective in November 2013, the Company adopted the 2013 Plan. The Company initially reserved 2,850,000 shares of common stock for issuance under the 2013 Plan. In both January 2015 and 2014, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 800,000 pursuant to the evergreen provisions of the 2013 Plan. On June 16, 2015, the stockholders of Company approved, at the Company s 2015 Annual Meeting of Stockholders, an amendment to the 2013 Plan to increase the number of shares of common stock available for issuance under the plan by 3,100,000 shares, to increase by 100,000 shares the maximum number of shares available for issuance of options, stock appreciation rights and other similar awards to any one participant in any calendar year for purposes of meeting the requirements for qualified performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code), and to eliminate the evergreen provisions of the 2013 Plan under which 800,000 shares were automatically added to the plan on each of January 1, 2014 and 2015.

Stock options granted under the 2013 Plan may be either incentive stock options (ISOs) as defined by the Code, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally two to three years) and the exercise prices of such options. Options have a maximum term of 10 years. The exercise price of ISOs granted under the 2013 Plan must be at least equal to the fair market value of the common stock on the date of grant.

Total stock-based compensation expense, related to all of the Company s share-based awards to employees, directors and consultants recognized during the three and nine months ended September 30, 2015 and 2014, was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Research and development	**$ 1,220,602**	$ 788,496	**$ 2,892,258**	$ 1,020,746
General and administrative	**1,645,388**	914,149	**4,574,337**	1,172,114
Total share-based compensation expense	**$ 2,865,990**	$ 1,702,645	**$ 7,466,595**	$ 2,192,860

The following table describes the weighted-average assumptions used for calculating the value of options granted during the nine months ended September 30, 2015 and 2014:

	2015	**2014**
Dividend yield	**0%**	**0%**

Expected volatility	**80%**	**80%**
Weighted-average risk-free interest rate	**1.8%**	**2.2%**
Expected term	**6.3 years**	**6.3 years**

Information regarding the stock options activity including with respect to grants to employees, directors and consultants as of September 30, 2015, and changes during the nine-month period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life
Outstanding at December 31, 2014	2,233,460	$ 9.20	7.3 years
Options granted	815,973	$ 19.04	9.3 years
Options exercised	(159,864)	$ 1.99	2.7 years
Options canceled or expired	(13,500)	$ 3.26	7.7 years
Outstanding at September 30, 2015	2,876,069	$ 12.42	7.6 years
Vested or expected to vest at September 30, 2015	2,876,069	$ 12.42	
Exercisable at September 30, 2015	1,387,369	$ 6.96	6.1 years

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5. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

On May 31, 2005, the Company entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company (BMS), pursuant to which the Company holds a license to certain patents and know-how of BMS relating to ITI-007 and other specified compounds. The agreement was amended on November 3, 2010. The licensed rights are exclusive, except BMS retains rights in specified compounds in the fields of obesity, diabetes, metabolic syndrome and cardiovascular disease. However, BMS has no right to use, develop or commercialize ITI-007 and other specified compounds in any field of use. The Company has the right to grant sublicenses of the rights conveyed by BMS. The Company is obliged under the license to use commercially reasonable efforts to develop and commercialize the licensed technology. The Company is also prohibited from engaging in the clinical development or commercialization of specified competitive compounds.

Under the agreement, the Company made an upfront payment of $1.0 million to BMS, a milestone payment of $1.25 million in December 2013, and a milestone payment of $1.5 million in December 2014 following the initiation of the Company s first Phase 3 clinical trial for ITI-007 for patients with exacerbated schizophrenia. Possible milestone payments remaining total $12.0 million, including $2.0 million payable by the Company upon the FDA s acceptance of a New Drug Application. Under the agreement, the Company may be obliged to make other milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million. The Company is also obliged to make tiered single digit percentage royalty payments on sales of licensed products. The Company is obliged to pay to BMS a percentage of non-royalty payments made in consideration of any sublicense.

The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of ten years after first commercial sale of a licensed product in such country, expiration of the last licensed patent covering a licensed product, its method of manufacture or use, or the expiration of other government grants providing market exclusivity, subject to certain rights of the parties to terminate the agreement on the occurrence of certain events. On termination of the agreement, the Company may be obliged to convey to BMS rights in developments relating to a licensed compound or licensed product, including regulatory filings, research results and other intellectual property rights.

The Takeda Pharmaceutical License and Collaboration Agreement and Termination Agreement

On February 25, 2011, the Company entered into a license and collaboration agreement (the Takeda License Agreement) with Takeda Pharmaceutical Company Limited (Takeda) under which the Company agreed to collaborate to research, develop and commercialize its proprietary compound ITI-214 and other selected compounds that selectively inhibit PDE1 for use in the prevention and treatment of human diseases. As part of the agreement, the Company assigned to Takeda certain patents owned by the Company that claim ITI-214 and granted Takeda an exclusive license to develop and commercialize compounds identified in the conduct of the research program that satisfy specified criteria. However, the Company retained rights to all compounds that do not meet the specified criteria and the Company continues to develop PDE1 inhibitors outside the scope of the agreement.

On October 31, 2014, the Company entered into an agreement with Takeda terminating the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to the Company. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to the Company. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. The Company intends to explore the development of its PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

Other License Agreement

In May 2002, the Company entered into a license agreement (the License) and research agreement with a university. Under the provisions of the License, the Company is entitled to use this organization s patented technology and other intellectual property relating to diagnosis and treatment of central nervous system disorders.

The License expires upon expiration of the patent rights or 15 years subsequent to the first sale of products developed through this License. ITI is required to make future milestone payments for initiation of clinical trials and approval of a New Drug Application (NDA). Should ITI commercialize the technology related to this License, ITI would be required to make royalty payments, and would also be required to pay fees under any sublicense agreements with third parties.

In addition, ITI is required to use at least $1.0 million annually of its resources for the development and commercialization of the technology until ITI submits an NDA. ITI met its spending requirements in 2014 and 2015. There were no other payments made or required for the three and nine months ended September 30, 2015 and 2014.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K filed on March 12, 2015. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under Risk Factors in our Annual Report on Form 10-K filed on March 12, 2015, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

Overview

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. Our lead drug candidate, ITI-007, is in Phase 3 clinical development as a first-in-class treatment for schizophrenia. Current medications available for the treatment of schizophrenia do not adequately address the broad array of symptoms associated with this CNS disorder. Use of these current medications also is limited by their substantial side effects. ITI-007 is designed to be effective across a wider range of symptoms, treating both the acute and residual phases of schizophrenia, with improved safety and tolerability.

