ACADIA PHARMACEUTICALS INC
Form 424B5
November 26, 2018
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-228546

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated November 26, 2018

Prospectus supplement

(To prospectus dated November 26, 2018)

$200,000,000

Common Stock

We are selling $200,000,000 of shares of our common stock.

Our common stock is listed on The Nasdaq Global Select Market under the symbol ACAD . On November 23, 2018, the last reported sale price for our common stock on The Nasdaq Global Select Market was $18.51 per share.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds to ACADIA before expenses	$	$

(1) See Underwriting for additional information regarding total underwriting compensation.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to an additional $30,000,000 of shares of our common stock at the public offering price, less the underwriting discounts and commissions.

Investing in our common stock involves significant risks. See Risk Factors and the documents incorporated by reference into this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus supplement or the accompanying prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

Entities affiliated with Baker Bros. Advisors L.P. and two of our directors, Julian C. Baker and Dr. Stephen Biggar, have indicated an interest in purchasing an aggregate number of shares of the common stock offered in this offering at the price offered to the public to maintain at least their current pro-rata percentage ownership (approximately 22.8%) of our common stock. Because these indications of interest are not binding agreements or commitments to purchase, any or all of these entities may determine to purchase fewer or more shares than it has indicated an interest in purchasing, or elect not to purchase any shares in this offering. The underwriters may also determine to sell fewer, more or no shares in this offering to any or all of these entities.

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2018.

BofA Merrill Lynch **J.P. Morgan** **Goldman Sachs & Co. LLC**

The date of this prospectus supplement is November , 2018

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated November 26, 2018, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. You should assume that the information contained in this prospectus supplement is accurate as of the date on the cover page of this prospectus supplement only and that any information we have incorporated by reference or included in the accompanying prospectus is accurate only as of the date given in the document incorporated by reference or as of the date of the prospectus, as applicable, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

We have not, and the underwriters have not, authorized anyone to provide you with different information than that which is contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Certain Information by Reference.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement to ACADIA , the Company , we , our or similar references mean ACADIA Pharmaceuticals Inc. together with its wholl owned subsidiaries.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference may include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the factors described under the heading Risk Factors in this prospectus supplement and the financial and other information incorporated by reference in this prospectus supplement and the accompanying prospectus, as well as the information included in any free writing prospectus that we have authorized for use in connection with this offering, before making an investment decision.

Company Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug, NUPLAZID (pimavanserin), which was approved by the U.S. Food and Drug Administration, or FDA, in April 2016 for the treatment of hallucinations and delusions associated with Parkinson s disease psychosis, or PD Psychosis, and is the only drug approved in the United States for this condition. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5- HT_{2A} receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PD Psychosis in our Phase 3 pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA for the treatment of PD Psychosis. We hold worldwide commercialization rights to pimavanserin. We launched NUPLAZID in the United States in May 2016 with the recommended dosing of 34 mg once a day taken as two 17 mg tablets. In June 2018, the FDA approved a 34 mg NUPLAZID capsule formulation that provides patients with the recommended 34 mg once daily dose in a single, small capsule, reducing patient pill burden versus the previous administration of two 17 mg tablets. In addition, the FDA approved a 10 mg NUPLAZID tablet that provides an optimized lower dosage strength in those patients who are concomitantly receiving strong cytochrome 3A4 inhibitors which can inhibit the metabolism of NUPLAZID.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PD Psychosis and we plan to continue to study the use of pimavanserin in multiple disease states. For example, we believe dementia-related psychosis represents one of our most important opportunities for further exploration. In December 2016, we announced positive top-line results from our Phase 2 study exploring the utility of pimavanserin for the treatment of Alzheimer s disease psychosis, or AD Psychosis, a disorder for which no drug is currently approved by the FDA. Following our End-of-Phase 2 Meeting with the FDA and agreement with the agency on our clinical development plan, we initiated our Phase 3 HARMONY relapse prevention study in the fourth quarter of 2017, which allows us to evaluate pimavanserin for a broader indication than AD Psychosis alone. More specifically, HARMONY will evaluate pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, which includes psychosis in patients with Alzheimer s disease, dementia with Lewy bodies, Parkinson s disease dementia, vascular dementia and frontotemporal dementia. Furthermore, in the fourth quarter of 2017, the FDA granted Breakthrough Therapy Designation to pimavanserin for this dementia-related psychosis indication.

We also believe schizophrenia represents a disease with multiple unmet needs and we are currently exploring the utility of pimavanserin in this area. Despite a large number of FDA-approved therapies for schizophrenia, current drugs do not adequately address some very important symptoms of schizophrenia, such as the inadequate response to current antipsychotic treatment of psychotic symptoms and negative symptoms. In the fourth quarter of 2016, we initiated two studies evaluating the adjunctive use of pimavanserin in patients with schizophrenia. ENHANCE-1 is a Phase 3 study evaluating pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate

response to their current antipsychotic therapy. We expect to report

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top-line results of the ENHANCE-1 study mid-2019. ADVANCE is a Phase 2 study evaluating pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia.

According to the National Institute of Mental Health, major depressive disorder (MDD) affects approximately 16 million adults in the United States, with approximately 2.5 million adults treated with adjunctive therapy. The majority of people who suffer from MDD do not respond adequately to initial antidepressant therapy. In October 2018, we announced positive top-line results from CLARITY, a Phase 2 study evaluating pimavanserin for adjunctive treatment in 207 patients with MDD who had a confirmed inadequate response to existing first-line, SSRI or SNRI, antidepressant therapy. In the study, pimavanserin met the pre-specified primary and key secondary endpoints with statistical significance and positive results were also observed in seven additional secondary endpoints including response rate, improvement in sexual function, and a reduction in daytime sleepiness. Pimavanserin was generally well-tolerated in the study with no meaningful weight gain observed or impact on motor function. We plan to meet with the FDA and initiate two Phase 3 clinical trials in adjunctive MDD in first half of 2019.

In August 2018, we acquired an exclusive North American license to develop and commercialize trofinetide for Rett syndrome and other indications from Neuren Pharmaceuticals. Rett syndrome is a debilitating neurological disorder that occurs in females following apparently normal development for the first six months of life. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, disorganized breathing patterns, scoliosis and sleep disturbances. Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function. Trofinetide has been granted FDA Fast Track Status and Orphan Drug Designation in the U.S. and Europe for the treatment of Rett syndrome. Currently, there are no approved medicines for the treatment of Rett syndrome. We plan to initiate a Phase 3 randomized, double-blind placebo-controlled study evaluating trofinetide in girls with Rett syndrome in the second half of 2019.

The following table summarizes our product candidates and programs:

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Corporate Information

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. In 1997, we reincorporated in Delaware. Our executive offices are located at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130, and our telephone number is (858) 558-2871. Our website address is www.acadia-pharm.com. Information contained on our website is not a part of this prospectus supplement, the accompanying prospectus or any of the documents incorporated by reference herein.

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The Offering

Common stock offered by us	$200,000,000 of shares
Common stock to be outstanding immediately after this offering	135,827,985 shares (or 137,448,731 shares if the underwriters exercise in full their option to purchase additional shares, based on an assumed offering price of $18.51 per share, which is the last reported sale price of our common stock on The Nasdaq Global Select Market on November 23, 2018)
Option to purchase additional shares	The underwriters have an option to purchase up to $30,000,000 of additional shares of our common stock. The underwriters may exercise this option at any time within 30 days from the date of this prospectus supplement.
Use of proceeds	We intend to use the net proceeds of this offering to fund ongoing commercialization efforts for NUPLAZID, ongoing and new clinical trials and development efforts for pimavanserin and trofinetide, and for general corporate purposes, including working capital. See Use of Proceeds .
Nasdaq Global Select Market Listing	Our common stock is listed on The Nasdaq Global Select Market under the symbol ACAD .
Risk Factors	Investing in our common stock involves a high degree of risk. See Risk Factors .

The number of shares of our common stock to be outstanding immediately after this offering is based on 125,023,015 shares outstanding as of September 30, 2018 and assumes the sale of $200,000,000 of shares of common stock at $18.51 per share, the last reported sale price for our common stock on The Nasdaq Global Select Market on November 23, 2018. This number of shares excludes, as of September 30, 2018:

- 19,189,706 shares of common stock issuable upon the exercise of outstanding stock options under our equity incentive plans, with a weighted average exercise price of $28.57 per share;
- 7,862,012 shares of common stock available for future grants under our equity incentive plans;
- 85,754 shares of common stock available for issuance under our employee stock purchase plan; and

500,000 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $0.01 per share.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase additional shares and no exercise of outstanding stock options or warrants.

Entities affiliated with Baker Bros. Advisors L.P. and two of our directors, Julian C. Baker and Dr. Stephen Biggar, have indicated an interest in purchasing an aggregate number of shares of the common stock offered in this offering at the price offered to the public to maintain at least their current pro-rata percentage ownership (approximately 22.8%) of our common stock. Because these indications of interest are not binding agreements or commitments to purchase, any or all of these entities may determine to purchase fewer or more shares than it has indicated an interest in purchasing, or elect not to purchase any shares in this offering. The underwriters may also determine to sell fewer, more or no shares in this offering to any or all of these entities.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. Our business, prospects, financial condition or operating results could be materially adversely affected by the risks identified below, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the information contained in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and other documents which are incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety, and other documents that we file from time to time with the SEC.

Risks Related to This Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, negatively impact our commercialization activities for NUPLAZID (pimavanserin) and any other product candidate we develop that receives regulatory approval, delay the development of our product candidates, including pimavanserin and trofinetide, and cause the price of our common stock to decline.

