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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 13, 2017**

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**001-37977**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Block 10-1 **Blanchardstown Corporate Park, Ballycoolin** **Dublin 15, Ireland** (Address of Principal Executive Offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

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

Item 7.01 Regulation FD Disclosure.

On November 13, 2017, the Company posted to its website a set of presentation materials in conjunction with its investor and analyst update meeting for Noctiva™. A copy of this presentation is attached hereto as Exhibit 99.1.

The information responsive to this Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Presentation materials dated November 13, 2017*

* This information shall be deemed to be "furnished" and not filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVADEL PHARMACEUTICALS PLC

By: /s/ Phillandas T. Thompson
Phillandas T. Thompson
Senior Vice President, General Counsel and Corporate Secretary

Date: November 13, 2017

Exhibit Index

99.1 Presentation materials dated November 13, 2017.*

Avadel®

Noctiva™
Analyst and Investor Presentation

Monday, November 13, 2017

Safe Harbor

This presentation may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: (i) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including that our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (the "Drug") or we may not effectively exploit such market opportunity, that significant safety or drug interaction problems could arise with respect to the Drug, that we may not successfully increase awareness of nocturia and the potential benefits of the Drug, and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (ii) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2016, in particular under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®,Vazculep® and Akovaz® products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; and our dependence on key personnel to execute our business plan. Except as may be required by law, we disclaim any obligation to publicly update any forward-looking statements to reflect events after the date of this presentation.

Avadel: a new chapter

- Closing our history of solely focusing on drug delivery
- Transitioning from dependence on partners to self-funded innovation
- Welcoming long-term and sustainable growth
- Committing to building shareholder value through diversified specialty product offerings

- Welcome and thanks to Avadel's senior team members here today:
  - Greg Divis, EVP & CCO
  - Mike Kanan, CFO
  - Phil Thompson, GC
- Welcome to presenters:
  - Alan J. Wein MD, PhD (Hon)
  - Roger Dmochowski, MD, MMHC, FACS
  - Samuel Herschkowtiz, MD, CEO, Serenity
  - Seymour Fein, MD, CMO, Serenity
  - Steve A. Kaplan, MD
  - Greg Divis, EVP & CCO

Agenda

- Nocturia market overview
  - Condition and its consequences; Alan Wein, MD, PhD(Hon) FACS
  - Current treatment options; Roger Dmochowski, MD, MMHC, FACS
- Noctiva overview
  - Innovation and the invention; Samuel Herschkowitz, MD, Chief Executive Officer, Serenity Pharmaceuticals, LLC
  - Clinical overview; Seymour Fein, MD, Chief Medical Officer, Serenity Pharmaceuticals, LLC
  - Clinician's perspective; Steven Kaplan, MD
  - Commercial update; Greg Divis, Executive Vice President and Chief Commercial Officer, Avadel
- Panel Q&A
- Closing remarks and company update; Mike Anderson, Avadel

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Nocturia, the Condition and Its Consequences

Alan J. Wein, MD, PhD(Hon), FACS

Founders Professor and Emeritus Chief of Urology
Director, Residency Program in Urology
University of Pennsylvania
Perelman School of Medicine
PENN Medicine

Nocturia: waking 2 or more times per night to urinate

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Nocturia is

- Highly prevalent – impacts over **40 million** Americans[1]
- Under-recognized as a distinct condition
- Associated with significant sleep disruption
- Increasingly bothersome based on number of voids per night
- Linked to health complications and a negative impact on quality of life

Nocturia is **NOT**

- Simply due to OAB or BPH
- Merely a normal part of aging
- A disease that only affects the elderly
- Something that should be ignored

1. Bosch JLH, Weiss JP. The prevalence and causes of nocturia. *J Urol.* 2010;184(2):440-446.

Prevalence, diagnosis, and treatment rates of nocturia[1-7]

