SUPERNUS PHARMACEUTICALS INC
Form 10-K/A
January 20, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

COMMISSION FILE NUMBER: 001-35518

or

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

FOR THE TRANSITION PERIOD FROM TO

SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware		**20-2590184**
(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification Number)
1550 East Gude Drive, Rockville, MD	**(301) 838-2500**	**20850**
(Address of Principal Executive Offices)	(Registrant s telephone number, including area code)	(zip code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

TITLE OF EACH CLASS:	**NAME OF EACH EXCHANGE ON WHICH REGISTERED:**
Common Stock, $0.001 Par Value	The NASDAQ Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o

(Do not check if a
smaller reporting company)

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

As of June 30, 2015, the aggregate market value of the common stock held by non-affiliates of the registrant based on the closing price of the common stock on The NASDAQ Global Market was $659,264,478.

The number of shares of the registrant s common stock outstanding as of January 17, 2017 was 50,121,242.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant s definitive Proxy Statement for its 2016 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant s 2015 fiscal year end, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Explanatory Note

Unless the context requires otherwise, the words Supernus, we, our, and the Company refer to Supernus Pharmaceuticals, Inc. and its subsidiaries.

Supernus Pharmaceuticals, Inc. (the Company) is filing this Amendment No. 1 on Form 10-K/A (the Amended Form 10-K) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the Original Form 10-K), which was originally filed with the Securities and Exchange Commission (SEC) on March 9, 2016 (the Original Filing Date), to reflect the restatement of consolidated financial statements (Restatement) as described below.

In this Amended Form 10-K for the fiscal year ended December 31, 2015, we are restating our previously issued and audited consolidated financial statements and the related disclosures for the fiscal years ended December 31, 2015 and 2014. As discussed in further detail below and in Note 2 to the accompanying consolidated financial statements, the Restatement is the result of a misapplication in the guidance on accounting for revenue recognition related to the sale of future revenues (as described below). We assessed the impact of this misapplication on our prior interim and annual consolidated financial statements and concluded that the impact was material to these consolidated financial statements. Consequently, we have restated the prior period consolidated financial statements identified above. All amounts in this Amended Form 10-K affected by the Restatement reflect such amounts as restated. For a more detailed explanation of these matters and resulting restatements, please see Part I, Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations; Part II, Item 8: Financial Statements Note 2 to the Consolidated Financial Statements; and Part II, Item 9A: Controls and Procedures.

For the convenience of the reader, this Amended Form 10-K sets forth the Original Form 10-K for the fiscal year ended December 31, 2015 in its entirety, as amended by and to reflect the Restatement and includes certain restated information for the fiscal year ended December 31, 2014.

Background of Restatement

In July 2014, the Company entered into a royalty monetization transaction and recorded the transaction with Healthcare Royalty Partners III, L.P. (HC Royalty) as revenue referencing guidance under ASC 605, Revenue Recognition. In August 2016, the Company was informed by its former independent registered public accounting firm, Ernst and Young LLP (EY), that a royalty monetization transaction for another client had recently been reviewed by the SEC Office of the Chief Accountant (the OCA). The OCA had concluded that that transaction should have been recorded as a liability rather than as revenue. Accordingly, Supernus undertook to re-evaluate the accounting for the 2014 transaction.

Having conferred with the Company s prior auditor, EY, and the company s current auditor KPMG LLP (KPMG), in October 2016, the Company submitted to the OCA a request to post clear the Company s accounting for the royalty monetization transaction from 2014. In its submission, the Company concluded that the terms and conditions of the agreement met the criteria for revenue recognition under SAB 104 and ASC 605-10. On November 9, 2016, the OCA completed its review and informed the Company that the royalty monetization transaction should have been recorded as a debt obligation in 2014 in accordance with ASU 470-10-25. As a result, on November 10, 2016, the Company s Audit Committee concluded that the Company s consolidated financial statements for the years ended December 31, 2014 and December 31, 2015, and related reports of the Company s independent registered public accounting firms thereon, and the interim quarterly reports in those years beginning with the third quarter of 2014, and the interim quarterly reports for the first and second quarters in 2016, should no longer be relied upon and should

be restated.