If you purchase the common stock sold in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on an assumed public offering price of $18.51 per share (the last reported sale price for our common stock on The Nasdaq Global Select Market on November 23, 2018) and our net tangible book value as of September 30, 2018, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $15.51 per share with respect to the net tangible book value of the common stock. See Dilution for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

In addition, we have a significant number of stock options and warrants outstanding. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, and the documents incorporated by reference herein and therein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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 benefits to be derived from NUPLAZID (pimavanserin) and from our drug candidates, including trofinetide;
- the potential market opportunities for pimavanserin and our drug candidates;
- our strategy for the commercialization of NUPLAZID;
- our plans for exploring and developing pimavanserin for indications other than Parkinson s disease psychosis and trofinetide for Rett syndrome;
- our plans and timing with respect to seeking regulatory approvals;
- the potential commercialization of any of our drug candidates that receive regulatory approval;
- the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID and our drug candidates;
- our strategy for discovering, developing and, if approved, commercializing drug candidates;
- our existing and potential future collaborations;
- our estimates of future payments, revenues and profitability;
- our estimates regarding our capital requirements, future expenses and need for additional financing;

possible changes in legislation; and

our use of the proceeds from this offering.

In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, plan, anticipate, believe, estimate, project, predict, potential and similar expressions (including their use in negative) intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in the documents incorporated by reference herein, usually under the heading Risk Factors. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. Before deciding to purchase our common stock, you should carefully consider the risk factors incorporated by reference herein, in addition to the other information set forth in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference herein.

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USE OF PROCEEDS

We estimate the net proceeds to us from this offering will be approximately $188,500,000 ($216,850,000 if the underwriters option to purchase additional shares is exercised in full), after payment of the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $10,000,000 increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus supplement, would increase (decrease) the net proceeds to us by approximately $9,450,000, after payment of the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering to fund ongoing commercialization efforts for NUPLAZID, including a planned direct-to-consumer marketing campaign, ongoing and new clinical trials and development efforts for pimavanserin and trofinetide, and for general corporate purposes, which may include research, development and commercialization expenses, capital expenditures, working capital, and selling, general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. Although we currently have no specific agreements, commitments or understandings with respect to any acquisition or investment, we evaluate acquisition and investment opportunities and may engage in related discussions with other companies from time to time.

The amounts and timing of these expenditures will depend on a number of factors, such as the timing and progress of our commercialization activities, research and development efforts, the timing of regulatory review and approval of our product candidates, the timing and progress of any partnering efforts, and the competitive environment for our product candidates. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds from this offering. Accordingly, our management will have broad discretion in the application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short term, interest-bearing instruments.

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DILUTION

Our net tangible book value as of September 30, 2018 was approximately $219,009,000, or $1.75 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2018. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 10,804,970 shares of our common stock in this offering at an assumed public offering price of $18.51 per share (the last reported sale price for our common stock on The Nasdaq Global Select Market on November 23, 2018) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2018 would have been approximately $407,509,000, or $3.00 per share. This represents an immediate increase in net tangible book value of $1.25 per share to existing stockholders and immediate dilution in net tangible book value of $15.51 per share to investors purchasing our common stock in this offering at the assumed public offering price.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$ 18.51
Net tangible book value per share as of September 30, 2018	$ 1.75	
Increase in net tangible book value per share attributable to new investors purchasing our common stock in this offering	1.25	
As adjusted net tangible book value per share on September 30, 2018, after giving effect to this offering		3.00
Dilution per share to new investors purchasing our common stock in this offering		$ 15.51

The table above assumes for illustrative purposes that an aggregate of 10,804,970 shares of our common stock are sold in this offering at an assumed public offering price of $18.51 per share (the last reported sale price for our common stock on The Nasdaq Global Select Market on November 23, 2018), for aggregate gross proceeds of $200.0 million. A $1.00 increase (decrease) in such assumed public offering price would increase (decrease) the dilution per share to new investors by approximately $0.99 per share, assuming that the number of shares sold by us, as set forth in the preceding sentence, remains the same.

We may also increase or decrease the number of shares we are offering from the assumed number of shares set forth on the cover page of this prospectus supplement. An increase of $10.0 million in the number of shares offered by us from the assumed amount of shares set forth on the cover page of this prospectus supplement would increase our as adjusted net tangible book value after this offering by approximately $9,450,000, or approximately $0.06 per share, and the dilution per share to new investors would be approximately $15.45 per share, assuming that the assumed public offering price remains the same. Similarly, a decrease of $10.0 million in the amount of shares offered by us from the assumed amount of shares set forth on the cover page of this prospectus supplement would decrease our as adjusted net tangible book value after this offering by approximately $9,450,000, or approximately $0.06 per share, and the dilution per share to new investors would be approximately $15.57 per share, assuming that the assumed public offering price remains the same.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares that we offer in this offering, and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase up to $30.0 million of additional shares of common stock at an assumed public offering price of $18.51 per share (the last reported sale price for our

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common stock on The Nasdaq Global Select Market on November 23, 2018), the as-adjusted net tangible book value after this offering would be $3.17 per share, representing an increase in net tangible book value of $1.42 per share to existing stockholders and immediate dilution in net tangible book value of $15.34 per share to investors purchasing our common stock in this offering at the assumed public offering price.

The above discussion and table are based on 125,023,015 shares outstanding as of September 30, 2018, and exclude as of that date:

- 19,189,706 shares of common stock issuable upon the exercise of outstanding stock options under our equity incentive plans, with a weighted average exercise price of $28.57 per share;
- 7,862,012 shares of common stock available for future grants under our equity incentive plans;
- 85,754 shares of common stock available for issuance under our employee stock purchase plan; and
- 500,000 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $0.01 per share.

To the extent that options or warrants outstanding as of September 30, 2018 have been or may be exercised or other shares issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC and are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
J.P. Morgan Securities LLC	
Goldman Sachs & Co. LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus supplement and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$

Underwriting discounts and commissions			
Proceeds to ACADIA before expenses	$	$	$

We estimate that the expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately $500,000. We have agreed to reimburse the underwriters for certain of their expenses incurred in connection with this offering in an amount up to $15,000.

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Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus supplement, to purchase up to $30.0 million of additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter s initial amount reflected in the above table.

No Sales of Similar Securities

We and each of our executive officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open put equivalent position within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC.

Among other exceptions, the lock-up agreements permit our officers and directors, at any time after the date that is 30 days after the date of this prospectus supplement, to sell shares of common stock pursuant to a written plan, as currently existing as of the date of the lock-up agreement, meeting the requirements of Rule 10b5-1(c) under the Exchange Act, if then permitted by us and applicable law; provided that any filing made under the Exchange Act in connection therewith shall state that such sales were made pursuant to a written plan meeting the requirements of Rule 10b5-1(c) under the Exchange Act.

These restrictions terminate after the close of trading of the common stock on and including the 90th day after the date of this prospectus supplement. Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC and may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

NASDAQ Global Select Market Listing

The shares are listed on The Nasdaq Global Select Market under the symbol ACAD .

Price Stabilization, Short Positions

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of

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shares than they are required to purchase in this offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of this offering.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Passive Market Making

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in the common stock on The Nasdaq Global Select Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker s bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters and dealers are not required to engage in passive market making and may end passive market making activities at any time.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute the prospectus supplement and the accompanying prospectus by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial

instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant Member State), no offer of shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;

B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus supplement has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus supplement may only do so in circumstances in which no obligation arises for us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for us or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant

implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within

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Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons).

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre (DIFC)

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (DFSA). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities.

Further, this prospectus supplement does not constitute a public offer of securities in the

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United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus supplement has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Australia

This prospectus supplement:

- does not constitute a disclosure document under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC) as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Act. Accordingly, the shares may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person

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for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Singapore

This prospectus supplement has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus supplement and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e)

as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority (CMA) pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution

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number 1-28-2008, as amended (the CMA Regulations). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorised financial adviser.

Notice to Prospective Investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to Prospective Investors in China

This prospectus supplement does not constitute a public offer of the shares, whether by sale or subscription, in the People s Republic of China (the PRC). The shares are not being offered or sold directly or indirectly in the PRC to or for the benefit of, legal or natural persons of the PRC.

Further, no legal or natural persons of the PRC may directly or indirectly purchase any of the shares or any beneficial interest therein without obtaining all prior PRC s governmental approvals that are required, whether statutorily or otherwise. Persons who come into possession of this document are required by the issuer and its representatives to observe these restrictions.

Notice to Prospective Investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the FSCMA), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the FETL). The shares have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia (Commission) for the Commission s approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus supplement and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its

equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an

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individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus supplement is subject to Malaysian laws. This prospectus supplement does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to Prospective Investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorised to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, the shares are not offered, and the Offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

(i) the offer, transfer, sale, renunciation or delivery is to duly registered banks, mutual banks, financial services provider, financial institution, the Public Investment Corporation (in each case registered as such in South Africa), a person who deals with securities in their ordinary course of business, or a wholly owned subsidiary of a bank, mutual bank, authorised services provider or financial institution, acting as agent in the capacity of an authorised portfolio manager for a pension fund (duly registered in South Africa), or as manager for a collective investment scheme (registered in South Africa); or

(ii) the contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than R1,000,000.