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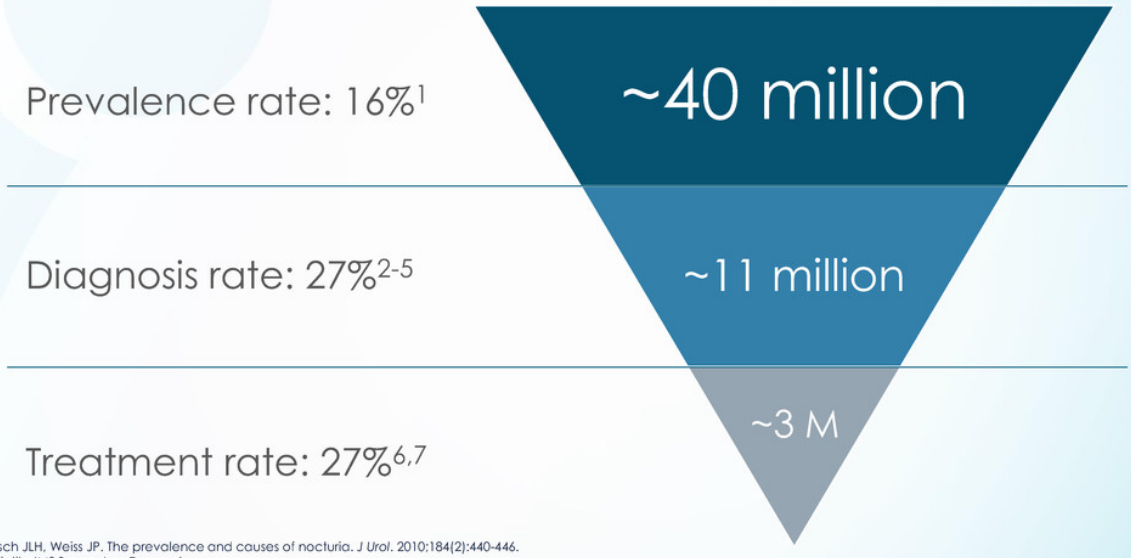
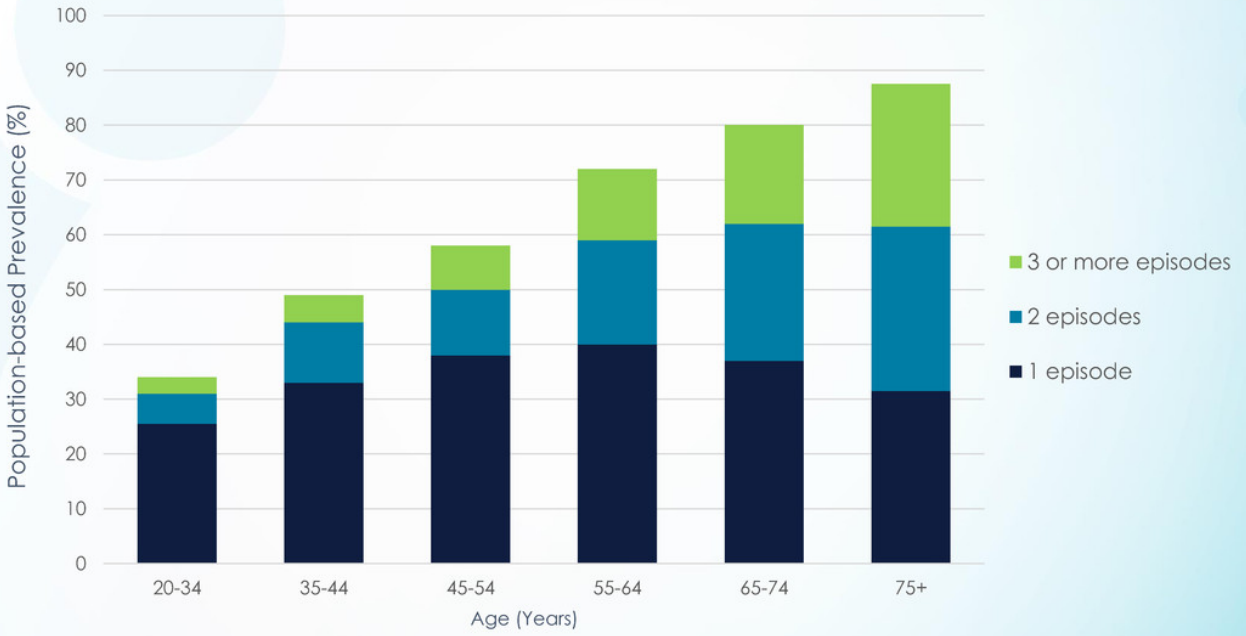