The Company is restating in this Amended Form 10-K its consolidated financial statements for the fiscal years ended December 31, 2015 and 2014. The adjustments to our consolidated financial statements related to the 2014 royalty monetization transaction resulted in the following changes:

- The $30.0 million proceeds of the transaction have now been recorded in the third quarter of 2014 as a non-recourse debt, rather than revenue;

- Revenue and operating income in the third quarter of 2014 have been reduced by approximately $30.0 million; and

- Royalties received by the counterparty to the royalty monetization transaction are now recognized by the Company as non-cash royalty revenue. The $30.0 million of non-recourse liability is reduced by the same amount, and then increased by the non-cash implied interest expense to be recognized.

The revisions referenced above result in noncash financial statement corrections, principally reducing net income and

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increasing liability, but will have no impact on the Company s current or previously reported cash and marketable securities position and no impact on net product sales.

In connection with the Restatement, the Company also made the following corrections:

- Recording current tax expense related to an increase in our reserve for an uncertain tax position related to alternative minimum taxes in the fourth quarter of 2014 that had been previously recognized in the second quarter of 2015;

- An adjustment to the Statement of Cash Flows for the years ended December 31, 2015 and 2014 to adjust cash used in investing activities, with an offset to cash provided by operations for certain accrued legal fees that have been deferred;

- The correction of an immaterial error to correctly recognize stock compensation expense associated with the January 2014 stock option awards to the Board. These options have a twelve month vesting period, though the Company originally began recognizing compensation expense over a four-year vesting term. This error was corrected during 2015. Correcting this immaterial error results in an increase in selling, general, and administrative expense (SG&A) in 2014, and a corresponding decrease in SG&A expense in 2015; and

- The reclassification of a Certificate of Deposit (CD), originally purchased during the first quarter of 2015 and continually renewed on a quarterly basis, as a current marketable security. This CD has 91 days to maturity and the Company incorrectly classified this amount as cash and cash equivalents on the balance sheets at March 31, 2015, June 30, 2015, September 30, 2015 and December 31, 2015. We have corrected the balance sheets in all periods to reflect the reclassification from cash and cash equivalents to current marketable securities.

An explanation of the impact of each of these revisions on our financial statements is contained in Note 2 to the consolidated financial statements contained in Part II, Item 8: Financial Statements.

Items Amended in this Annual Report on Form 10-K/A

The following items of this Amended Form 10-K include restated financial data: (i) Part II, Item 6: Selected Financial Data; (ii) Part II, Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations; and (iii) Part II, Item 8: Financial Statements. The following items of this Annual Report on Form 10K/A also include amendments due to the restatement: (i) Part I, Item 1A. Risk Factors and

(ii) Part II, Item 9A. Controls and Procedures.

Information not affected by the Restatement is unchanged and reflects the disclosures made as of the Original Filing Date and is not intended to speak as of any subsequent date. No statements made herein should be assumed to be accurate as of any subsequent date. Accordingly, this Amended Form 10-K should be read in conjunction with our subsequent filings with the SEC, as information in such filings may update or supersede certain information contained in this Amended Form 10-K.

Restatement of Other Financial Statements

In addition to the restated audited consolidated financial statements and related disclosures for the fiscal years ended December 31, 2015 and 2014, included in this Amended Form 10-K, the Restatement requires the restatement of our unaudited condensed consolidated financial statements and related disclosures for the quarters ended September 30, 2014, March 31, 2015, June 30, 2015, September 30, 2015, March 31, 2016 and June 30, 2016. Concurrently with this filing, we are filing the following amended Forms 10-Q with respect to these periods to address the corrections:

- Form 10-Q/A for the quarter ended September 30, 2015, which contains restated unaudited condensed consolidated financial statements and related disclosures for the three and nine month periods ended September 30, 2015 and 2014;

- Form 10-Q/A for the quarter ended March 31, 2016, which contains restated unaudited condensed consolidated financial statements and related disclosures for the three month periods ended March 31, 2016 and 2015; and

- Form 10-Q/A for the quarter ended June 30, 2016, which contains restated unaudited condensed consolidated financial statements and related disclosures for the three and six month periods ended June 30, 2016 and 2015.

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Internal Control Considerations

Management has assessed the effect of the restatement on the Company s internal control over financial reporting and believes that this restatement represents a material weakness in its internal control over financial reporting for all periods under restatement. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. For a discussion of management s consideration of the material weakness identified, see Part II, Item 9A: Controls and Procedures included in this Quarterly Report. In addition, this Amended Form 10-K includes currently-dated certifications from the Company s Chief Executive Officer and Chief Financial Officer, as required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002.