This document does not, nor is it intended to, constitute an *offer to the public* (as that term is defined in the South African Companies Act, 2008 (the SA Companies Act) and does not, nor is it intended to, constitute a prospectus prepared and registered under the SA Companies Act. This document is not an *offer to the public* and must not be acted on or relied on by persons who do not fall within Section 96(1)(a) of the SA Companies Act (such persons being referred to as relevant persons). Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in

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accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering

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LEGAL MATTERS

The validity of the common stock offered by this prospectus supplement and the accompanying prospectus will be passed upon for us by Cooley LLP, San Diego, California. Latham & Watkins LLP, San Diego, California, is counsel for the underwriters in connection with this offering.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements (and schedule) included in our Annual Report on Form 10-K for the year ended December 31, 2017, and the effectiveness of our internal control over financial reporting as of December 31, 2017, as set forth in their reports, which are incorporated by reference in this prospectus supplement and elsewhere in the registration statement. Our financial statements (and schedule) are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference in this prospectus supplement and the accompanying prospectus for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC s website at http://www.sec.gov.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is part of this prospectus supplement and the accompanying prospectus. Later information filed with the SEC will update and supersede this information.

We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement until the termination of the offering of the shares covered by this prospectus supplement (other than portions of Current Reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items):

- our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 27, 2018;

- The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 from our definitive proxy statement on Schedule 14A (other than information

furnished rather than filed), filed with the SEC on April 30, 2018;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018, June 30, 2018 and September 30, 2018, filed with the SEC on May 4, 2018, August 8, 2018 and November 6, 2018, respectively;

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our Current Reports on Form 8-K, filed with the SEC on June 8, 2018, July 23, 2018, October 31, 2018, November 5, 2018 and November 20, 2018; and

the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on May 19, 2004, including any amendments or reports filed for the purposes of updating this description.

You may request a copy of these filings at no cost, by contacting us at the following address or telephone number:

Investor Relations

ACADIA Pharmaceuticals Inc.

3611 Valley Centre Drive, Suite 300

San Diego, CA 92130

(858) 558-2871

In accordance with Rule 412 of the Securities Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

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PROSPECTUS

Common Stock

We may, from time to time, offer to sell common stock in amounts, at prices and on terms described in one or more supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest.

This prospectus describes some of the general terms that may apply to an offering of our common stock. The specific terms and any other information relating to a specific offering will be set forth in a post-effective amendment to the registration statement of which this prospectus is a part or in a supplement to this prospectus or may be set forth in one or more documents incorporated by reference in this prospectus. The amendment or supplement, as applicable, may also add, update or change information contained in this prospectus with respect to that specific offering.

Our common stock may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to purchasers; or through a combination of these methods. The names of any underwriter, dealer or agents involved in the sale of our common stock and their compensation will be described in an applicable prospectus supplement. See Plan of Distribution .

Our common stock is listed on The Nasdaq Global Select Market under the symbol ACAD . On November 23, 2018, the last reported sale price for our common stock was $18.51. You are encouraged to obtain current market quotations for shares of our common stock.

Our principal executive offices are located at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130, and our telephone number at that address is (858) 558-2871.

Investing in our common stock involves a high degree of risk. See Risk Factors on page 3 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 26, 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using the shelf registration process as a well-known seasoned issuer, as defined in Rule 405 under the Securities Act of 1933, as amended, or the Securities Act. By using a shelf registration statement, we may offer and sell from time to time in one or more offerings the common stock described in this prospectus. No limit exists on the aggregate number of shares of common stock we may sell pursuant to the registration statement.

This prospectus provides you with a general description of our common stock. Each time we sell shares of our common stock, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement, or information incorporated by reference in this prospectus or any prospectus supplement that is of a more recent date, may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should read both this prospectus and any applicable prospectus supplement, together with the additional information described below under the heading Where You Can Find More Information . This prospectus may not be used to consummate a sale of our common stock unless it is accompanied by a prospectus supplement. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to an offering of our common stock.

We have not authorized anyone to provide you with information other than the information contained or incorporated by reference in this prospectus and any related prospectus supplement, or in any free writing prospectus that we may authorize in connection with an offering of our shares of common stock. No one is making offers to sell or seeking offers to buy shares of our common stock in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus and any prospectus supplement is accurate only as of the date on the front of this prospectus or the prospectus supplement, as applicable, and that any information we have incorporated by reference in this prospectus or any prospectus supplement is accurate only as of the date given in the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

References in this prospectus to ACADIA , the Company , we , us and our refer to ACADIA Pharmaceuticals Inc. together with our wholly-owned subsidiaries.

ACADIA and NUPLAZID are our registered trademarks. Our logos and trademarks are the property of ACADIA Pharmaceuticals Inc. All other brand names or trademarks appearing in this prospectus are the property of their

respective holders. Use or display by us of other parties trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

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ACADIA PHARMACEUTICALS INC.

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. We have a portfolio of product opportunities led by our novel drug, NUPLAZID (pimavanserin), which was approved by the U.S. Food and Drug Administration, or FDA, in April 2016 for the treatment of hallucinations and delusions associated with Parkinson s disease psychosis, or PD Psychosis, and is the only drug approved in the United States for this condition. NUPLAZID is a selective serotonin inverse agonist, or SSIA, preferentially targeting 5- HT_{2A} receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PD Psychosis in our Phase 3 pivotal trial and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA for the treatment of PD Psychosis. We hold worldwide commercialization rights to pimavanserin. We launched NUPLAZID in the United States in May 2016 with the recommended dosing of 34 mg once a day taken as two 17 mg tablets. In June 2018, the FDA approved a 34 mg NUPLAZID capsule formulation that provides patients with the recommended 34 mg once daily dose in a single, small capsule, reducing patient pill burden versus the previous administration of two 17 mg tablets. In addition, the FDA approved a 10 mg NUPLAZID tablet that provides an optimized lower dosage strength in those patients who are concomitantly receiving strong cytochrome 3A4 inhibitors which can inhibit the metabolism of NUPLAZID.

We believe that pimavanserin has the potential to address important unmet medical needs in neurological and psychiatric disorders in addition to PD Psychosis and we plan to continue to study the use of pimavanserin in multiple disease states. For example, we believe dementia-related psychosis represents one of our most important opportunities for further exploration. In December 2016, we announced positive top-line results from our Phase 2 study exploring the utility of pimavanserin for the treatment of Alzheimer s disease psychosis, or AD Psychosis, a disorder for which no drug is currently approved by the FDA. Following our End-of-Phase 2 Meeting with the FDA and agreement with the agency on our clinical development plan, we initiated our Phase 3 HARMONY relapse prevention study in the fourth quarter of 2017, which allows us to evaluate pimavanserin for a broader indication than AD Psychosis alone. More specifically, HARMONY will evaluate pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, which includes psychosis in patients with Alzheimer s disease, dementia with Lewy bodies, Parkinson s disease dementia, vascular dementia and frontotemporal dementia. Furthermore, in the fourth quarter of 2017, the FDA granted Breakthrough Therapy Designation to pimavanserin for this dementia-related psychosis indication.

We also believe schizophrenia represents a disease with multiple unmet needs and we are currently exploring the utility of pimavanserin in this area. Despite a large number of FDA-approved therapies for schizophrenia, current drugs do not adequately address some very important symptoms of schizophrenia, such as the inadequate response to current antipsychotic treatment of psychotic symptoms and negative symptoms. In the fourth quarter of 2016, we initiated two studies evaluating the adjunctive use of pimavanserin in patients with schizophrenia. ENHANCE-1 is a Phase 3 study evaluating pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to their current antipsychotic therapy. We expect to report top-line results of the ENHANCE-1 study mid-2019. ADVANCE is a Phase 2 study evaluating pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia.

According to the National Institute of Mental Health, major depressive disorder (MDD) affects approximately 16 million adults in the United States, with approximately 2.5 million adults treated with adjunctive therapy. The majority of people who suffer from MDD do not respond adequately to initial antidepressant therapy. In October 2018, we announced positive top-line results from CLARITY, a Phase 2 study evaluating pimavanserin for adjunctive treatment in 207 patients with MDD who had a confirmed inadequate response to existing first-line, SSRI or SNRI, antidepressant therapy. In the study, pimavanserin met the pre-specified primary and key secondary endpoints with

statistical significance and positive results were also observed in seven additional secondary endpoints including response rate, improvement in sexual function, and a reduction in daytime sleepiness. Pimavanserin was generally well-tolerated in the study with no meaningful

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weight gain observed or impact on motor function. We plan to meet with the FDA and initiate two Phase 3 clinical trials in adjunctive MDD in first half of 2019.

In August 2018, we acquired an exclusive North American license to develop and commercialize trofinetide for Rett syndrome and other indications from Neuren Pharmaceuticals. Rett syndrome is a debilitating neurological disorder that occurs in females following apparently normal development for the first six months of life. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, disorganized breathing patterns, scoliosis and sleep disturbances. Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function. Trofinetide has been granted FDA Fast Track Status and Orphan Drug Designation in the U.S. and Europe for the treatment of Rett syndrome. Currently, there are no approved medicines for the treatment of Rett syndrome. We plan to initiate a Phase 3 randomized, double-blind placebo-controlled study evaluating trofinetide in girls with Rett syndrome in the second half of 2019.

We were incorporated in Delaware in January 1997. Our principal executive offices are located at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130, and our telephone number at that address is (858) 558-2871. Our website address is www.acadia-pharm.com. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. Our business, prospects, financial condition or operating results could be materially adversely affected by the risks identified below, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the information contained in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and other documents which are incorporated by reference in this prospectus in their entirety, and other documents that we file from time to time with the SEC.

Risks Related to Our Business

Our prospects are highly dependent on the successful commercialization of NUPLAZID, which received approval in April 2016 from the U.S. Food and Drug Administration, or FDA, as a treatment for hallucinations and delusions associated with Parkinson s disease psychosis, and became available for prescription in the United States in May 2016. To the extent NUPLAZID is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

NUPLAZID is our only drug that has been approved for sale and it has only been approved for the treatment of hallucinations and delusions associated with Parkinson s disease psychosis, or PD Psychosis, in the United States. We are focusing a significant portion of our activities and resources on NUPLAZID, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize NUPLAZID in the United States.