1. Bosch JLH, Weiss JP. The prevalence and causes of nocturia. *J Urol*. 2010;184(2):440-446.
2. QuintilesIMS Secondary Research.
3. Lee LK, Goren A, Zou KH, et al. Potential benefits of diagnosis and treatment on health outcomes among elderly people with symptoms of overactive bladder. *Int J Clin Pract*. 2016;70(1):66-81.
4. Decision Resources. *Treatment Algorithm in OAB*.
5. Vuichoud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. *J Urol*. 2015;22(51):1-6.
6. Helfand BT, Evans RM, McVary KT. A comparison of the frequencies of medical therapies for overactive bladder in men and women: analysis of more than 7.2 million aging patients. *Eur Urol*. 2010;57(4):586-591.
7. Goldman HB, Anger JT, Esinduy CB, et al. Real-world patterns of care for the overactive bladder syndrome in the United States. *Urology*. 2016;87:64-69.

The prevalence and frequency of nocturia increase with age[1]



1. Markland AD, Richter HE, Fwu CW, Eggers P, Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *J Urol*. 2011;186(2):589-593.

Nocturia impacts both men and women

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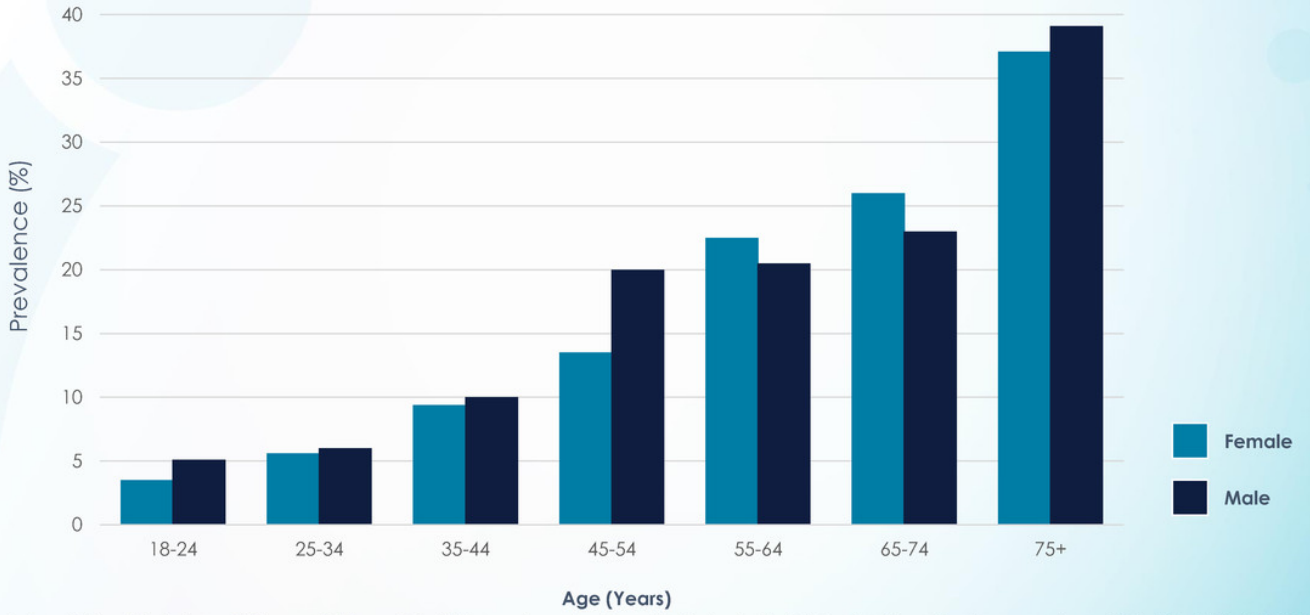
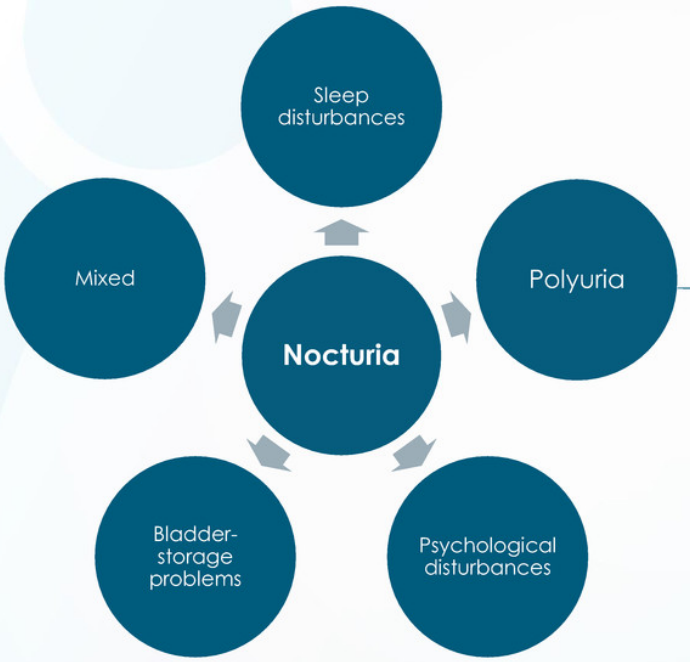
Prevalence of Nocturia (≥2 Voids/Night) by Age in a US Community Study (N=5204)[1]