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SUPERNUS PHARMACEUTICALS, INC.

FORM 10-K/A

For the Year Ended December 31, 2015

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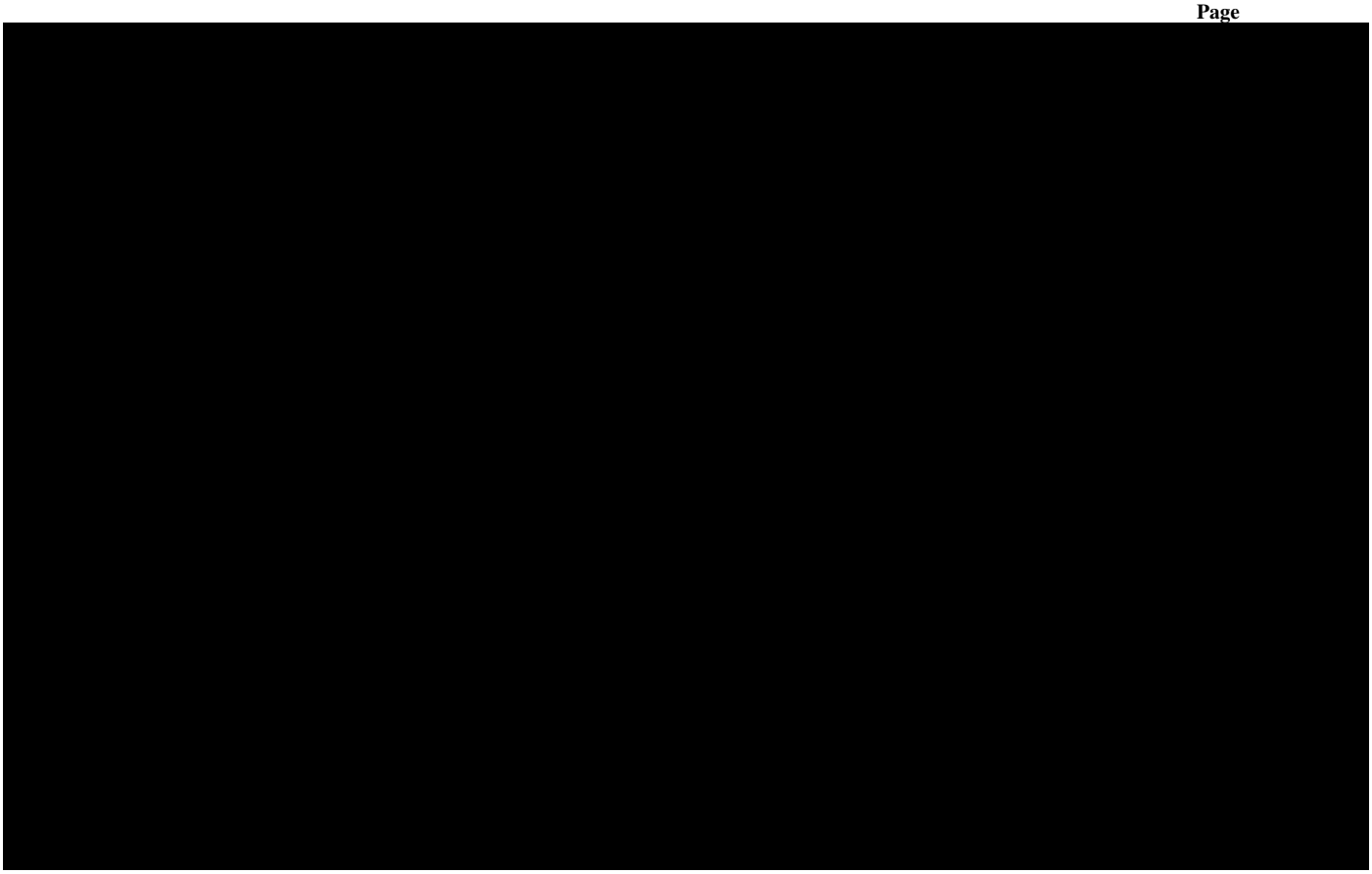

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Unless the content requires otherwise, the words Supernus, we, our and the Company refer to Supernus Pharmaceuticals, Inc. and its subsidiary

We are the owners of various U.S. federal trademark registrations(®) and registration applications( ), including the following marks referred to in this Annual Report on Form 10-K/A pursuant to applicable U.S. intellectual property laws: Supernus®, Oxtellar XR®, Trokendi XR®, Microtrol®, Solutrol®, and the registered Supernus Pharmaceuticals logo.