Successful commercialization of NUPLAZID is subject to many risks. Prior to NUPLAZID, we had never, as an organization, launched or commercialized any product, and there is no guarantee that we will be able to successfully commercialize NUPLAZID for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial team and have hired our U.S. sales force, we will need to refine and further develop the team in order to successfully commercialize NUPLAZID. Even if we are successful in developing our commercial team, there are many factors that could cause the commercialization of NUPLAZID to be unsuccessful, including a number of factors that are outside our control. Because no drug has previously been approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, it is especially difficult to estimate NUPLAZID s market potential. The commercial success of NUPLAZID depends on the extent to which patients and physicians recognize and diagnose PD Psychosis and accept and adopt NUPLAZID as a treatment for hallucinations and delusions associated with PD Psychosis, and we do not know whether our or others estimates in this regard will be accurate. For example, if the patient population suffering from hallucinations and delusions associated with PD Psychosis is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take NUPLAZID due to its boxed warning, perceived safety issues or for other reasons, the commercial potential of NUPLAZID will be limited. We have limited information about how physicians, patients and payors have responded and will respond to the pricing of NUPLAZID. We have changed, and may continue to change, the price of NUPLAZID from time to time. Physicians may not prescribe NUPLAZID and patients may be unwilling to use NUPLAZID if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative publicity related to NUPLAZID or negative development for NUPLAZID in our post-marketing commitments, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of NUPLAZID. Thus, significant uncertainty remains regarding the commercial potential of NUPLAZID.

If the commercialization of NUPLAZID is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

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If we do not obtain regulatory approval of NUPLAZID for other indications in the United States, or for any indication in foreign jurisdictions, we will not be able to market NUPLAZID for other indications or in other jurisdictions, which will limit our commercial revenues.

While NUPLAZID (pimavanserin) has been approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market NUPLAZID for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of NUPLAZID by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis does not ensure that foreign jurisdictions will also approve NUPLAZID for that indication, nor does it ensure that NUPLAZID will be approved by the FDA for any other indication. In the fourth quarter of 2016, we initiated clinical studies of pimavanserin in schizophrenia and depression and, in the fourth quarter of 2017, we initiated a Phase 3 study of pimavanserin in dementia-related psychosis, an indication for which no drug has been approved. There is no guarantee that any of these studies will be successful, or that the FDA or any regulatory authority in foreign jurisdictions will approve NUPLAZID for any of those indications. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit NUPLAZID for approval for other indications or in other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in PD Psychosis. In addition, strategic considerations need to be taken into account when determining whether and when to submit NUPLAZID for approval in other jurisdictions. For example, in the fourth quarter of 2016, the European Medicines Agency, or EMA, approved our proposed pediatric investigation plan related to our planned submission of a marketing authorization application, or MAA, for NUPLAZID in Europe. However, in light of our continuing clinical development of pimavanserin in indications other than in PD Psychosis, and the time-limited data exclusivity currently granted by the EMA that commences on first approval of a product in Europe, we deferred submission of the MAA and we do not yet have a revised estimate of when we will make that filing. If we do not receive marketing approval for NUPLAZID for any other indication or from any regulatory agency outside of the United States, we will never be able to commercialize NUPLAZID for any other indication in the United States or for any indication in any other jurisdiction. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to NUPLAZID do not meet our or others expectations, the market price of our common stock could decline significantly.

Even though the FDA has granted approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, the terms of the approval may limit its commercial potential. Additionally, NUPLAZID is still subject to substantial, ongoing regulatory requirements.

Even though the FDA has granted approval of NUPLAZID, the scope and terms of the approval may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. The FDA has approved NUPLAZID only for the treatment of hallucinations and delusions associated with PD Psychosis. The label for NUPLAZID also contains a boxed warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients

with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis.

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Additionally, NUPLAZID is approved only for the treatment of hallucinations and delusions associated with PD Psychosis, rather than for the treatment of PD Psychosis and/or other symptoms of PD Psychosis, which may cause confusion for prescribing physicians. This confusion could result in physicians not prescribing NUPLAZID for patients diagnosed with PD Psychosis. In addition, the boxed warning may discourage physicians from prescribing NUPLAZID to patients diagnosed with PD Psychosis, including those with dementia.

In connection with the FDA approval, we committed to conduct the following post-marketing studies: (i) a randomized, placebo-controlled withdrawal study in PD Psychosis patients treated with NUPLAZID, (ii) studies to collect additional data to add to the NUPLAZID safety database from an aggregate of at least 500 predominantly frail and elderly subjects on NUPLAZID in one or more randomized, placebo-controlled studies of eight or more weeks duration, (iii) a drug-drug interaction study with NUPLAZID and a strong CYP3A4 inducer, and (iv) re-analysis of tissue samples from certain previously conducted pre-clinical studies. We have completed the re-analysis of tissue samples but the remaining studies are ongoing. If we fail to comply with our remaining post-marketing commitments, or if the results of the post-marketing studies, or any other ongoing or planned clinical studies of NUPLAZID, are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID will also continue to be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes, good clinical practices, international council for harmonization guidelines and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our nonclinical and clinical development and for any clinical trials that we conduct post- approval.

Discovery of any issues post-approval, including any safety concerns, such as unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on NUPLAZID or on us, including:

- withdrawal of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension of any ongoing clinical studies;

refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;

restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or

seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to discontinue the commercialization of NUPLAZID, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

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NUPLAZID has only been studied in a limited number of patients and in limited populations. As we continue to commercialize NUPLAZID, it is becoming available to a much larger number of patients and in broader populations, and we do not know whether the results of NUPLAZID use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.

Prior to commencing our commercial launch of NUPLAZID in May 2016, NUPLAZID was administered only to a limited number of patients and in limited populations in clinical studies, including our successful pivotal -020 Phase 3 trial with NUPLAZID for the treatment of PD Psychosis, or the -020 Study. While the FDA granted approval of NUPLAZID based on the data included in the NDA, including data from the -020 Study, we do not know whether the results when a large number of patients and broader populations are exposed to NUPLAZID, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of NUPLAZID that served as the basis for the approval of NUPLAZID. New data relating to NUPLAZID, including from adverse event reports and post-marketing studies in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of NUPLAZID from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing NUPLAZID marketing applications for indications other than in PD Psychosis and/or in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We currently have very limited experience as a company in marketing and distributing pharmaceutical products and rely on a limited network of third-party distributors and pharmacies to distribute NUPLAZID. If we are unable to effectively commercialize NUPLAZID, we may not be able to generate adequate product revenues.

NUPLAZID is our only drug that has been approved for sale by any regulatory body, and it became available for prescription in the United States in May 2016. As such, we currently have limited experience commercializing pharmaceutical products as an organization. In order to successfully market NUPLAZID, we must continue to develop our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to maintain and develop adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize NUPLAZID and may not become profitable.

We employ our own internal specialty sales force to commercialize NUPLAZID for the treatment of PD Psychosis as part of our commercialization strategy in the United States. We will need to refine and further develop our sales force as we continue our commercialization efforts, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully refine and further develop our sales force.

Additionally, our strategy in the United States includes distributing NUPLAZID solely through a limited network of third-party specialty distributors and specialty pharmacies. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID in the United States, they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors or pharmacies, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. If we are unable to maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, we would be exposed to substantial distribution risk.

In the event we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of specialty distributors and specialty pharmacies, our ability to

effectively commercialize NUPLAZID and generate product revenues would be limited.

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If we are unable to effectively train and equip our sales force, our ability to successfully commercialize NUPLAZID will be harmed.

Prior to its launch in May 2016, none of the members of our sales force had ever promoted NUPLAZID. In addition, NUPLAZID is the first drug approved by the FDA for the treatment of hallucinations and delusions associated with PD Psychosis. As a result, we are and will continue to be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis to neurologists, select psychiatrists, and pharmacists and physicians in long-term care facilities. In addition, we must ensure that consistent and appropriate messages about NUPLAZID are being delivered to our potential customers by our sales force. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and its proper administration, our efforts to successfully commercialize NUPLAZID could be put in jeopardy, which would negatively impact our ability to generate product revenues.

NUPLAZID may not gain acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.

The degree of market acceptance by physicians, healthcare professionals and third-party payors of NUPLAZID, and any other product for which we obtain regulatory approval, and our profitability and growth, will depend on a number of factors, including:

the ability to provide acceptable evidence of safety and efficacy;

the scope of the approved indication(s) for the product;

the inclusion of any warnings or contraindications in the product label;

the relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

the availability of alternative treatments;

pricing and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or our collaborators sales and marketing strategy; and

our ability to obtain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability.