1. Coyne KS, Zhou Z, Bhattacharyya SK, Thompson CL, Dhawan R, Versi E. The prevalence of nocturia and its effect on health-related quality of life and sleep in a community sample in the USA. *BJU Int*. 2003;92(9):948-954.

Multiple factors can cause nocturia[1]



24-hour polyuria

Nocturnal polyuria

- Overproduction of urine at night
- >33% of daily urine volume produced at night

1. Wein A, Lose GR, Fonda D. Nocturia in men, women and the elderly: a practical approach. *Br J Urol.* 2002;90(suppl 3):28-31.

Nocturnal polyuria (NP) is present in the majority of patients with nocturia

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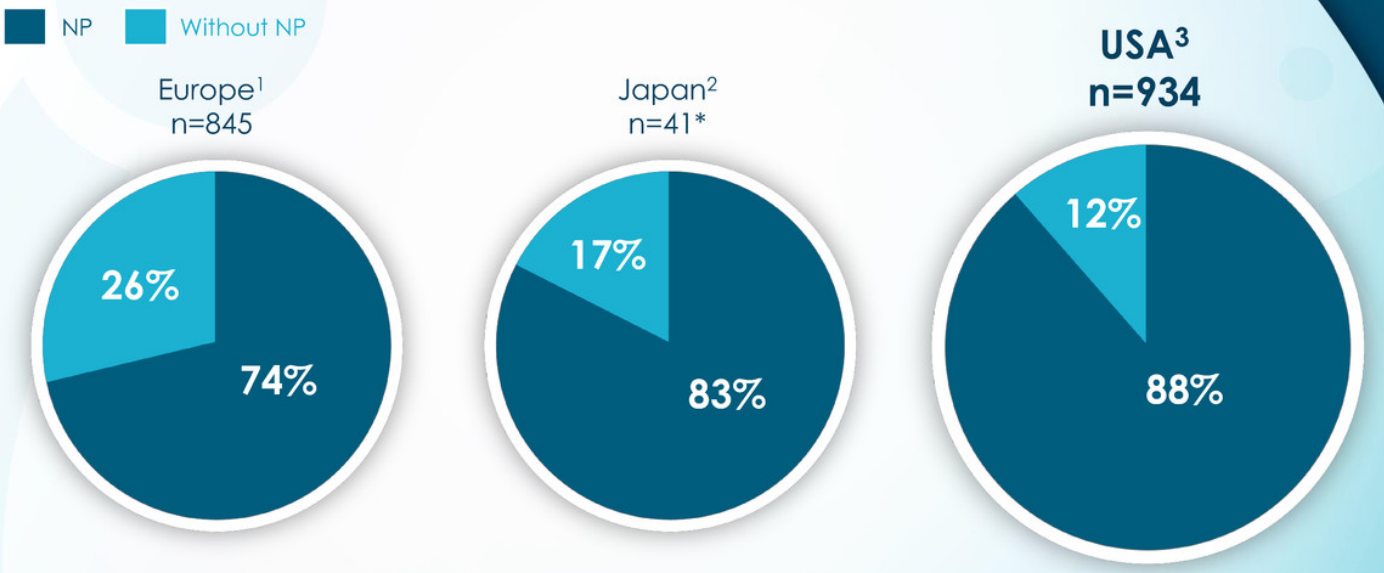
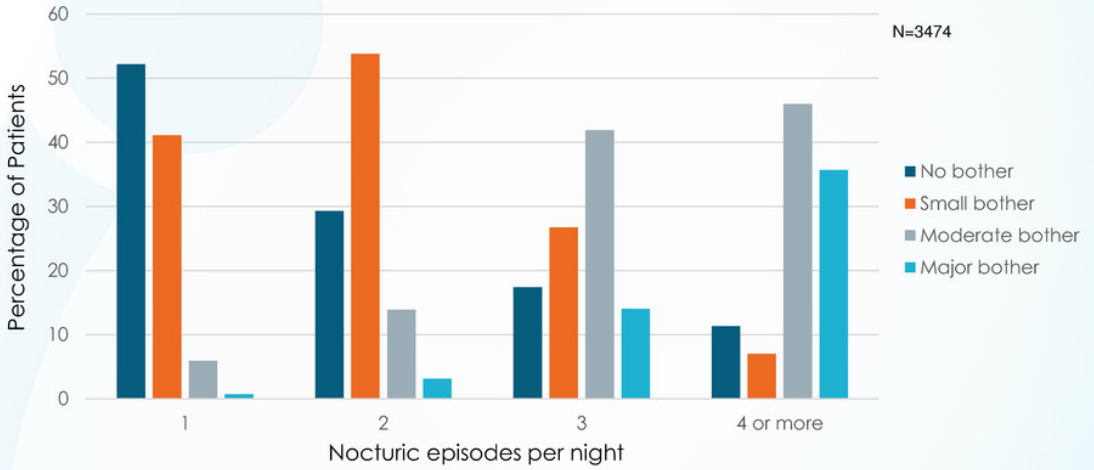


*Males only.

1. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn*. 2004;23(4):322-330.
2. Chang SC, Lin AT, Chen KK, Chang LS. Multifactorial nature of male nocturia. *Urology*. 2006;67(3):541-544.
3. Weiss JP. Prevalence of nocturnal polyuria in nocturia. *J Urol*. 2009;181(4):538.

Degree of bother increases with number of episodes per night[1]



"Nocturia is the most bothersome symptom in patients with LUTS/BPH, having a significant impact on quality of life."[2]

~Chapple, et al.