All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K/A are referred to without the ® and *TM* symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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PART I

This Annual Report on Form 10-K/A contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, that involve risks and uncertainties. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Annual Report other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, seek, anticipate, should, could, would, potential, or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in Business, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results.

ITEM 1. BUSINESS.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. In 2013, we launched Oxtellar XR (extended-release oxcarbazepine) and Trokendi XR (extended-release topiramate), our two novel treatments for patients with epilepsy. In addition, we are developing multiple product candidates in psychiatry to address significant unmet medical needs and market opportunities for the treatment of Impulsive Aggression (IA) and for the treatment of attention deficit hyperactivity disorder (ADHD). With SPN-810, we are initially developing the product to treat IA in patients who have ADHD. There are currently no approved products indicated for the treatment of IA. We subsequently plan to develop SPN-810 for treatment of IA in other CNS diseases, such as autism, bipolar disorder, schizophrenia, and some forms of dementia.

Our extensive expertise in product development has been built over the past 25 years: initially as a standalone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. We market our products in the United States through our own specialty sales force and have and will continue to seek strategic collaborations with other pharmaceutical companies to license our products outside the United States.

Our neurology portfolio consists of Oxtellar XR and Trokendi XR, which are the first once-daily extended release oxcarbazepine and topiramate products, respectively, indicated for epilepsy in the U.S. market. These products are differentiated compared to their immediate release counterpart products by offering convenient once-daily dosing and unique pharmacokinetic profiles. We believe that a once-daily dosing regimen improves compliance, and that the unique smooth and steady pharmacokinetic profiles of once-daily dosing mitigate the blood level fluctuations that are typically associated with immediate release products that can result in adverse events (AEs) or decreased efficacy.

Underlying our net product revenues of $143.5 million in 2015 is strong growth in prescriptions for Oxtellar XR and Trokendi XR. Total prescriptions as reported by Intercontinental Marketing Services (IMS) have shown a steady increase quarter over quarter as shown in the following graph.

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Strong Prescription Growth

Two Successful Product Launches

Source: IMS Monthly Prescriptions

Given the large and growing base of prescriptions for both topiramate and oxcarbazepine (annualized prescriptions of total topiramate market of 14.3 million and total oxcarbazepine market of 4.5 million), we expect to continue to expand our revenues for Oxtellar XR and Trokendi XR for the foreseeable future. We believe these products, together, have the potential to collectively achieve peak net sales in excess of $500 million annually.

Oxtellar XR is indicated for add-on, adjunctive or concomitant therapy of partial seizures in adults and in children 6 years to 17 years of age. Trokendi XR is indicated for initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures, and as add-on therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures or with seizures associated with Lennox-Gastaut syndrome.

Our psychiatry product candidates include SPN-810 (molindone hydrochloride) and SPN-812 (viloxazine hydrochloride). We are developing SPN-810 as a novel treatment for IA in patients who have ADHD and SPN-812 for the treatment of ADHD. We initiated the Phase III clinical trials for SPN-810 during the third quarter of 2015 and initiated a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015. Patient dosing for all trials are anticipated in the first quarter of 2016. We expect to receive data from the first trial for SPN-810 in mid-2017 and data from the Phase IIb trial for SPN-812 by early 2017.

We have a successful track record of developing and launching novel products by applying proprietary technologies to known drugs to improve existing therapies and expand the treatment to new indications. Our key proprietary technology platforms include: Microtrol, Solutrol and EnSoTrol. These technologies have been utilized to create nine marketed products, including Trokendi XR and Oxtellar XR, Adderall XR, Intuniv (developed for Shire), and Orenitram (developed for United Therapeutics Corporation) as well as our key product candidates SPN-810 and SPN-812.

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Products and Product Candidates

The table below summarizes our current pipeline of novel products and product candidates.