ITI-007 for the Treatment of Schizophrenia

On September 16, 2015, we announced top-line clinical results from our first Phase 3 clinical trial of ITI-007 for the treatment of patients with schizophrenia. This randomized, double-blind, placebo-controlled Phase 3 clinical trial was conducted at 12 sites in the United States with 450 patients randomized (1:1:1) to receive either 60 mg of ITI-007, 40 mg of ITI-007 or placebo once daily in the morning for 28 days. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (4 weeks) on the centrally rated Positive and Negative Syndrome Scale, or PANSS, total score. In this trial, the once-daily dose of 60 mg of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint). Moreover, the 60 mg dose of ITI-007 showed significant antipsychotic efficacy as early as week 1, which was maintained at every time point throughout the entire study. ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint. In addition, the 60 mg dose of ITI-007 met the key secondary endpoint of statistically significant improvement on the Clinical Global Impression Scale for Severity of Illness, or CGI-S. The 40 mg dose of ITI-007 also demonstrated a statistically significant improvement versus placebo on the CGI-S, though not formally tested against placebo since it did not separate on the primary endpoint. Consistent with previous studies, ITI-007 had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids.

On September 16, 2015, we also announced top-line data from an open-label positron emission tomography, or PET, study of ITI-007 examining brain occupancy of striatal D2 receptors. This study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily ITI-007 oral administration. In this trial, the 60 mg dose of ITI-007 was associated with a mean of approximately 40% striatal dopamine D_2 receptor occupancy. As predicted by preclinical and earlier clinical data, ITI-007 demonstrated antipsychotic effect at relatively low striatal D_2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D_2 receptors. We believe this mechanism likely contributes to the favorable safety profile of ITI-007, with reduced risk for hyperprolactinemia, akathisia, extrapyramidal symptoms, and other motoric side effects.

The top-line results from our first Phase 3 clinical trial of ITI-007 confirm the earlier Phase 2 results that we announced in December 2013, in which ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this Phase 2 trial, 335 patients were randomized to receive one of four treatments: 60 mg of ITI-007, 120 mg of ITI-007, 4 mg of risperidone (active control) or placebo in a 1:1:1:1 ratio, orally once daily for 28 days. The primary endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. In this study, ITI-007 met the trial s pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the PANSS total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety.

We are also conducting a second Phase 3 clinical trial in schizophrenia that we initiated in the second quarter of 2015, with approximately 580 patients planned to be enrolled in the trial. In this trial, we are randomizing patients to two doses of ITI-007 (60 mg or 20 mg), risperidone (active control) or placebo over a 6-week treatment duration, and the primary outcome measure is change from baseline to Day 42 on the PANSS total score. Subject to timely enrollment, we anticipate top-line results from the second Phase 3 clinical trial will be available in mid-2016.

In addition to our two Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned New Drug Application, or NDA, for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or in the first half of 2017.

Other Indications for ITI-007

Following communication with the FDA, we are also proceeding with a Phase 3 development program of ITI-007 for the treatment of depressive episodes associated with bipolar disorder (bipolar depression). The Phase 3 program in bipolar depression consists of two multicenter, randomized, double-blind, placebo-controlled clinical trials. The first Phase 3 trial will evaluate ITI-007 as a monotherapy and the second Phase 3 trial will evaluate ITI-007 as an adjunctive therapy with lithium or valproate. The primary endpoint for both studies will be the Montgomery Asberg Depression Rating Scale, or MADRS following 6 weeks of treatment. The MADRS is a 10 item scale designed to measure the overall severity of depressive symptoms and has been used as a primary tool for registration trials supporting drug approval in unipolar and bipolar depression. Patients with a major depressive episode associated with Bipolar I or Bipolar II disorder are planned to be enrolled in each trial and we will be evaluating once-daily doses of ITI-007 at 40 mg and 60 mg. We plan to commence these studies in late 2015.

In addition, in the fourth quarter of 2014, we announced the top-line data from ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease. The completion of this study marks an important milestone in our strategy to develop low doses of ITI-007 for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results to date indicate that ITI-007 is safe and well-tolerated across a range of low doses, has linear- and dose-related pharmacokinetics and improves cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position ITI-007 as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions. We plan to initiate additional clinical programs evaluating ITI-007 in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer s disease, in late 2015 or the first half of 2016.

We are also pursuing clinical development of ITI-007 for the treatment of additional CNS diseases and disorders. At the lowest doses, ITI-007 has been demonstrated to act primarily as a potent 5-HT2A serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer s disease, Huntington s disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be useful for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases.

Given the potential utility for ITI-007 and follow-on compounds to treat these additional indications, we may investigate, either on our own or with a partner, agitation, aggression and sleep disturbances in additional diseases that include autism spectrum disorders; depressive disorder; intermittent explosive disorder; non-motor symptoms and motor complications associated with Parkinson s disease; and post-traumatic stress disorder. We hold exclusive, worldwide commercialization rights to ITI-007 and a family of compounds from Bristol-Myers Squibb Company pursuant to an exclusive license.

Other Product Candidates

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase type 1, or PDE1. We believe PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) and Takeda Pharmaceutical Company Limited, or Takeda, entered into a license and collaboration agreement, or the Takeda License Agreement, under which we agreed to collaborate to research, develop and commercialize our proprietary compound ITI-214 and other selected compounds that selectively inhibit PDE1 for use in the prevention and treatment of human diseases. On October 31, 2014, we entered into an agreement with Takeda terminating the Takeda License Agreement, or the Termination Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. On September 15, 2015, Takeda completed the transfer of the Investigational New Drug, or IND, for ITI-214 to us. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to explore the development of our PDE1 program, including ITI-214 for the treatment of several CNS and

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non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications.

Our pipeline also includes pre-clinical programs that are focused on advancing drugs for the treatment of cognitive dysfunction, in both schizophrenia and Alzheimer s disease, and for disease modification and the treatment of neurodegenerative disorders, including Alzheimer s disease.

We have assembled a management team with significant industry experience to lead the discovery and development of our product candidates. We complement our management team with a group of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia and other CNS disorders, including Nobel laureate, Dr. Paul Greengard, one of our co-founders.