1. Tikkinen KA, Johnson TM, Tammela TL, et al. Nocturia frequency, bother, and quality of life: how often is too often? A population-based study in Finland. *Eur Urol.* 2010;57(3):488-496.
2. Chapple CR, Batista JE, Berges R, et al. The impact of nocturia in patients with LUTS/BPH: need for new recommendations. *Eur Urol.* 2006;5(1)(suppl):12-18.

The first few hours of sleep are the most important[1-3]

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> ***"A single episode of nocturia had greater adverse effects if this occurred in the first 4 hours of sleep (where slow wave restorative sleep occurs) as opposed to the second 4 hours."[1]***
>
> *~Van Kerrebroeck, et al.*

- Deep, slow-wave, restorative sleep occurs during the first hours, while less restorative, lighter sleep predominates later
- Waking during the first 3 to 4 hours is more likely to leave a person groggy/tired the next day

1. Kerrebroeck PV, Drake M, Rees J. Nocturia: what do we need to know in 2017? Identify the cause and tailoring the treatment. *Eur Med J Urol.* 2017;5(1):32-37.
2. Stanley N. The underestimated impact of nocturia on quality of life. *Eur Urol.* 2005;4(7):17-19.
3. Akerstedt T, Nilsson PM. Sleep as restitution: an introduction. *J Intern Med.* 2003;254(1):6-12.