Product	Indication	Status
Oxtellar XR	Epilepsy	Launched
Trokendi XR	Epilepsy*	Launched
SPN-810	IA**	Phase III
SPN-812	ADHD	Phase IIb
SPN-809	Depression	Phase II ready

* Supplemental New Drug Application submitted in August 2015 for treatment in adults for prophylaxis of migraine headache.

** Initial program is in patients with ADHD, with a plan to follow on in other indications, such as IA in patients with autism, bipolar disorder, schizophrenia, and some forms of dementia.

We are continuing to expand our intellectual property portfolio to provide additional protection for our technologies, products, and product candidates. We currently have five U.S. patents issued covering Oxtellar XR and six U.S. patents issued covering Trokendi XR, providing patent protection expiring no earlier than 2027 for each product.

Our Strategy

Our vision is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry. Key elements of our strategy to achieve this vision are to:

- *Drive growth and profitability.* We will continue to drive the revenue growth of Trokendi XR and Oxtellar XR by continuing to dedicate sales and marketing resources in the United States.

- *Advance our pipeline toward commercialization.* In 2015, we started trials for our product candidates in our psychiatry portfolio: SPN-810 as a novel treatment for IA in patients who have ADHD and SPN-812 for the treatment of ADHD. We initiated the Phase III clinical trials for SPN-810 during the third quarter of 2015 and a Phase IIb clinical trial for SPN-812 in the fourth quarter of 2015.

- *Target strategic business development opportunities.* We are actively exploring a broad range of strategic opportunities that fit well with our strong presence in CNS. This includes in-licensing products and entering into co-promotion partnerships which are synergistic with our sales force call point for our marketed products and product candidates, co-development partnerships for our pipeline products, and growth opportunities through value-creating and transformative merger and acquisition transactions.

- *Continue to grow our pipeline.* We plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts.

Our Neurology Portfolio

Oxtellar XR and Trokendi XR are the first once-daily extended release oxcarbazepine and topiramate products indicated for patients with epilepsy in the U.S. market. These products differ from the immediate release products by offering once-daily dosing and unique pharmacokinetic profiles which we believe can have very positive clinical effects for some patients. We believe a once-daily dosing regimen improves adherence, making it more probable that patients maintain sufficient levels of medication in their bloodstream to protect against seizures. In addition, the unique smooth and steady pharmacokinetic profiles of our once-daily formulations reduce the peak to trough blood level fluctuations that are typically associated with immediate release products and may result in increased AEs, more symptomatic side effects and decreased efficacy.

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Epilepsy Overview

Epilepsy is a complex neurological disorder characterized by spontaneous recurrence of unprovoked seizures, which are sudden surges of electrical activity in the brain that impair a person s mental and/or physical abilities.

Compliance with drug treatment regimens is critically important to achieving effective control for patients with epilepsy. Patient non-compliance with anti-epileptic drug (AED) therapy is a serious issue and remains the most common cause of breakthrough seizures. Not only is taking all prescribed doses critical for epileptic patients, but the timing of when patients take their prescribed doses can also be crucial.

We believe extended release products, and in particular Trokendi XR and Oxtellar XR, offer important advantages in the treatment of epilepsy. The release profiles of extended release products can produce more consistent and steadier plasma concentrations as compared to immediate release products, potentially resulting in fewer side effects, better tolerability, fewer emergency room visits, and improved efficacy. Improved tolerability may help patients improve adherence, have fewer breakthrough seizures and, correspondingly, enjoy a better quality of life.

Trokendi XR

Trokendi XR is the first once-daily extended release topiramate product indicated for patients with epilepsy in the U.S. market, and is designed to improve patient adherence over the current immediate release products, which must be taken multiple times per day. Trokendi XR s pharmacokinetic profile results in lower peak plasma concentrations, higher trough plasma concentrations, and slower input rate. This results in smoother and more consistent plasma concentrations than immediate release topiramate formulations can deliver. We believe that such a profile mitigates blood level fluctuations that are frequently associated with many side effects as well as mitigating the likelihood of breakthrough seizures that patients can suffer when taking immediate release products. Side effects may lead patients to skip doses, which could place them at higher risk for breakthrough seizures.