Since inception, we have devoted substantially all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of September 30, 2015, our accumulated deficit was $164.2 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and pre-clinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

Our corporate headquarters and laboratory are located in New York, New York.

Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

Revenues

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales for at least the next several years. We did not have any revenues for the three months ended September 30, 2015 and our revenues for the nine months ended September 30, 2015 have been from a government grant. For the three and nine months ended September 30, 2014, revenues were from our recently terminated license and collaboration agreement with Takeda. We will not receive any further revenue under the Takeda License Agreement, which was terminated on October 31, 2014. We have received and may continue to receive grants from U.S. government agencies and foundations.

We do not expect any revenues that we may generate in the next several years to be significant enough to fund our operations.

Expenses

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. It is difficult to estimate the costs or the timelines in which those costs will be incurred. Our lead program, ITI-007 for the treatment of schizophrenia, consumes a significant portion of our current, as well as projected, resources. We intend to pursue other disease indications that ITI-007 may address including for the treatment of depressive episodes associated with bipolar disorder (bipolar depression) and the treatment of behavioral disturbances associated with dementia and related disorders, including Alzheimer s disease, but there are large costs associated with pursuing FDA approval for those indications, which would include the cost of additional clinical trials.

Our ITI-002 program has a compound, ITI-214, in Phase 1 development. We intend to explore the development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications. We do not anticipate a significant increase in our operating expenses related to our PDE development programs in 2015. Our other projects are still in the pre-clinical stages, and will require extensive funding not only to complete pre-clinical testing, but to enter into and complete clinical trials. Expenditures that we incur on these projects will be subject to availability of funding in addition to the funding required for the advancement of ITI-007. Any failure or delay in the advancement of ITI-007 could require us to re-allocate resources from our other projects to the advancement of ITI-007, which could have a significant material adverse impact on the advancement of these other projects and on our results of operations. Our operating expenses are comprised of (i) research and development expenses and (ii) general and administrative expenses. Our research and development costs are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and

- fees paid to external parties who provide us with contract services, such as pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments.

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General and administrative expenses are incurred in three major categories:

- salaries and related benefit costs;
- patent, legal and professional costs; and
- office and facilities overhead.

We expect that research and development expenses will continue to increase substantially as we continue with our Phase 3 development of ITI-007 for the treatment of patients with schizophrenia and initiate our anticipated trials in bipolar disorder and in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer s disease. We also expect that our general and administrative costs will increase substantially from prior periods primarily due to the increased costs associated with being a public reporting entity, which would include adding additional personnel. We granted options to purchase 1,108,000 shares of our common stock in the year ended December 31, 2014 and have granted options to purchase an additional 815,973 shares of our common stock through September 30, 2015. We will recognize expense associated with these options over the next three years in both research and development expenses and general and administrative expenses. We expect this non-cash expense to be material and affect quarter to quarter and year to date comparisons in the upcoming year. We expect to continue to grant stock options and other stock-based awards in the future, which will increase our stock-based compensation expense in future periods.

The following table sets forth our revenues and operating expenses for the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
	(Unaudited)		*(Unaudited)*	
Revenues	**$**	$ 124	**$ 61**	$ 511
Expenses				
Research and Development	**28,457**	4,046	**64,853**	9,585
General and Administrative	**3,892**	2,582	**11,649**	6,616
	32,349	6,628	**76,502**	16,201
Interest Income, net	**189**	88	**482**	198
Net Loss	**$ (32,160)**	$ (6,416)	**$ (75,959)**	$ (15,492)

Comparison of Three and Nine Month Periods Ended September 30, 2015 and September 30, 2014

Revenues

Revenues decreased for the three and nine months ended September 30, 2015 as compared to the three and nine months ended September 30, 2014 by approximately $124,000 and $451,000, respectively, as revenue during the three and nine months ended September 30, 2014 were from a license and collaboration agreement with Takeda, which has since been terminated, as compared to revenue of approximately $0 and $61,000 during the three and nine months ended September 30, 2015 from a government grant.

Research and Development Expenses

Research and development expenses increased to $28.5 million for the three month period ended September 30, 2015 as compared to $4.0 million for the three month period ended September 30, 2014. This change of $24.5 million is due primarily to an increase of approximately $16.3 million of costs associated with outside clinical testing and approximately $7.0 million from nonclinical testing and the remainder due to increased labor and labor related costs in the three month period ended September 30, 2015 over the three month period ended September 30, 2014. The vast majority of the increase is due to costs associated with our ITI-007 Phase 3 clinical program. In late 2014 we began a Phase 3 clinical trial of ITI-007 in patients with schizophrenia and incurred the majority of the costs for this trial in the first three quarters of 2015. In addition, we started our second Phase 3 clinical trial of ITI-007 in schizophrenia in June 2015 and incurred significant costs for this trial in the third quarter of 2015. In 2014, we did not incur significant costs related to clinical trials. Amounts payable to external parties comprise a significant portion of our research and development costs. In the three months ended September 30, 2015, we incurred approximately $25.8 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $2.5 million in the three month period ended September 30, 2014. Of these external costs, approximately $25.5 million in the three months ended September 30, 2015 and $2.5 million in the three month period ended September 30, 2014 were for ITI-007 related projects. The remaining amounts for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe benefits, materials, supplies and facilities and maintenance costs and were approximately $2.6 million and $1.5 million in the three months ended September 30, 2015 and 2014, respectively. The increase in these internal costs is due primarily to hiring additional research and development employees in 2015 in addition to increased stock option based compensation.

Research and development expenses increased to $64.9 million for the nine month period ended September 30, 2015 as compared to $9.6 million for the nine month period ended September 30, 2014. This change of $55.3 million is due primarily to an increase of approximately $40.9 million of costs associated with outside clinical testing and approximately $10.9 million from nonclinical testing and the remainder due to increased labor and travel expenses in the nine month period ended September 30, 2015 over the nine month period ended September 30, 2014. The vast majority of the increase is due to costs associated with conducting our ITI-007 Phase 3 clinical program. In late 2014, we began a clinical trial of ITI-007 in patients with schizophrenia and incurred the majority of the costs for this trial in 2015. In addition, we started our second Phase 3 clinical trial of ITI-007 in schizophrenia in June 2015 and incurred significant costs for this trial in the third quarter of 2015. In 2014, we did not incur significant costs related to clinical trials. Amounts payable to external parties comprise a large portion of our research and development costs. In the nine months ended September 30, 2015, we incurred approximately $58.1 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $6.3 million in the nine month period ended September 30, 2014. Of these external costs, approximately $57.6 million in the nine months ended September 30, 2015 and $6.0 million in the nine month period ended September 30, 2014 were for ITI-007 related projects. The remaining amounts for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe benefits, materials, supplies and facilities and maintenance costs and were approximately $6.7 million and $3.3 million in the nine months ended September 30, 2015 and 2014, respectively. The increase in these internal costs is due primarily to hiring additional research and development employees in 2015 in addition to increased stock option based compensation.