With respect to NUPLAZID specifically, successful commercialization will depend on whether and to what extent physicians, long-term care facilities and pharmacies, over whom we have no control, determine to utilize NUPLAZID. NUPLAZID is available to treat hallucinations and delusions associated with PD Psychosis, an indication for which no other FDA-approved pharmaceutical treatment currently exists. Because of this, it is particularly difficult to estimate NUPLAZID s market potential and how physicians, payors and patients will respond to changes in the price of NUPLAZID. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of NUPLAZID, and a variety of assumptions directly impact the estimates for NUPLAZID s market potential, including assumptions regarding the prevalence of PD Psychosis, the rate of diagnosis of PD Psychosis, the prevalence and rate of hallucinations and delusions in patients diagnosed with PD Psychosis, the rate of physician adoption of NUPLAZID, the potential impact of payor restrictions regarding NUPLAZID, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of NUPLAZID. For example, certain research suggests that patients with Parkinson s disease may be hesitant to report symptoms of PD Psychosis to

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their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson s disease may not ask about or identify symptoms of PD Psychosis. For these reasons, even if PD Psychosis occurs in high rates among patients with Parkinson s disease, it may be underdiagnosed. Even if PD Psychosis is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PD Psychosis, and if they do prescribe treatment, they may prescribe other drugs, even though they are not approved in PD Psychosis, instead of NUPLAZID. Additionally, NUPLAZID is approved only for the treatment of hallucinations and delusions associated with PD Psychosis, rather than for the treatment of PD Psychosis and/or other symptoms of PD Psychosis, which may cause confusion for prescribing physicians. This confusion could result in physicians not prescribing NUPLAZID for patients diagnosed with PD Psychosis. In addition, even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PD Psychosis, issues may arise with respect to patient adherence and compliance rates. For example, the current recommended dosing of NUPLAZID is two 17 mg tablets, taken together once a day. Patients may elect, whether at the direction of their physician or otherwise, to take only one tablet a day instead of two, to take tablets at different times during the day, or to otherwise not adhere to the recommended dosing, any of which could result in far lower efficacy. The FDA has approved our NDA for a 34 mg capsule for NUPLAZID to, among other things, try to mitigate this risk. The 34 mg capsule is now commercially available. We also submitted a supplemental NDA, or sNDA, for a 10 mg tablet to the FDA, which was also approved and is now commercially available. The 10 mg tablet provides an optimized lower dosage strength in those patients who are concomitantly receiving strong cytochrome 3A4 inhibitors which can inhibit the metabolism of NUPLAZID. Both the 34 mg and the 10 mg doses are intended to be taken once a day. Patients may elect, whether at the direction of their physician or otherwise, to not adhere to the recommended dosing, which could result in far lower efficacy for the 10 mg and 34 mg doses. If patients do not adhere to the recommended dosing of NUPLAZID, patients and physicians may believe that NUPLAZID is less effective, and as a result they may stop taking it and prescribing it.

The label for NUPLAZID also contains a boxed warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD Psychosis. There has also been recent attention to publicly reported deaths of patients that were prescribed NUPLAZID, and the FDA conducted an evaluation of available information about NUPLAZID. On September 20, 2018 the U.S. FDA issued a statement concluding: The U.S. FDA has completed a review of all post marketing reports of deaths and serious adverse events (SAEs) reported with the use of NUPLAZID. Based on an analysis of all available data, FDA did not identify any new or unexpected safety findings with NUPLAZID, or findings that are inconsistent with the established safety profile currently described in the drug label. After a thorough review, FDA s conclusion remains unchanged that the drug s benefits outweigh its risks for patients with hallucinations and delusions of Parkinson s disease psychosis. Regardless, perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

Thus, the commercial success of NUPLAZID depends on acceptance by patients and physicians, and there are a number of factors that could skew our or others estimates about prescribing behaviors and market adoption.

Our ability to generate product revenues will be diminished if NUPLAZID does not receive coverage from payors or sells for inadequate prices, or if patients have unacceptably high co-pay amounts.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others, to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party commercial payors is critical to product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when lower cost therapeutic

alternatives are already available or subsequently become available. Even

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with coverage for NUPLAZID, or other products we may market, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use NUPLAZID if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for NUPLAZID depends significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly alternative is available, even if not approved for the indication for which NUPLAZID is approved.

In many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with NUPLAZID, and any other products we may market, which could negatively impact our profitability.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling NUPLAZID at less than an optimized price could impact our revenues and overall success as a company. We have changed, and may continue to change, the price of NUPLAZID from time to time, however, we do not know if the price we have selected, or may select in the future, for NUPLAZID is or will be the optimized price. Additionally, we do not know whether and to what extent third-party payors will react to any possible future changes in the price of NUPLAZID. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Further, one payor s determination to provide coverage and reimbursement for a product does not assure that other payors also will provide coverage and reimbursement for the product. Therefore, coverage and reimbursement for NUPLAZID may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of NUPLAZID to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID or any other products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize NUPLAZID, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

Healthcare reform measures may negatively impact our ability to sell NUPLAZID or our product candidates, if approved, profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell NUPLAZID, and any other potential products, as described in greater detail in the Government Regulation section of our Annual Report on Form 10-K for the year ended December 31, 2017. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines,

individual imprisonment, exclusion from federal health care programs, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not

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been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management s attention away from the operation of our business.

We expect that the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, including NUPLAZID. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare s prescription drug benefits program. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the individual mandate . Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called Cadillac tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the donut hole , and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Given that the current patient population for NUPLAZID is primarily Medicare beneficiaries, accelerating the closure of the coverage gap and the increase in the discount that must be paid, could have a significant impact on the Company s business in 2019 and beyond. More recently, in July 2018, CMS announced that it is suspending further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress could consider additional legislation to repeal or repeal and replace other elements of the ACA. At this time, the ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry and its impact to our business is unclear.

An expansion in the government s role in the U.S. healthcare industry may increase existing congressional or governmental agency scrutiny on price increases, such as the ones we have implemented for NUPLAZID, cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using NUPLAZID or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, the Trump administration s budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. The Trump

administration also released a Blueprint , or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug

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manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize NUPLAZID or any other products for which we may receive regulatory approval.

We are subject, directly and indirectly, to federal, state and foreign healthcare laws and regulations, including healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are directly, and indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our sales, marketing, grants, charitable donations, and education programs and constrain the business or financial arrangements with healthcare providers, physicians, charitable foundations that support Parkinson s disease patients generally, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of our products for which we obtain marketing approval. In addition, we are subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services

resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under

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the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;

the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

the U.S. federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act , which was enacted as part of the ACA and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value made to physicians, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

analogous state and local laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities and/or the registration of pharmaceutical sales and medical representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers, and the European General Data Protection

Regulation, or GDPR, which became effective in May 2018 and contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation, including companies like us that conduct clinical trials in the EU; we anticipate that over time we may expand our business operations to include additional operations in the EU and with such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental

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authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. For example, contributions to third-party charitable foundations are a current area of significant governmental and congressional scrutiny, and we could face action if a federal or state governmental authority were to conclude that our charitable contributions to foundations that support Parkinson s disease patients generally are not compliant. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, for NUPLAZID, and any other product candidates that may be approved, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of NUPLAZID, or any other product candidates that may be approved, outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price, or AMP, and best price, or BP, for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of

government payors. For example, failure to submit monthly/quarterly AMP and BP data on

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a timely basis could result in a civil monetary penalty of $18,107 per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

The FDA granted marketing approval of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis, and we could face liability if a regulatory authority determines that we are promoting NUPLAZID for any off-label uses.

A company may not promote off-label uses for its drug products. An off-label use is the use of a product for an indication or patient population that is not described in the product s FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician s choice of drug treatment made in the physician s independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of NUPLAZID, and any other products we may market, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management s attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice, or DOJ, and various U.S. Attorneys Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA, DOJ, or any other governmental agency initiates an enforcement action against us, including as a result of the civil investigative demand mentioned below, or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation. In September 2018, we received a civil investigative demand, or CID, from the DOJ pursuant to the Federal False Claims Act requesting certain documents and information related to our sales and marketing of NUPLAZID. We are cooperating with the DOJ s request. Responding to the CID will require considerable resources and no assurance can be given as to the timing or outcome of the DOJ s investigation.

We expect our net losses to continue for at least the next few years and are unable to predict the extent of future losses or when we will become profitable, if ever.

We have experienced significant net losses since our inception. As of September 30, 2018, we had an accumulated deficit of approximately $1.4 billion. We expect to incur net losses over the next few years as we invest in the commercialization of NUPLAZID and advance our development programs.

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Even though we began commercializing NUPLAZID in the United States in May 2016, we still expect to incur significant expenses and net losses for at least the next few years as we continue our commercialization efforts for NUPLAZID and pursue the further development of NUPLAZID and our product candidates. Substantially all of our revenues since May 2016 were from net product sales of NUPLAZID.

We expect that our near-term revenues will be substantially dependent on our ability to generate net product sales of NUPLAZID. To the extent that we cannot generate significant revenues from the sale of NUPLAZID to cover our expenses, including the significant expenses associated with commercializing NUPLAZID and continuing to develop pimavanserin in additional indications, we may never achieve profitability and/or may have to reduce our commercialization and/or research and development activities to become profitable, which would harm our future growth prospects. Additionally, to obtain revenues from product candidates other than NUPLAZID, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, manufacturing and marketing compounds with significant market potential. We may never succeed in these activities and may never generate revenues from our commercialization of NUPLAZID, or from other product candidates that may be approved, that are significant enough to achieve profitability.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully continue the development and commercialization of NUPLAZID or successfully develop and commercialize our product candidates.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents, and investment securities totaled $214.1 million at September 30, 2018. While we believe that our existing cash resources will be sufficient to fund our cash requirements through at least the next twelve months, we may require significant additional financing in the future to continue to fund our operations. 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 ongoing and planned development activities for pimavanserin, post-marketing studies for NUPLAZID to be conducted over the next several years, ongoing and planned commercial activities for NUPLAZID, and other research and development programs;
- the costs of maintaining and developing our sales and marketing capabilities for NUPLAZID;
- the costs of establishing, or contracting for, sales and marketing capabilities for other product candidates;
- the amount of U.S. product sales from NUPLAZID;
- the costs of preparing applications for regulatory approvals for NUPLAZID in jurisdictions other than the United States, and potentially in additional indications other than in PD Psychosis, and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID for commercial use in the United States;

our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in jurisdictions other than the United States or in additional indications other than in PD Psychosis, or from other product candidates;

the costs of acquiring additional product candidates or research and development programs;

the scope, prioritization and number of our research and development programs;

the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators ability to make payments under these agreements;

our ability to enter into new collaboration and license agreements;

the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;

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- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;

- the costs of maintaining or securing manufacturing arrangements and supply for clinical or commercial production of pimavanserin or other product candidates; and

- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of 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. These events, coupled with other factors, may limit our access to additional financing in the future. 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 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 may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

The pivotal Phase 3 study with NUPLAZID for PD Psychosis, the results of which were announced in November 2012, was our first successful pivotal Phase 3 trial and there is no guarantee that future studies with pimavanserin will be successful.