In August 2015, the United States Food and Drug Administration (FDA) accepted for review the Company s Supplemental New Drug Application (sNDA) for Trokendi XR, requesting FDA approval to expand the indication for Trokendi XR to include treatment in adults for prophylaxis of migraine headache. Under the Prescription Drug User Fee Act guidelines, the FDA has set a target date in the second quarter of 2016 to complete its review.

Oxtellar XR

Oxtellar XR is the only once-daily extended release oxcarbazepine product indicated for the treatment of patients with epilepsy in the U.S. as adjunctive therapy. With its novel pharmacokinetic profile showing lower peak plasma concentrations, a slower rate of input, higher trough plasma concentrations, and smoother and more consistent blood levels compared to immediate release products, we believe Oxtellar XR improves the tolerability of oxcarbazepine and thereby reduces symptomatic side effects. In addition, Oxtellar XR once-per-day dosing is designed to improve patient adherence compared to the current immediate release products that must be taken multiple times per day.

In a retrospective medical chart review of 200 patients treated with immediate release oxcarbazepine or Oxtellar XR, Oxtellar XR was associated with a significantly lower rate of inpatient hospitalization stays, lower rate of emergency department visits, and a higher rate of compliance. The patient charts were obtained from 17 geographically and clinically diverse sites across the U.S. and included non-academic and academic affiliated practices, general neurology, pediatric neurology, and epilepsy centers.

Oxtellar XR was one of several products prescribed to children whose safety profile was reviewed at a Pediatric Advisory Committee meeting in March 2015. The committee voted for the FDA to continue its safety monitoring of this product per its current routine. As suggested by the FDA as part of its routine review, safety information has been added to the Oxtellar XR label so that it comports with the Reference Listed Drug, Trileptal.

Sales and Marketing

We have established a commercial organization in the U.S. to support current and future sales of Oxtellar XR and Trokendi XR. We believe our current sales force of over 150 sales representatives is effectively targeting healthcare providers, primarily neurologists, to support and grow our epilepsy franchise. Simultaneously promoting two epilepsy products allows us to leverage our commercial infrastructure with these prescribers. Assuming our sNDA is approved by the FDA, our intentions are to support the migraine indication without incrementally expanding the sales force.

If we obtain FDA approval for any of our product candidates in our psychiatry portfolio, we anticipate adding sales representatives who can market our psychiatry products to the relevant population of physicians.

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Manufacturing

We currently depend on third-party commercial manufacturing organizations (CMOs) for all manufacturing operations, including raw materials, dosage form production, and packaging. This encompasses product for commercial use, as well as product for preclinical research and clinical trials.

We have entered into agreements with Patheon Pharmaceuticals Inc., Packaging Coordinators, Inc. and Catalent Pharma Solutions, leading CMOs headquartered in North America, for the manufacture and packaging of the final commercial products Oxtellar XR and Trokendi XR. These CMOs offer a comprehensive range of contract manufacturing and packaging service. Both commercial products as well as our product candidates are sourced from single third-party suppliers.

We do not own or operate manufacturing facilities for the production of any of our product candidates beyond Phase II clinical trials, nor do we have plans to develop our own manufacturing operations for Phase III clinical materials or commercial products in the foreseeable future. We currently employ internal resources to manage our manufacturing contractors.

Epilepsy Competition

Trokendi XR competes with all immediate release and extended release topiramate products, including Topamax, Qudexy XR, their related generic products as well as other anti-epileptic products. Oxtellar XR competes with all immediate release oxcarbazepine products, including Trileptal and its related generics as well as other anti-epileptic products.

Our Psychiatry Portfolio

Our psychiatry portfolio includes three product candidates for the treatment of psychiatric disorders. The most advanced product candidate, SPN-810, has fast track status and is expected to be the first product approved for IA. SPN-812 and SPN-809 are the same active ingredient being developed for ADHD and depression, respectively. SPN-812 is currently in a Phase IIb trial and SPN-809 is Phase II ready.

IA Overview

The ADHD market, estimated as 69 million prescriptions as of 2015, is projected to grow at 3% annually, to approximately 75 million prescriptions by 2019. Market research we have conducted shows that, for adolescents and children, approximately 40% of ADHD prescriptions are currently written by child psychiatrists, psychiatrists, child neurologists, and high prescribing pediatricians. By 2019, we project that this group of physicians will collectively write approximately 16 million prescriptions for ADHD medication. Of these 16 million ADHD prescriptions, roughly one-third will be written for patients with IA or with IA and other comorbidities.