As development of ITI-007 for the treatment of schizophrenia progresses, we anticipate costs for that program to increase considerably in the remainder of 2015 and in the next several years as we conduct Phase 3 and other clinical trials. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product and the creation of an inventory of drug product in anticipation of possible FDA approval. In addition we plan to spend increasing amounts to further our development of ITI-007 for other indications, including but not limited to, the treatment of depressive episodes associated with bipolar disorder (bipolar depression), for treatment of behavioral disturbances associated with dementia and related disorders, and for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer s disease, Huntington s disease and autism spectrum disorders, among other indications.

As of September 30, 2015, we employed 22 full time personnel in our research and development group as compared to 14 full time personnel at September 30, 2014. We expect to hire additional staff as we increase our development efforts and grow our business in the upcoming years.

We currently have several projects, in addition to ITI-007, that are in the research and development stages, including in the areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including Alzheimer s disease, among others. We have used internal resources and incurred expenses not only in relation to the development of ITI-007, but also in connection with these additional projects as well. We have not, however, reported these costs on a project by project basis, as these costs are broadly spread among these projects. The external costs for these projects have been minimal and are reflected in the amounts discussed in this section Research and Development Expenses.

During previous years we also incurred costs that were both reimbursable and non-reimbursable under the Takeda License Agreement. For the three and nine months ended September 30, 2015, we incurred no direct costs that were billable to Takeda. For the three months ended September 30, 2014, we incurred no direct costs that were billable to Takeda and for the nine months ended September 30, 2014, $40,000 of direct costs were billed to Takeda, all in the second quarter of 2014. As we refine our strategy for the PDE1 inhibitor program that was returned to us from Takeda, we do not expect a significant increase in our operating expenses related to our PDE development programs in the remainder of 2015.

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The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA s Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA, after completion of all clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs;
- satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from pre-clinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the section entitled Risk Factors in our Annual Report on Form 10-K filed with the SEC on March 12, 2015, as updated from time to time in our other periodic and current reports filed with the SEC.

General and Administrative Expenses

General and administrative expenses increased for the three month period ended September 30, 2015 as compared to the three month period ended September 30, 2014 by approximately $1.3 million, or 51%. The increase is primarily the result of approximately $0.7 million of higher stock option expense and the remainder due to higher accounting, rent and facilities costs, labor and state and local franchise and capital taxes. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the three months ended September 30, 2015 and 2014 were approximately 60% and 61%, respectively, of our total general and administrative costs. The next major categories of our general and administrative expenses are patent costs, legal and other professional fees and, to a lesser extent, facilities and general office-related overhead.

General and administrative expenses increased for the nine month period ended September 30, 2015 as compared to the nine month period ended September 30, 2014 by approximately $5.0 million, or 76%. The increase is primarily the result of approximately $3.4 million of higher stock option expense and to a much lesser extent to increased labor costs and state and local franchise and capital taxes. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the nine months ended September 30, 2015 and 2014 were approximately 58% and 44%, respectively, of our total general and administrative costs. The next major categories of our general and administrative expenses are patent costs, legal, accounting and other professional fees and, to a lesser extent, facilities and general office-related overhead.

We expect general and administrative costs to increase significantly as we hire additional staff, expand our operations, including initial preparation for potential commercial activities, and incur additional costs associated with being a public company and complying with exchange listing and SEC requirements, including the additional complexities and related costs of our transition at the end of 2015 from an emerging growth company to a large accelerated filer under the rules of the SEC. These increases could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

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Liquidity and Capital Resources

Through September 30, 2015, we provided funds for our operations by obtaining approximately $716.2 million of cash primarily through public and private offerings of our common stock and other securities, grants from government agencies and foundations and payments received under the recently terminated Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future, and Takeda has no ongoing funding obligations following the termination of the Takeda License Agreement on October 31, 2014. On March 11, 2015, we completed a public offering of 5,411,481 shares of our common stock for aggregate gross proceeds of approximately $129.9 million and net proceeds of approximately $121.8 million. On September 28, 2015, we completed a public offering of 7,935,000 shares of our common stock for aggregate gross proceeds of approximately $345.2 million and net proceeds of approximately $327.4 million.

As of September 30, 2015, we had a total of approximately $510.7 million in cash and cash equivalents and available-for-sale investment securities, and approximately $10.4 million of short-term liabilities consisting entirely of liabilities from operations. Excluding the increase in net cash of approximately $121.8 million and $327.4 million from the public offerings in March 2015 and September 2015, respectively, we spent approximately $67.2 million in cash for operations and equipment and we reduced working capital by approximately $67.8 million for the nine months ended September 30, 2015. This use of cash was primarily for conducting clinical trials and non-clinical testing, including manufacturing related activities and funding recurring operating expenses.

We expect to use cash of up to $37 million during the fourth quarter of 2015, which we expect would result in total cash used of up to $105 million for the year 2015. For the year 2016 we expect to spend between approximately $130 million and $160 million. We expect these expenditures to be due primarily to the development of ITI-007 in patients with schizophrenia, behavioral disturbances in dementia, bipolar disorder and depressive disorders, our ITI-007 long acting injectable development program through pre-clinical and early clinical development, research and preclinical development of our other product candidates, the continuation of manufacturing activities in connection with the development of ITI-007, recurring expenses and costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to ITI-007, and expenses associated with our other development programs and general operations. We expect that cash expenditures will continue to increase after 2016 as we further expand the ITI-007 clinical stage programs, the ITI-007 long acting injectable development program through pre-clinical and early clinical development; research and preclinical development of our other product candidates; and the continuation of manufacturing and pre-commercial activities in connection with the development of ITI-007. We believe that our existing cash and cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2018.