The historical rate of failures for product candidates in clinical development is extremely high. In November 2012, we announced results from the -020 Study. Additionally, in December 2016, we announced positive top-line results from our Phase 2 exploratory study of pimavanserin in patients with AD Psychosis. Even though we successfully completed this Phase 2 exploratory study, or the -019 Study, and the -020 Study, those results are not predictive of the results of any additional studies that we are currently undertaking or may undertake in the future with pimavanserin, including the post-marketing studies we committed to conduct in connection with FDA approval of NUPLAZID and the ongoing studies of pimavanserin in various indications. We believe that pimavanserin also may have utility in indications other than in PD Psychosis, such as in dementia-related psychosis, schizophrenia, and depression. However, prior to the efficacy study that we initiated in the fourth quarter of 2017, we had never tested pimavanserin in clinical studies where the primary outcome was for the broad indication of dementia-related psychosis, and prior to the study in major depressive disorder that we initiated in the fourth quarter of 2016, we had never tested pimavanserin in clinical studies in depression. Additionally, prior to the studies in schizophrenia that we initiated in the fourth quarter of 2016, we had only conducted a Phase 2 trial for pimavanserin as a co-therapy treatment in schizophrenia. There is no guarantee that we will have the same level of success with pimavanserin in other indications that we had with the -020 Study, or that we will have the same level of success with pimavanserin in dementia-related psychosis or in other indications that we had with the -019 Study. Further, there is no guarantee that we will be successful at all in ongoing or future studies for additional indications or in our post-marketing studies, or that future results of studies of NUPLAZID for treatment in PD Psychosis or for other indications, including dementia-related psychosis, will be consistent with those from the -019 Study or -020 Study.

If we do not successfully complete additional development of NUPLAZID, we will be unable to market and sell NUPLAZID or products derived from it for indications other than the treatment of hallucinations and delusions associated with PD Psychosis, or to generate related product revenues.

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We do not have a partner for the development of pimavanserin, and are solely responsible for the advancement of this program and commercialization of the product.

We have full responsibility for the pimavanserin program throughout the world. We expect our research and development costs for continued development of pimavanserin to be substantial. While we currently are undertaking the ongoing development work for pimavanserin, including clinical trials of pimavanserin for indications other than in PD Psychosis, in the future we would need to add resources and raise additional funds in order to take this product candidate to market for indications other than in PD Psychosis or in jurisdictions outside the United States, and to conduct the necessary sales and marketing activities, and to conduct further development activities, if we do not secure a partner. Our current strategy is to commercialize NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis in the United States using our specialty sales force focused primarily on neurologists, a small group of psychiatrists, and pharmacists and physicians in long-term care facilities who treat PD Psychosis patients. In addition, if we are approved to commercialize NUPLAZID in markets outside of the United States, we will more than likely need to establish one or more strategic alliances in the future for that purpose. Without future collaboration partners in the United States and abroad, we might not be able to realize the full value of NUPLAZID.

We conducted, and continue to revisit, our life-cycle planning project for pimavanserin that was initiated in 2015 and through which we have formulated a multi-year plan to develop pimavanserin in additional indications other than in PD Psychosis, including in dementia-related psychosis, schizophrenia and depression, as described above. Given the unique profile of pimavanserin, together with the list of potential indications we could pursue, this has been a substantial and important undertaking. Our life-cycle planning process will be ongoing as we evaluate appropriate indications for pimavanserin to pursue as we seek to maximize the opportunities for this compound. If our life-cycle planning and execution is not conducted successfully, then we may not realize the full value from pimavanserin or may devote substantial resources to develop pimavanserin for indications that are ultimately not successful or do not yield adequate returns. Furthermore, even though NUPLAZID is approved for the treatment of hallucinations and delusions associated with PD Psychosis, a failure in a subsequent study for another indication, including our ongoing studies in dementia-related psychosis, schizophrenia and depression, or a failure in our post-marketing studies could harm our ability to successfully market NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis or could lead to it being withdrawn from the market. If we are unable to develop pimavanserin for other indications, we may not be able to maximize the potential of the compound and that could have a material adverse effect on our future revenues and our success as a company.

Pimavanserin is currently in development for several additional indications other than in PD Psychosis, and we are initiating the development of trofinetide for Rett syndrome. Drug development is a long, expensive and unpredictable process with a high risk of failure.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates is extremely high. In fact, we had an unsuccessful Phase 3 trial with NUPLAZID in 2009. An unfavorable outcome in any of our ongoing or future development efforts or in the post-marketing studies for NUPLAZID could be a major set-back for the program and for us, generally. In particular, an unfavorable outcome in our NUPLAZID

program or in the post-marketing studies may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate this program and could have a material adverse effect on us and the value of our common stock. In the fourth quarter of 2017, we initiated a Phase 3 study of

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pimavanserin in patients with dementia-related psychosis, and in the fourth quarter of 2016 we initiated both a Phase 2 and a Phase 3 study of pimavanserin as an adjunctive treatment in patients with schizophrenia as well as a Phase 2 study of pimavanserin as an adjunctive treatment in patients with major depressive disorder. We may plan and conduct additional studies in other indications in the future, and plan to initiate a Phase 3 study of trofinetide in Rett syndrome in the second half of 2019.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious or safe;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not be consistent with positive results of earlier trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;

obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and

patient recruitment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

competition for internal and external resources, including clinical sites and study patients, that we may choose to allocate to other programs;

ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;

imposition of clinical holds by regulatory authorities or institutional review boards;

failure to conduct clinical trials in accordance with regulatory requirements;

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patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial;

lower than anticipated screening or retention rates of patients in clinical trials;

serious adverse events or side effects experienced by participants; and

insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

We previously have depended, and in the future may depend, on collaborations with third parties to develop and commercialize selected product candidates other than pimavanserin, and we have limited control over how those third parties conduct development and commercialization activities for such product candidates.

In the past, we have selectively entered into collaboration agreements with third parties. We relied on our collaborators for financial resources and for development, regulatory, and commercialization expertise for selected product candidates and we had limited control over the amount and timing of resources that our collaborators devoted to our product candidates. We may choose to rely on collaborations in the future for certain portions of our pimavanserin program or other product candidates, or for the commercialization of NUPLAZID in certain territories outside of the United States.

Our collaborators may fail to develop or effectively commercialize products using our product candidates or technologies because they:

do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus;

decide to pursue a competitive product developed outside of the collaboration; or

cannot obtain the necessary regulatory approvals.

We also face competition in our search for new collaborators, if we seek a new partner for our pimavanserin program or other programs. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

If conflicts arise with our collaborators, they may act in their self-interests, which may be adverse to our interests.

Conflicts may arise in our collaborations due to one or more of the following:

disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current environment when companies, including large established ones, may be seeking to reduce external payments;

disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;

disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;

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disagreements with respect to ownership of intellectual property rights;

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;

delay or reduction of a collaborator s development or commercialization efforts with respect to our product candidates; or

termination or non-renewal of the collaboration.

Conflicts arising with our collaborators could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

In addition, in our past collaborations, we generally have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under the applicable program. Any collaborations we establish in the future may have the effect of limiting the areas of research that we may pursue, either alone or with others. Conversely, the terms of any collaboration we may establish in the future might not restrict our collaborators from developing, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our collaborators to competing products and their withdrawal of support for our product candidates or may otherwise result in lower demand for our potential products.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to conduct clinical trials for our product candidates on our own. We rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if:

these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;

these third parties need to be replaced; or

the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. We currently use several contract research organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures.

Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons.

Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even

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fewer are approved for marketing. We cannot assure you that, even if clinical trials are completed, either we or our collaborators will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Even if we or our collaborators successfully complete the clinical trials of product candidates and apply for such required authorizations, the product candidates, such as pimavanserin, may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory clearances required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by competitors.

We currently depend, and in the future will continue to depend, on third parties to manufacture NUPLAZID and our product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID or our product candidates.

We have no manufacturing facilities and only limited experience as an organization in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, NUPLAZID and our product candidates.

We have contracted with Patheon Pharmaceuticals Inc. and Catalent Pharma Solutions, LLC to manufacture NUPLAZID drug product for commercial use in the United States. Additionally, we have contracted with Siegfried AG to manufacture active pharmaceutical ingredient, or API, to be used in the manufacture of NUPLAZID drug product for commercial use. However, we have not entered into any agreements with any alternate suppliers for NUPLAZID drug product or NUPLAZID API. Even if we are able to enter into other long-term agreements with manufacturers for commercial supply on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of NUPLAZID. Additionally, if any of our product candidates in addition to NUPLAZID are approved by the FDA or other regulatory agencies for commercial sale, or if NUPLAZID is approved for commercial sale in jurisdictions outside the United States, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

Even though we have agreements with Patheon and Catalent for the manufacture of NUPLAZID drug product and with Siegfried for the manufacture of NUPLAZID API for commercial use, and even if we successfully enter into long-term agreements with other manufacturers, the FDA may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. Presently, we only have one supplier of API and one supplier for each form of drug product (tablet and capsule) for our NUPLAZID

(pimavanserin) program. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market NUPLAZID or any of our product candidates. While we believe that there will be alternative sources available to manufacture NUPLAZID and 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.