IA is not limited to individuals with ADHD. IA occurs in patients with other CNS disorders, including autism, alzheimer s, bipolar disorder, oppositional defiant disorder, conduct disorder, and intermittent explosive disorder. Market research we have conducted indicates that the prevalence of IA in autistic children and adolescents is approximately 45%, and the prevalence of IA in children and adolescents with bipolar disorder is approximately 60%. By 2019, we project that the estimated number of prescriptions for IA in these two categories would range between 4.0 million and 4.5 million.

ADHD Overview

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6% to 9% of all school-age children and 3% to 5% of adults in the United States(1). An estimated 50% of children with ADHD continue to meet criteria for ADHD into adolescence(2). For the year ended December 31, 2015, according to data from IMS, the U.S. market for ADHD prescription drugs was $11.0 billion with 69 million prescriptions.

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(1) Dopheide, J.A., *Attention-Deficit- Hyperactivity Disorder: An Update*, published June 2009 in *Pharmacotherapy*.

(2) Floet, A.M.W., *Attention- Deficit/Hyperactivity Disorder*, published February 2010 in *Pediatrics in Review*.

(3) The MTA Cooperative Group, *A 14-month randomized clinical trial of treatment strategies for attention- deficit/hyperactivity disorder*, published December 1999 in *Archives of General Psychiatry*.

Diagnosis of ADHD requires a comprehensive clinical evaluation based on identifying patients who exhibit the core symptoms of inattention, hyperactivity, and impulsivity. Although many children may be inattentive, hyperactive or impulsive, the level

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of severity and degree of functional impairment, as well as considerations of what may be behind the underlying symptoms, determine which children meet the diagnosis and should be treated for ADHD.

Current Treatments for IA in Patients with ADHD

Currently, there are no approved medications for the treatment of IA. IA is characteristic of individuals who spontaneously react more strongly than normal to stimuli by committing verbal or physical acts against other people, property, or themselves. Based on our discussions with medical experts, the current treatment options for IA in patients with ADHD include psychosocial interventions, such as school-based or family-based behavioral therapies, which are usually not wholly effective. In the large, multisite Multimodal Treatment Study of Children with ADHD(3), a seminal clinical trial designed by experts from key stakeholder communities such as the National Institute of Mental Health, researchers observed that after 14 months of either ADHD medication-only or a regimen that combined ADHD medication with behavioral interventions, 44% of those children with ADHD (or 26% of the total sample size in the trial) who initially exhibited aggression still had what can be described as IA at the end of the trial, demonstrating that psychosocial interventions may not work for a large percentage of children with ADHD who exhibit aggressive behaviors.

In response, doctors have also tried to treat this group with off-label use of prescription medicines, such as mood stabilizers, stimulants and anti-psychotic drugs. Results have varied, but anti-psychotic drugs appear to have the best therapeutic potential. Unfortunately, many of these agents are associated with adverse effects including obesity, dyskinesia, lipid abnormalities, marked increases in prolactin, and increase in diabetes, which is of particular concern when treating pediatric populations.

SPN-810 (molindone hydrochloride)

We are developing SPN-810 (molindone hydrochloride) as a novel treatment for IA in patients who have ADHD. During 2014, the FDA granted fast track designation for SPN-810 for the treatment of IA in ADHD in conjunction with standard ADHD treatment. The fast track designation allows for more frequent interactions with the FDA, for the early submission of some sections of the marketing application, and carries the potential for an expedited review category for the New Drug Application (NDA). In early April 2015, the Company submitted to the FDA the IA outcome and assessment scale we propose to use in the Phase III SPN-810 trials. This scale was developed by the Company in close cooperation with the FDA, using current, stringent standards of testing theory and scale development. We met with the FDA in July 2015 to review this scale and to review our proposed primary endpoint for the Phase III trials. The FDA accepted our scale and agreed with our proposed primary endpoint. In December 2015, Supernus and FDA came to an agreement, via the Special Protocol Assessment process, on the conduct of our Phase III program for SPN-810.

Molindone hydrochloride was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban, albeit at much higher dosages (50 to 225mg/day) than we are using in our development program (18 and 36 mg/day). Moban has not been commercially available since 2010 and the FDA has confirmed that this withdrawal from the market was not due to issues with safety or efficacy. Molindone hydrochloride is unusual among anti-psychotics in that it is less likely to be associated with weight gain and, in preclinical models, has not caused increases in prolactin levels as seen with other drugs.