We will require significant additional financing in the future to continue to fund our operations. We believe that we have the funding in place to complete the additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with schizophrenia. With the proceeds from our recent public offering we believe that we have the funds to complete our proposed clinical trials of ITI-007 in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate. We will also be funding clinical trials of ITI-007 for the treatment of behavioral disturbances in dementia; preclinical and clinical development of ITI-007 long acting injectable development program; more clinical trials of ITI-007 for the treatment of depression; continued clinical development of our PDE1 program, including ITI-214; and to fund research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of ITI-007. We anticipate requiring additional funds to obtain regulatory approval for ITI-007 in patients with dementia, including Alzheimer s disease, for further development of ITI-007 in patients with bipolar disorder, depressive disorders and other indications, and for development of our other product candidates. We have incurred losses in every year since inception with the exception of 2011, when we received an up-front fee and a milestone payment related to the Takeda License Agreement. These losses have resulted in significant cash used in operations. For the nine months ended September 30, 2015, we used net cash in operating activities and purchases of equipment of approximately $68.0 million and expect to use additional cash of between approximately $167 and $197 million from the beginning of the fourth quarter of 2015 through the end of 2016. While we have several research and development programs underway, the ITI-007 program has advanced the furthest and will continue to consume increasing amounts of cash for conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of ITI-007 and our other product candidates, we expect the amount of cash needed to fund operations to increase significantly over the next several years.

With the termination of the Takeda License Agreement in October 2014, we will not receive milestone payments and expense reimbursements, including patent filing costs, from Takeda and will be responsible for the costs of developing ITI-214. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to explore the development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, but we do not anticipate a significant increase in our operating expenses related to our PDE development programs during the remainder of 2015.

We seek to balance the level of cash, cash equivalents and investments on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. Until we can generate significant revenues from operations, we will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding.

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We cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. Due to the volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our ITI-007 program could have a material adverse impact on our ability to raise additional capital.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate pre-clinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead product candidate ITI-007, ITI-214, and our other pre-clinical stage product candidates; (2) delay, limit, reduce or terminate our discovery research or pre-clinical development activities; or (3) enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our product candidates, technologies or intellectual property at an earlier stage of development and on less favorable terms than we would otherwise agree.

Our cash is maintained in checking accounts, money market accounts, money market mutual funds, U.S. Government Agency Securities, certificates of deposit, commercial paper, corporate notes and corporate bonds at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited interest income. We do not expect interest income to be a significant source of funding over the next several quarters. Our investment portfolio has not been adversely impacted by the problems in the credit markets that have existed over the last several years, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

In 2014, we entered into a long-term lease, which was in amended in March 2015, for 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Due to the amortization of total lease payments, we have recognized $0.9 million of deferred rent in the nine months ended September 30, 2015. The deferred rent balance will incrementally increase over the next two years. We occupied these facilities as our headquarters in March 2015, replacing our previous laboratories and offices. The lease, as amended, has a term of eleven years. We expect that our facility related costs will increase moderately as a result of leasing this facility.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

Total contractual obligations as of September 30, 2015 are summarized in the following table (in thousands):

		Payments Due By Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations	$ 15,782	$ 918	$ 4,340	$ 4,743	$ 5,781

The table of Contractual Obligations and Commitments does not reflect that, under the License Agreement with BMS, we may be obligated to make future milestone payments to BMS totaling $12.0 million, including $2.0 million payable by us upon the FDA s acceptance of an NDA that we submit; to make other future milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million; to make tiered single digit percentage royalty payments on sales of licensed products; and to pay BMS a percentage of non-royalty payments made in consideration of any sublicense. The table also does not reflect ongoing obligations for clinical trials and other related material transactions that are not long term in nature.

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Critical Accounting Policies and Estimates

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. We evaluate our estimates, judgments, and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2014 and Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes to our critical accounting policies during the three and nine months ended September 30, 2015.

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition and stock-based compensation. Actual results may differ from those estimates and under different assumptions or conditions.

Recently Issued Accounting Pronouncements

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our financial statements, see Recently Issued Accounting Pronouncements in our Annual Report on Form 10-K for the year ended December 31, 2014 filed on March 12, 2015.

Certain Factors That May Affect Future Results of Operations

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company s future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the accuracy of our estimates regarding expenses, future revenues, uses of cash, capital requirements and the need for additional financing; the initiation, cost, timing, progress and results of our development activities, pre-clinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; the election by any collaborator to pursue research, development and commercialization activities; our ability to obtain future reimbursement and/or milestone payments from our collaborators; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to successfully commercialize our product candidates; the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials; our ability to obtain additional financing; the use of the proceeds from our securities offerings; our expectations regarding the additional management attention and costs that will be required as we transition from an emerging growth company to a large accelerated filer; and our ability to attract and retain key scientific or management personnel.

Words such as may, anticipate, estimate, expect, may, project, intend, plan, believe, potential, p will, would, could, should, continue and words and terms of similar substance used in connection with any discu of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management s present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to, those set forth under the heading Risk Factors in our most recent Annual Report on Form 10-K, as updated from time to time in our subsequent periodic and current reports filed with the SEC.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q or in any document incorporated by reference might not occur. Stockholders are

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cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to the Company or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity. As of September 30, 2015, we had cash, cash equivalents and marketable securities of approximately $510.7 million, consisting of cash deposited in a highly rated financial institution in the United States and in a short-term U.S. Treasury money market fund, as well as high-grade corporate bonds and commercial paper. The primary objective of our investment activities is to preserve our capital for the purpose of funding operations and we do not enter into investments for trading or speculative purposes. We believe that we do not have material exposure to high-risk investments such as mortgage-backed securities, auction rate securities or other special investment vehicles within our money-market fund investments. We believe that we do not have any material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, would reduce future investment income.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

Item 4. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the three months ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

The following are material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 12, 2015.

We currently do not have, and may never have, any products that generate significant revenues.

We have a limited operating history on which to evaluate our business and prospects. To date, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA and other regulatory authorities in the European Union and elsewhere will approve them for commercialization. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. In September 2015, we announced top-line results from our first Phase 3 clinical trial of our most advanced drug candidate, ITI-007, in schizophrenia. We also initiated enrollment of our second Phase 3 clinical trial of ITI-007 in schizophrenia in the second quarter of 2015 and, subject to timely enrollment, we anticipate that top-line results from this trial will be available in mid-2016. In addition, all rights with respect to ITI-214, which has advanced into Phase 1 clinical trials that we previously granted to Takeda were recently returned to us in connection with the termination of the Takeda License Agreement. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to explore the development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, which may include cognition in Parkinson s disease, cognition in Alzheimer s disease, cognition in schizophrenia and in other non-CNS indications. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

There is no guarantee that our planned clinical trials for ITI-007 in schizophrenia or in other indications will be successful.