The manufacturers of NUPLAZID and our product candidates, including Catalent, Patheon and Siegfried, are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs, and

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we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture NUPLAZID and our product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA s strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, or result in issues maintaining regulatory approval of NUPLAZID and any other product candidate that receives regulatory approval, negatively impact our commercialization of NUPLAZID, or lead to significant delays in the launch and commercialization of any other products we may have in the future. Failure by our 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.

The manufacture of pharmaceutical products 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. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of NUPLAZID or our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize NUPLAZID in the United States, or provide any product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for NUPLAZID and any other approved products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of NUPLAZID or our product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, including NUPLAZID, or develop our product candidates, including pimavanserin for indications beyond PD Psychosis.

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of central nervous system disorders, including neuropsychiatric and related disorders. We are currently hiring, and in the future we expect to need to continue to hire, additional personnel as we expand our research and development efforts for pimavanserin and commercial activities for NUPLAZID. We face competition for experienced scientists, clinical operations personnel, commercial and other

personnel from numerous companies and academic and other research institutions. Competition for qualified personnel is particularly intense in the San Diego, California area. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater

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financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede our commercialization efforts for NUPLAZID and the achievement of our research and development objectives.

All of our employees are at will employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry key person insurance covering members of senior management.

We have recently increased the size of our organization, and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.

As of September 30, 2018, we employed approximately 410 employees. Although we have already added several capabilities, we will need to add additional qualified personnel and resources. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize NUPLAZID and any other product candidates that receive regulatory approval and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, as we commercialize NUPLAZID, we will need to support the training and ongoing activities of our sales force and expect to need to expand the size of our employee base for managerial, operational, financial, and other resources. To that end, we must be able to:

manage our development efforts effectively;

integrate additional management, administrative and manufacturing personnel;

develop our marketing and sales organization; and

maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

As we grow as an organization and expand as a commercial-stage company, we may make certain changes to our organization in order to properly manage our growth, which may include changes to the composition of our board of directors and management. Any such changes may be disruptive to us as an organization, which could harm our business.

As we continue to grow as an organization, including by expanding our development efforts and building out our capabilities for the ongoing commercialization of NUPLAZID, we have implemented, and will continue to evaluate and may implement additional, changes to our organization that may be appropriate in order to properly manage and direct our growth as a commercial-stage company. These changes may include changes to the size and composition of our management and/or board of directors, as appropriate, to include individuals with substantial experience in managing or serving on the boards of directors of commercial-stage pharmaceutical companies. For example, during 2015 and 2016, five long-standing board members either resigned from the board or did not stand for re-election, and during approximately the same timeframe our board elected three new

board members. We hired a new head of Regulatory Affairs in February 2017 and, in March 2017, we hired a new Chief Commercial Officer following the retirement of our prior chief commercial officer. In September 2018, we hired a new head of Medical Affairs and a new Chief Scientific Officer and head of External Innovation, both of which are newly-created roles. In addition, in October 2018, our Chief Financial Officer left ACADIA for another healthcare company. We may decide to hire other executive level employees as we grow. Any such significant changes to the organization may distract management or otherwise be disruptive to us as a company, which could harm our business.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.

A key element of our strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological disorders, or for therapeutic indications that complement or augment our current product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and we have limited experience in identifying acquisition targets, successfully completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited. In particular, if we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization that we have assembled for the marketing and sale of NUPLAZID.

The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits. Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop NUPLAZID or our product candidates, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates, and our business and prospects would therefore be harmed.

If we fail to comply with the obligations in agreements under which we license intellectual property rights from third parties, we could lose license rights to certain of our product candidates.

In August 2018, we entered into a license agreement with Neuren Pharmaceuticals Limited, or Neuren, and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications, and we may enter into additional license agreements in the future.

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Our agreement with Neuren imposes, and we expect that future agreements where we in-license intellectual property will impose, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the related product candidates, which would have a material adverse effect on our business.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the success of our commercialization of NUPLAZID in the United States for the treatment of hallucinations and delusions associated with PD Psychosis;
- the status and cost of our post-marketing commitments for NUPLAZID;

the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;

the status and cost of development and commercialization of pimavanserin for indications other than in PD Psychosis and in jurisdictions other than the United States;

the status and cost of development and commercialization of our product candidates, including compounds being developed under our collaborations;

whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates or products;

whether we generate revenues or reimbursements by achieving specified research, development or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;

whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;

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the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;

the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;

the timing of our satisfaction of applicable regulatory requirements;

the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;

the effect of competing technologies and products and market developments;

the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID; and

general and industry-specific economic conditions.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent of current-year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

Our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of

the Code and corresponding provisions of state law, if a corporation undergoes an ownership change, which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Changes to U.S. and non-U.S. tax laws could materially adversely affect us.

During 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to ACADIA Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary. Our goals for the

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establishment of ACADIA Pharmaceuticals GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. Future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hope to achieve by establishing this operational structure. Additionally, taxing authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such changes in tax law are enacted, or our licensing of worldwide intellectual property rights for pimavanserin to our Swiss subsidiary is otherwise challenged, this could materially adversely affect our business. For example, we have been evaluating the impact of the December 2017 U.S. tax law changes on our current structure and future plans and may decide to make changes based on that evaluation.

We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of central nervous system disorders. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We have incurred, and expect to continue to incur, significant costs as a result of laws and regulations relating to corporate governance and other matters.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002, or SOX, and rules adopted or proposed by the SEC and by The Nasdaq Stock Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. In the future, if we are not able to issue an evaluation of our internal control over financial reporting, as required, or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Changes or modifications in financial accounting standards, including those related to revenue recognition may harm our results of operations.

From time to time, the Financial Accounting Standards Board, or FASB, either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial

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position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09, which supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles. ASU 2014-09 is a comprehensive new revenue recognition model that requires an entity to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. ASU 2014-09 also requires additional disclosures about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. We adopted this new standard for the year beginning January 1, 2018 and have elected to apply the new standard using the modified retrospective method. The cumulative effect of initially applying the new revenue standard was not material and therefore, there was no adjustment to the opening balance of retained earnings. We do not expect a material impact on our net income on an ongoing basis however, any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of product or collaboration revenue, our operating results could be significantly affected.

Earthquake or fire damage to our facilities could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego are located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, while our facilities have not been adversely impacted by local wildfires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition, and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes. While we do have fire insurance for our property and equipment located in San Diego, any damage sustained in a fire could cause a delay in our research and development efforts and our results of operations could be materially and adversely affected.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates, including NUPLAZID, and technologies, as well as successfully defending these rights against third-party challenges. Any misappropriation of our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and contracts requiring confidentiality and nondisclosure.

With regard to patents, although we have filed numerous patent applications worldwide with respect to pimavanserin, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering our product candidates and technologies is uncertain due to a number of factors, including:

we may not have been the first to make the inventions covered by our pending patent applications or issued patents;

we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;

others may develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;

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- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or are easily susceptible to challenges by third parties;
- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the United States Supreme Court limiting patent-eligible subject matter;
- the passage of The Leahy-Smith America Invents Act, or the America Invents Act, introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business, however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our freedom to operate. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or United States PTO, to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved.

Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act to a first-to-file system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the United States PTO and foreign patent agencies in several stages over the lifetime of the patent. The United States PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in

abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

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

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality, nondisclosure, and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. We also have not entered into any noncompete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the United States PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review that allow third parties to challenge the validity of an issued patent in front of the United States PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges

that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was

anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the United States PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, United States PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger s burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the United States PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the United States PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the United States PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

While we are not currently subject to any pending intellectual property litigation or patent challenges, and are not aware of any such threatened litigation or patent challenges, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify product candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds.

We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, which could potentially be trebled if we are found to have willfully infringed a party s patent rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, or at all.

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

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be

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compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. For example, some of our patent applications may cover the uses of gene sequences. The patentability of gene sequences and the use of gene sequences has been seriously undermined by recent decisions of the United States Supreme Court. The United States PTO s interpretation of the Supreme Court s decisions and the standards for patentability it sets forth are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings as mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the United States PTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a first-to-invent system to a first-to-file system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

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Risks Related to Our Industry

We are subject to stringent regulation in connection with the marketing of NUPLAZID and any other products derived from our product candidates, which could delay the development and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, including NUPLAZID, in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, the FDA and other regulatory agencies may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate.

Outside the United States, the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our product candidates may be delayed or suspended, which may delay or impede our ability to generate product revenues.

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

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. 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, the use of NUPLAZID for the treatment of hallucinations and delusions associated with PD Psychosis competes with off-label use of antipsychotic drugs, including the generic drugs quetiapine and clozapine. If approved, pimavanserin for the treatment of dementia-related psychosis would compete with off-label use of antipsychotic drugs, including the generic drugs risperidone and quetiapine, and drugs indicated for the treatment of Alzheimer s disease and dementia in patients with Alzheimer s disease, including Aricept, marketed by Eisai Inc. and Pfizer Inc., and Namenda, marketed by Forest Laboratories, LLC, a wholly-owned subsidiary of Actavis. Pimavanserin for the adjunctive treatment of schizophrenia, if approved for that indication, would compete with Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., and generic drugs, including olanzapine, risperidone, aripiprazole and clozapine. Pimavanserin for the adjunctive treatment of major depressive

disorder, if approved for that indication, would compete with Rexulti, off-label use of antipsychotic drugs and the generic drugs olanzapine, risperidone, aripiprazole and clozapine. In the area of chronic pain, potential products would compete with Lyrica, marketed by Pfizer, and Cymbalta, marketed by Eli Lilly, as well as a variety of generic or proprietary opioids.