In addition, we believe the lower doses tested for the proposed indication of IA in ADHD should be better tolerated than the higher doses approved to treat schizophrenia. The Phase IIb trial with SPN-810, which included 121 patients, showed that there was no difference in weight gain between patients treated with SPN-810 and placebo. Although initially we are developing SPN-810 as a novel treatment for IA in patients who have ADHD, if we are successful in demonstrating the effectiveness of SPN-810 in ADHD, we may then develop the product candidate for the treatment of other indications that can exhibit IA, e.g., patients with IA in autism, bipolar disorder, schizophrenia, and some forms of dementia. In the aggregate, we believe the addressable market for SPN-810 is greater than $5.5 billion, including $3.0 billion in ADHD, $1.5 billion in autism and $1.0 billion in bipolar disorder.

We are developing an intellectual property position around the novel synthesis process for this product candidate, its novel use in IA, and novel formulations. Patents, if issued, from the applications could expire from 2029 to 2033. We have one patent issued in each of the U.S., Mexico and Australia markets, covering modified release formulations of molindone. In another family, covering the novel process of synthesis of the active ingredient, we have one patent issued in the U.S. In a third family, covering use of molindone in treating IA, we have one patent issued in Japan. We own all of the pending applications.

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SPN-810 Development Program

In 2012, we completed a Phase IIb multicenter, randomized, double-blind, placebo-controlled trial in the United States in pediatric subjects 6 to 12 years of age diagnosed with ADHD and IA that is not controlled by optimal stimulant and behavioral therapy. The primary objective of the study was to assess the effect of SPN-810 in reducing IA as measured by the Retrospective-Modified Overt Aggression Scale (R-MOAS) after at least three weeks of treatment. Secondary endpoints included the rate of remission of IA and measurement of the effectiveness of SPN-810 on Clinical Global Impression (CGI) and ADHD scales as well as evaluation of the safety and tolerability of the drug. Patients who completed the study were offered the opportunity to continue into an open-label phase of six months duration.

Analysis of treatment comparison was performed using both parametric and non-parametric statistical methods. The parametric method assumes that data are normally distributed. Under this method, mean results of each treatment group at the end of three weeks of treatment were compared to baseline in R-MOAS score for each of the four dose groups (high, medium, low and placebo) using the t-test. The non-parametric method does not assume that data are normally distributed. Under this method, the median results of the change from baseline at the end of three weeks of treatment in R-MOAS were computed for each of the four dose groups (high, medium, low and placebo). These are compared using the Wilcoxon Rank-sum test. Statistical analyses were performed to compare the median of each of the treatment groups: high, medium, low, with placebo at the end of 3 weeks of treatment using change from baseline to visit 10 in R-MOAS score as outcome variable. There was a statistically significant difference between the low dose and placebo (p=0.031) and also between the medium dose and placebo (p=0.024) at the =0.05 level. There was no statistically significant difference between the high dose and placebo. Both the medium dose and low dose are superior to placebo. These results convinced us that both low and medium doses were effective, and this range of doses will be further evaluated in Phase III clinical trials.

A secondary efficacy variable was the proportion of children whose impulsive aggressive behavior remitted, with remission defined as R-MOAS ≤ 10 at the end of the study. Low and medium doses of SPN-810 showed statistically significant results versus placebo, with percent of patients who experienced remission of impulsive aggressive behavior of 51.9% (p=0.009) and 40.0% (p=0.043), respectively.

The CGI results (Severity and Improvement) are consistent with the findings for the R-MOAS, in that notable improvement (reduction in severity) occurred primarily in the low dose and medium dose groups. Scores on SNAP-IV Hyperactivity and Impulsivity items did not exhibit statistically significant differences across treatment groups, indicating that our efficacy against IA was specific, rather than being efficacious against the underlying ADHD. Numerical trends in SNAP-IV Oppositional Defiant Disorder scores, while not always significant, consistently favored the low dose and medium dose groups over placebo.

SPN-810 was well tolerated throughout the study across all doses. Sedation was the most frequently reported adverse reaction, with two subjects (7%) reporting this event in each of the four treatment groups including the placebo group. The next most frequently reporte