In our Phase 1 and Phase 2 clinical trials, our lead product candidate, ITI-007, has demonstrated improved sleep maintenance, antipsychotic efficacy, and clinical signals consistent with reduction in negative symptoms associated with schizophrenia, depression and anxiety, and other symptoms associated with impaired social function. In September 2015, we announced top-line clinical results from our first randomized, double-blind, placebo-controlled Phase 3 clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, a once-daily 60 mg dose of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint). In addition, the 60 mg dose of ITI-007 met the key secondary endpoint of statistically significant improvement on the CGI-S. We are currently planning confirmatory later-stage clinical trials and recently initiated enrollment of our second Phase 3 clinical trial of ITI-007 in schizophrenia in the second quarter of 2015.

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we plan to conduct further clinical trials in patients with schizophrenia and other indications, there is no guarantee that we will have the same level of success in these trials as we have had in our earlier clinical trials, or be successful at all.

In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, intermittent explosive disorder, non-motor disorders associated with Parkinson s disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested ITI-007 in Phase 2 clinical trials in the patient population for these other indications, except for ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer s disease, for which we announced top-line data in the fourth quarter of 2014.

If we do not successfully complete clinical development of ITI-007, we will be unable to market and sell products derived from it and to generate product revenues. Even if we do successfully complete clinical trials for ITI-007 in patients with schizophrenia, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit an NDA to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even less result in the NDA ultimately being approved by the FDA for commercialization.

We have recently completed our first Phase 3 clinical trial of ITI-007 for the treatment of schizophrenia and are proceeding with our second Phase 3 clinical trial of ITI-007 for the treatment of schizophrenia. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if successfully completed, are not sufficient for regulatory approval. If we are required to conduct additional clinical trials and non-clinical studies, our development of ITI-007 for schizophrenia will be more time-consuming and costly than we presently anticipate, which would have a material adverse effect on our business, results of operations and financial condition.

In June 2014, we held our end-of-Phase 2 meeting with the FDA to discuss our plans for initiating Phase 3 clinical trials of ITI-007 in schizophrenia. Following this meeting, we proceeded with our Phase 3 development program, in which we recently completed the first of two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with approximately 450 patients fully enrolled in the first Phase 3 clinical trial and approximately 580 patients planned to be enrolled in the second Phase 3 clinical trial. We completed enrollment of the first Phase 3 clinical trial in schizophrenia in the second quarter of 2015 and initiated enrollment of the second Phase 3 clinical trial in schizophrenia in the second quarter of 2015. In the first Phase 3 trial, we randomized patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. In the second Phase 3 trial, we are randomizing patients to receive one of four treatments: 60 mg ITI-007, 20 mg ITI-007, 4 mg risperidone (active control) or placebo in a 1:1:1:1 ratio. The second Phase 3 trial will be conducted for a 6-week treatment duration. We announced top-line results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia in September 2015 and anticipate that the results of the second Phase 3 clinical trial will be available, subject to timely enrollment, in mid-2016. Even though we believe that our recently completed Phase 3 trial and our on-going Phase 3 clinical trial and ongoing and planned clinical and non-clinical studies for ITI-007 in schizophrenia, if successful, will be sufficient to support our NDA, the FDA may not agree with one or more aspects of our clinical trial designs, including the duration of the trials, clinical endpoints, controls, dose ranges, collection of safety data, or adequacy of our non-clinical studies. If we submit an NDA and the FDA does not agree with our clinical and non-clinical designs, our development of ITI-007 in schizophrenia and other indications may be delayed, and we may incur additional costs and devote additional resources to address any concerns the FDA may have with our trial designs. In addition, we may be required to conduct additional clinical trials or studies, which could result in additional delays and costs. There is no assurance that we will complete the Phase 3 trials and other clinical and non-clinical studies within the timeframes and the costs that we currently expect, or at all, or in a manner that is acceptable to the FDA. Any delays or unplanned costs resulting from our Phase 3 clinical trials of ITI-007 in schizophrenia may have a material adverse effect on our business, results of operations and financial condition. Even if we eventually complete Phase 3 clinical testing, submit an NDA and receive approval of ITI-007, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve ITI-007 for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of ITI-007 or our other product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for ITI-007 would delay or prevent commercialization of ITI-007 and would materially adversely impact our business, results of operations and financial condition.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $510.7 million at September 30, 2015, which includes net proceeds of approximately $121.4 million from the public offering of shares of our common stock in March 2015 and approximately $327.4 million from the public offering of shares of our common stock in September 2015. While we believe that our existing cash, cash equivalents and investment securities, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2018, the amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status of our second Phase 3 clinical trial of ITI-007 in patients with acute exacerbated schizophrenia, the continued development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions, and our other planned clinical and non-clinical trials. Furthermore, we anticipate that we will need to secure additional funding to complete additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with acute exacerbated schizophrenia, for further development of ITI-007 for other indications, and for development of our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials, or we experience delays or other setbacks in our clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA would likely be delayed.

With the remaining proceeds from our public offerings in February 2014, March 2015 and September 2015 we intend to fund the following: the completion of two Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, one of which we announced top-line results in September 2015 and the second of which we initiated enrollment in the second quarter of 2015; the initiation of other planned clinical and non-clinical trials, including manufacturing, needed for anticipated regulatory approval of ITI-007 in patients with acute exacerbated schizophrenia and other potential additional indications; pre-launch activities for ITI-007 for the treatment of schizophrenia and, if it receives regulatory approval, to fund our initial commercialization efforts; initiation and completion of our clinical trials of ITI-007 in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate; clinical trials of ITI-007 for the treatment of behavioral disturbances in dementia; pre-clinical and clinical development of our

ITI-007 long acting injectable development program; one or more clinical trials of ITI-007 for the treatment of depression; the continued clinical development of our PDE1 program, including ITI-214; and to fund research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of ITI-007. The remaining proceeds, if any, will be used to fund new and ongoing research and development activities, new business opportunities, general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from these offerings to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of any future collaborators and us to reach the milestones, and other events or developments, triggering payments under any future collaboration agreements or to otherwise make payments under such agreements;
- our ability to enter into new, and to maintain any existing, collaboration and license agreements;

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- the extent to which any future collaborators are obligated to reimburse us for clinical trial costs under any future collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production;
- the costs of preparing applications for regulatory approvals for our product candidates;
- the costs of preparing for and establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product candidates; and
- the costs associated with litigation.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, private or public sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. Turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit our access to additional financing. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If we do obtain additional funding through equity offerings, the ownership of our existing stockholders and purchasers of shares of our common stock in any such offering will be diluted, and the terms of any financing may adversely affect the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also could be required to seek funds through arrangements with collaboration partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Safety issues with our product candidates, or with product candidates or approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval.