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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;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of NUPLAZID or any other product for which we obtain regulatory approval, or development or commercialization of our product candidates.

We face an inherent risk of product liability as a result of the commercial sales of NUPLAZID in the United States and the clinical testing of our product candidates, and will face an even greater risk following commercial launch of NUPLAZID in additional jurisdictions, if approved, or if we engage in the clinical testing of new product candidates or commercialize any additional products. For example, we may be sued if NUPLAZID or any other product we develop allegedly causes injury or is found to be otherwise unsuitable for administration in humans. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

exhaustion of any available insurance and our capital resources;

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the inability to commercialize our products or product candidates; and

a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of NUPLAZID, we may need to increase and expand this coverage, including if we commence larger scale trials and if other product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

Risks Related to Our Common Stock

Our stock price historically has been, and is likely to remain, highly volatile.

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

the success of our commercialization of NUPLAZID in the United States for the treatment of hallucinations and delusions associated with PD Psychosis;

the status and cost of our post-marketing commitments for NUPLAZID;

the status and cost of development and commercialization of pimavanserin for indications other than in PD Psychosis and in jurisdictions other than the United States;

the status and cost of development and commercialization of our product candidates, including compounds being developed under our collaborations;

whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates or products;

any other communications or guidance from the FDA or other regulatory authorities that pertain to NUPLAZID or our product candidates;

the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our collaborations;

market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;

announcements of technological innovations, new products, or other material events by our competitors or us, including any new products that we may acquire or in-license;

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

changes in, or failure to meet, securities analysts or investors expectations of our financial performance;

our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from the Nasdaq Stock Market;

additions or departures of key personnel;

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discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as blogs and chat rooms;

public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;

regulatory developments in the United States and in foreign countries;

the announcement of, or developments in, any litigation matters; and

economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company s securities, securities class action litigation has often been brought against that company. For example, in March 2015, following our announcement of the update to the timing of our planned NDA submission to the FDA for NUPLAZID for the treatment of PD Psychosis and the subsequent decline of the price of our common stock, two putative securities class action complaints were filed against us and certain of our current and former officers, which complaints were subsequently consolidated into one complaint. The complaint generally alleged that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the timing of our planned NDA submission to the FDA for NUPLAZID, thereby artificially inflating the price of our common stock. The parties agreed to a settlement in that case, which was approved by the court in January 2018. Additionally, between July 19 and August 3, 2018, following the recent negative publicity about NUPLAZID, three putative securities class action complaints were filed against us and certain of our current executive officers. The complaints generally allege that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding our business, operations, and prospects by failing to disclose that adverse events and safety concerns regarding NUPLAZID threatened initial and continuing FDA approval, and by failing to disclose that we engaged in business practices likely to attract regulatory scrutiny. If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation could result in substantial costs and divert our management s attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights. Under the registration rights agreement we have agreed that, if at any time and from time to time, the Baker Entities demand that we register their

shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. On April 1, 2016, we filed a registration statement covering the sale of up to 26,179,806 shares of our common stock, which includes 500,000 shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of September 30, 2018, and which represent approximately 21 percent of our outstanding shares. Our registration obligations under this registration rights agreement cover all shares now held or later acquired by the Baker Entities will be in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities sell a large number of our shares, or the market perceives that the

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Baker Entities intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We also may elect to sell an indeterminate number of shares on our own behalf pursuant to a registration statement or in a private placement, from time to time. Our stock price may decline as a result of the sale of the shares of our common stock included in any of these registration statements or future financings.

If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.

Our directors, executive officers and holders of five percent or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 2/3 percent stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15 percent or more of our common stock for three years unless the holder s acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Adverse securities and credit market conditions may significantly affect our ability to raise capital.

Historically, 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. These events, coupled with other factors, may limit our access to financing in the future. This could have a material adverse effect on our ability to access funding on acceptable terms, or at all, and our stock price may suffer further as a result.

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We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and the documents incorporated by reference herein and any applicable prospectus supplement may contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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 may include, but are not limited to statements about:

- the benefits to be derived from NUPLAZID (pimavanserin) and from our drug candidates, including trofinetide;
- the potential market opportunities for pimavanserin and our drug candidates;
- our strategy for the commercialization of NUPLAZID;
- our plans for exploring and developing pimavanserin for indications other than Parkinson s disease psychosis and trofinetide for Rett syndrome;
- our plans and timing with respect to seeking regulatory approvals;
- the potential commercialization of any of our drug candidates that receive regulatory approval;
- the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID and our drug candidates;
- our strategy for discovering, developing and, if approved, commercializing drug candidates;
- our existing and potential future collaborations;
- our estimates of future payments, revenues and profitability;
- our estimates regarding our capital requirements, future expenses and need for additional financing;

possible changes in legislation; and

our use of the proceeds from any offerings under this prospectus.

In some cases, you can identify forward-looking statements by terms such as may , will , should , could , would , plans , anticipates , believes , estimates , projects , predicts , potential and similar expressions (including their negative) intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading Risk Factors in our SEC filings, and may provide additional information in any applicable prospectus supplement. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus, the registration statement of which this prospectus is a part, the documents incorporated by reference herein, and any applicable prospectus supplement completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of our common stock offered under this prospectus. Unless we indicate otherwise in the applicable prospectus supplement, we anticipate that any net proceeds will be used for working capital and general corporate purposes. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any common stock sold pursuant to that prospectus supplement.

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PLAN OF DISTRIBUTION

We may sell the common stock to one or more underwriters for public offering and sale by them and may also sell the common stock to investors directly or through agents. We will name any underwriter or agent involved in the offer and sale of common stock in the applicable prospectus supplement. We have reserved the right to sell or exchange our common stock directly to investors on our own behalf in those jurisdictions where we are authorized to do so.

We may distribute the common stock from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We may also, from time to time, authorize dealers, acting as our agents, to offer and sell the common stock upon the terms and conditions set forth in the applicable prospectus supplement. We, or the purchasers of the common stock for whom the underwriters may act as agents, may compensate underwriters in the form of underwriting discounts or commissions, in connection with the sale of the common stock. Underwriters may sell the common stock to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agent. Unless otherwise indicated in the applicable prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase the common stock as a principal, and may then resell the common stock at varying prices to be determined by the dealer.

We will describe in the applicable prospectus supplement any compensation we pay to underwriters or agents in connection with the offering of our common stock, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Dealers and agents participating in the distribution of the common stock may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the common stock may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against certain civil liabilities, including liabilities under the Securities Act and to reimburse these persons for certain expenses. We may grant underwriters who participate in the distribution of the common stock we are offering under this prospectus an option to purchase additional shares in connection with the distribution.

To facilitate the offering of our common stock, certain persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the common stock. This may include over-allotments or short sales of the common stock, which involve the sale by persons participating in the offering of more common stock than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their option to purchase additional shares, if any. In addition, these persons may stabilize or maintain the price of the common stock by bidding for or purchasing common stock in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering

may be reclaimed if the common stock sold by them is repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the common stock at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

We may indemnify the underwriters, agents or dealers who participate in the distribution of our common stock against certain liabilities, including liabilities under the Securities Act. We may also contribute to payments that the underwriters, dealers or agents or any of their controlling persons may be required to make in respect of such liabilities. Certain underwriters, dealers or agents and their associates may engage in transactions with and perform services for us in the ordinary course of our business.

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LEGAL MATTERS

The validity of the common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements (and schedule) included in our Annual Report on Form 10-K for the year ended December 31, 2017, and the effectiveness of our internal control over financial reporting as of December 31, 2017, as set forth in their reports, which are incorporated by reference in this prospectus supplement and elsewhere in the registration statement. Our financial statements (and schedule) are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

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WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and we file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement under the Securities Act with respect to the common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits which are part of the registration statement. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and the exhibits filed as part of the registration statement. Our SEC filings are available to the public from the SEC s website at www.sec.gov. We maintain a website at www.acadia-pharm.com. The information contained in, or that can be accessed through, our website is not part of this prospectus.

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the following documents we filed with the SEC pursuant to Section 13 of the Exchange Act and any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act after the date of this prospectus until the termination of the offering of the shares covered by this prospectus (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K):

- Annual Report on Form 10-K for the fiscal year ended December 31, 2017;
- The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 from our definitive proxy statement on Schedule 14A (other than information furnished rather than filed) filed with the SEC on April 30, 2018;
- Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2018, June 30, 2018 and September 30, 2018;
- Current Reports on Form 8-K filed on June 8, 2018, July 23, 2018, October 31, 2018, November 5, 2018 and November 20, 2018;
- Description of our common stock contained in our registration statement on Form 8-A dated May 19, 2004; and
- All documents filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the last offering of common stock under this prospectus (excluding any portion of such documents which are furnished and not filed with the SEC).

You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Proxy Statement, and amendments, if any, to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at the SEC s website or our website as soon as reasonably practicable after

such material is electronically filed with, or furnished to, the SEC. The reference to our website does not constitute incorporation by reference of the information contained in our website. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus or the related registration statement.

You may request a copy of our SEC filings at no cost, by telephoning or writing us at the following address:

Investor Relations

ACADIA Pharmaceuticals Inc.

3611 Valley Centre Drive, Suite 300

San Diego, CA 92130

(858) 558-2871

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$200,000,000

Common Stock

PROSPECTUS SUPPLEMENT

BofA Merrill Lynch

J.P. Morgan

Goldman Sachs & Co. LLC

November , 2018