Problems with product candidates or approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as our product candidates could adversely affect the development, regulatory approval and commercialization of our product candidates. In 2012, the FDA released draft guidance recommending that prospective suicidality assessments be performed in clinical trials of any drug being developed for a psychiatric indication. Our development programs are focused on psychiatric indications. Our PDE1 program is a novel target and may have unexpected safety effects that do not appear until late in clinical development or after commercial approval. To date, none of our product candidates have experienced any serious and unexpected suspected adverse reactions that resulted in the submission of an IND safety report to the FDA; however, some approved products marketed by third parties for psychiatric indications that utilize different therapeutic targets or are in a different therapeutic class have experienced significant safety issues. As we continue the development and clinical trials of our product candidates, there can be no assurance that our product candidates will not experience significant safety issues.

Discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval, including withdrawal of the medicine from the market. Many drugs acting on the CNS include boxed warnings and precautions related to suicidal behavior or ideation, driving impairment, somnolence/sedation and dizziness, discontinuation, weight gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, sleep disturbances, and motor disturbances. If we or others later identify undesirable side effects caused by the mechanisms of action or classes of our product candidates or specific product candidates:

- we may be required to conduct additional clinical trials or implement a Risk Evaluation and Mitigation Strategies program prior to or following approval;

- regulatory authorities may not approve our product candidates or, as a condition of approval, require specific warnings and contraindications;

- regulatory authorities may withdraw their approval of the product and require us to take our drug off the market;

- we may have limitations on how we promote our drugs;

- sales of products may decrease significantly;

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we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which, in turn, could delay or prevent us from generating significant revenues from its sale.

Finally, if the FDA determines that a drug may present a risk of substance abuse, it can recommend to the Drug Enforcement Administration that the drug be scheduled under the Controlled Substances Act. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates, and severely harm our business and financial condition.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize ITI-007 and other product candidates, which may not be successful, and which may require us to transfer our production to one or more other third-party manufacturers, potentially delaying regulatory approval and commercialization.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for ITI-007 which achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on third-party manufacturers to manufacture and supply our product candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face significant delays in our clinical trials, regulatory approvals and product introductions and commercialization.

We have no manufacturing facilities and have limited experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including ITI-007, for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to amend our contracts with our current manufacturers or contract with other third parties to manufacture them in larger quantities at commercial scale. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts. We have not entered into a long-term agreement with our current third-party manufacturers or with any alternate suppliers. Although we intend to do so prior to any commercial launch of a product that is approved by the FDA in order to ensure that we maintain adequate supplies of commercial drug product, we may be unable to enter into such agreements or do so on commercially reasonable terms, which could delay a product launch or subject our commercialization efforts to significant supply risk.

Manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. The manufacture of pharmaceutical products in compliance with the cGMPs requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide product candidates in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or terminate the clinical trials completely.

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In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we request regulatory approval from the FDA. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers compliance with these regulations and standards. A failure of any of our current or future contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Failure by our current or future third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions. If the safety of any product supplied is compromised due to our manufacturers failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.

We do not currently have an organization for the sales, marketing or distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial, and related capabilities or make arrangements with third parties to perform these critical commercial services. There are risks involved with both establishing our own sales, marketing, managerial and related capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively, which could damage our reputation. If we do not establish adequate sales, marketing, and distribution capabilities, whether independently or in collaboration with third parties, we will not be successful in commercializing our product candidates, may not be able to generate product revenue and may not become profitable.

There are possible limitations on our use of net operating losses.

As of September 30, 2015, we had net operating loss carryforwards of approximately $148.8 million to reduce any future federal and state taxable income through 2034. Since we had net operating loss carryforwards as of December 31, 2014 and 2013, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. The net operating loss carryforwards of approximately $148.8 million as of September 30, 2015 will begin to expire in the year 2030 if unused. The use of our net operating loss carryforwards may be restricted due to changes in our ownership, including as a result of our public offerings in March 2015 and September 2015.

Many of our competitors have greater resources and capital than us, putting us at a competitive disadvantage. If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunity.

Competition in the pharmaceutical and biotechnology industries is intense and increasing. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

For example, our potential products for the treatment of schizophrenia would compete with, among other branded products, Abilify®, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Fanapt®, marketed by Novartis Pharmaceuticals, Seroquel XR®, marketed by AstraZeneca, Invega®, marketed by Janssen, Latuda®, marketed by Sunovion, and VRAYLAR®, marketed by Allergan. In addition, our products will compete with, among other generic antipsychotic drugs, haloperidol, risperidone, quetiapine, olanzapine and clozapine.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory approvals.

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

Numerous factors could result in substantial volatility in the trading price of our stock.

In the 12 months preceding September 30, 2015, the price per share of our common stock on the NASDAQ Global Select Market has ranged from a high of $60.79 to a low of $13.37. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price,. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- timing and announcement of regulatory developments and approvals or preliminary, interim or final results of clinical trials;
- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of medical innovations or new products by our competitors;

issuance of new or changed securities analysts reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the biopharmaceutical industry;

any future sales of our common stock or other securities in connection with raising additional capital or otherwise;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of biotechnology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors views of us.

We are required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to maintain effective internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2015. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we fail to maintain the effectiveness of our internal controls or fail to comply in a timely manner with the requirements of the Sarbanes-Oxley Act, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, this could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our independent registered public accounting firm as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

We will no longer be an emerging growth company beginning on December 31, 2015 after which we will not be able to take advantage of the reduced disclosure requirements applicable to emerging growth companies.

We will remain an emerging growth company under the Jumpstart Our Business Startups Act, or JOBS Act, until December 31, 2015. As an emerging growth company, we have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies. On December 31, 2015, we will become a large accelerated filer and the reduced disclosure obligations of emerging growth companies will no longer be available to us. As a result, we will need to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act beginning with our annual report on Form 10-K for the year ending December 31, 2015, will be required to hold a say-on-pay vote and a say-on-frequency vote at our 2016 annual meeting of stockholders, and will no longer be entitled to provide the reduced executive compensation disclosures permitted by emerging growth companies in our annual report on the Form 10-K and proxy statement for the year ending December 31, 2015. We expect that our transition from emerging growth company to large accelerated filer will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

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

(a) Unregistered Sales of Equity Securities

Not applicable.

(b) Use of Proceeds from Registered Securities

On February 5, 2014, we completed our initial public offering of 7,063,300 shares of our common stock at a price of $17.50 per share for aggregate gross proceeds of approximately $123.6 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on January 30, 2014 (File No. 333-193313), and a registration statement on Form S-1 filed pursuant to Rule 462(b) promulgated under the Securities Act (File No. 333-193676). Leerink Partners LLC and Cowen and Company, LLC acted as joint book-running managers for the offering and as representatives of the underwriters. Guggenheim Securities, LLC and JMP Securities LLC acted as co-managers for the offering. The offering commenced on January 24, 2014 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of approximately $115.4 million, after deducting approximately $7.4 million of underwriting discounts and commissions, and approximately $0.8 million of offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

We have invested the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as commercial paper and corporate debt securities, U.S. government securities, certificates of deposit and institutional money market funds. As of September 30, 2015, $92.8 million of the net proceeds of the offering had been used primarily for working capital purposes, including recurring expenses and preclinical and clinical trial costs related to the development of ITI-007. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus dated January 30, 2014 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on January 31, 2014. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

(c) Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three months ended September 30, 2015.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

On November 4, 2015, we hired Robert Davis as Senior Vice President, Chief Scientific Officer and entered into an employment agreement with him. The agreement provides for an annual salary of $400,000, subject to our annual review and adjustment in the discretion of our board of directors, and that Mr. Davis is eligible for bonus payments and equity grants as may be awarded by our board of directors. In addition, his employment agreement provides that we will pay the premium on a life insurance policy in an amount of $150,000. The employment agreement also provides that Mr. Davis is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement is three years and will be renewed for successive one year terms, unless we or Mr. Davis provides notice that we or he, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

If Mr. Davis employment is terminated for any reason, he will be entitled to compensation and benefits through the last day of his employment, including accrued but untaken vacation. If his employment is terminated due to his death or disability, we will also pay him or his estate the compensation which would otherwise have been payable to him through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If his employment is terminated without cause by us or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination, on condition that he executes a general release in our favor, returns all our property, and complies with his employment agreement, proprietary information, inventions, and non-competition agreement, and the general release: (a) payment of 12 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release he executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to his termination; and (c) all of his unvested equity grants will immediately vest. Mr. Davis will also be entitled to such severance benefits if we elect not to renew his employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Mr. Davis executing a general release in our favor, returning all our property, and complying with his employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Mr. Davis will not be eligible for such severance benefits if he or we wish to renew the agreement on different terms than those contained in his employment agreement. If his employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, he terminates his employment for good reason during such period, or he terminates his employment for any reason within one month following a change of control, he will be eligible for the following severance benefits following his employment termination: (a) payment of 18 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release,

(b) payment for 18 months of the portion of the COBRA premiums that we paid prior to his termination, and (c) all of his unvested equity grants will immediately vest. Such severance benefits following a change of control are payable on condition that he executes a general release in favor of us, returns all our property and complies with his post-termination obligations under his employment agreement, his proprietary information, inventions, and non-competition agreement, and his general release.

On November 5, 2015, we promoted Dr. Kimberly Vanover to Senior Vice President, Clinical Development. Previously Dr. Vanover served as our Vice President, Clinical Development. In connection with Dr. Vanover s promotion we entered into an employment agreement with her. The agreement provides for an annual salary of $340,000, subject to our annual review and adjustment in the discretion of our board of directors, and that Dr. Vanover is eligible for bonus payments and equity grants as may be awarded by our board of directors. In addition, her employment agreement provides that we will pay the premium on a life insurance policy in an amount of $150,000. The employment agreement also provides that Dr. Vanover is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement is three years and will be renewed for successive one year terms, unless we or Dr. Vanover provides notice that we or she, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

If Dr. Vanover s employment is terminated for any reason, she will be entitled to compensation and benefits through the last day of her employment, including accrued but untaken vacation. If her employment is terminated due to her death or disability, we will also pay her or her estate the compensation which would otherwise have been payable to her through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If her employment is terminated without cause by us or she terminates her employment for good reason, she will receive the following severance benefits following her employment termination, on condition that she executes a general release in our favor, returns all our property, and complies with her employment agreement, proprietary information, inventions, and non-competition agreement, and the general release: (a) payment of 12 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release she executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to her termination; and (c) all of her unvested equity grants will immediately vest. Dr. Vanover will also be entitled to such severance benefits if we elect not to renew her employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Dr. Vanover executing a general release in our favor, returning all our property, and complying with her employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Dr. Vanover will not be eligible for such severance benefits if she or we wish to renew the agreement on different terms than those contained in her employment agreement. If her employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, she terminates her employment for good reason during such period, or she terminates her employment for any reason within one month following a change of control, she will be eligible for the following severance benefits following her employment termination: (a) payment of 18 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release, (b) payment for 18 months of the portion of the COBRA premiums that we paid prior to her termination, and (c) all of her unvested equity grants will immediately vest. Such severance benefits following a change of control are payable on condition that she executes a general release in favor of us, returns all our property and complies with her post-termination obligations under her employment agreement, her proprietary information, inventions, and non-competition agreement, and her general release.

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Item 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1*	Employment Agreement dated August 3, 2015 by and between Intra-Cellular Therapies, Inc., and Michael I. Halstead.	X			
31.1	Certification of the Registrant s Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Registrant s Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014 (audited), (ii) Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2015 and 2014, (iii) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2015 and 2014, and (iv) Notes to Condensed Consolidated Financial Statements (unaudited).	X			

* Management contract or compensatory plan or arrangement.

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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.

	INTRA-CELLULAR THERAPIES, INC.
Date: November 5, 2015	By: /s/ Sharon Mates, Ph.D. Sharon Mates, Ph.D. Chairman, President and Chief Executive Officer
Date: November 5, 2015	By: /s/ Lawrence J. Hineline Lawrence J. Hineline Vice President of Finance and Chief Financial Officer

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