Nocturia and sleep disruption have far-reaching health effects[1-6]

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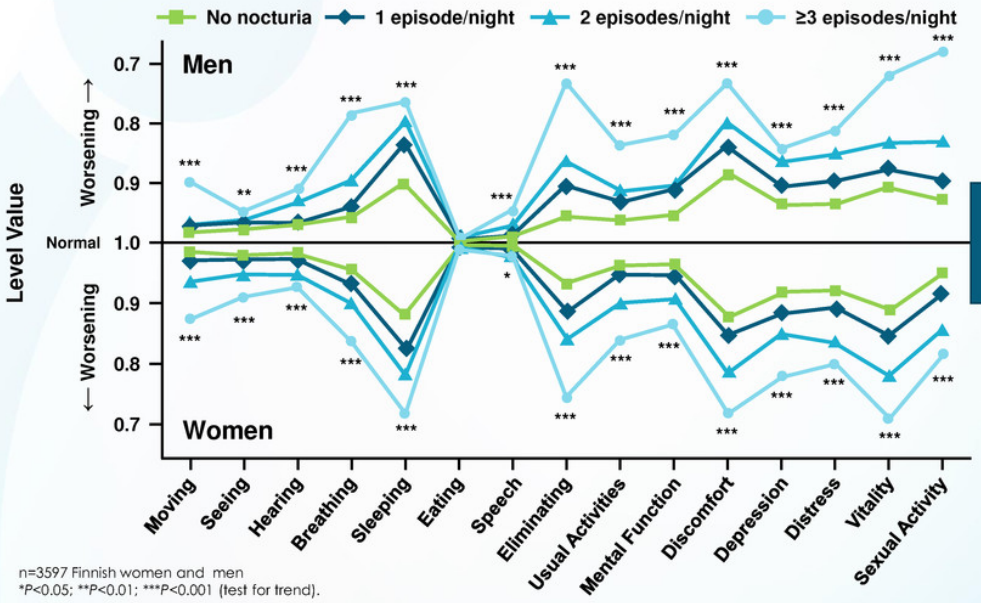
1. Kobelt G, Borgstrom F, Mattiassön A. Productivity, vitality and utility in a group of healthy professionally active individuals with nocturia. *BJU Int*. 2003;91(3):190-195.
2. Asplund R. Hip fractures, nocturia, and nocturnal polyuria in the elderly. *Arch Gerontol Geriatr*. 2006;43(3):319-326.
3. Van Dijk L, Kooij DG, Schellevis FG. Nocturia in the Dutch adult population. *BJU Int*. 2002;90(7):644-648.
4. Stewart RB, Moore MT, May FE, Marks RG, Hale WE. Nocturia: a risk factor for falls in the elderly. *J Am Geriatr Soc*. 1992;40(12):1217-1220.
5. Ponholzer A, Temml C, Wehrberger C, Marszalek M, Madersbacher S. The association between vascular risk factors and lower urinary tract symptoms in both sexes. *Eur Urol*. 2006;50(3):581-586.
6. Nakagawa H, Niu K, Hozawa A, et al. Impact of nocturia on bone fracture and mortality in older individuals: a Japanese longitudinal cohort study. *J Urol*. 2010;184(4):1413-1418.

Nocturia significantly impacts daily functioning of both women and men[1,2]



Worsening of nocturia is associated with greater impact

n=3597 Finnish women and men
*P<0.05; **P<0.01; ***P<0.001 (test for trend).

1. Tikkinen KA, Johnson TM, Tammela TL, et al. Nocturia frequency, bother, and quality of life: how often is too often? A population-based study in Finland. *Eur Urol.* 2010;57(3):488-496.
2. Sintonen H. The 15D instrument of health-related quality of life: properties and applications. *Ann Med.* 2001;33(5):328-336.

Nocturia impacts daytime sleepiness, naps, and sick leave[1]

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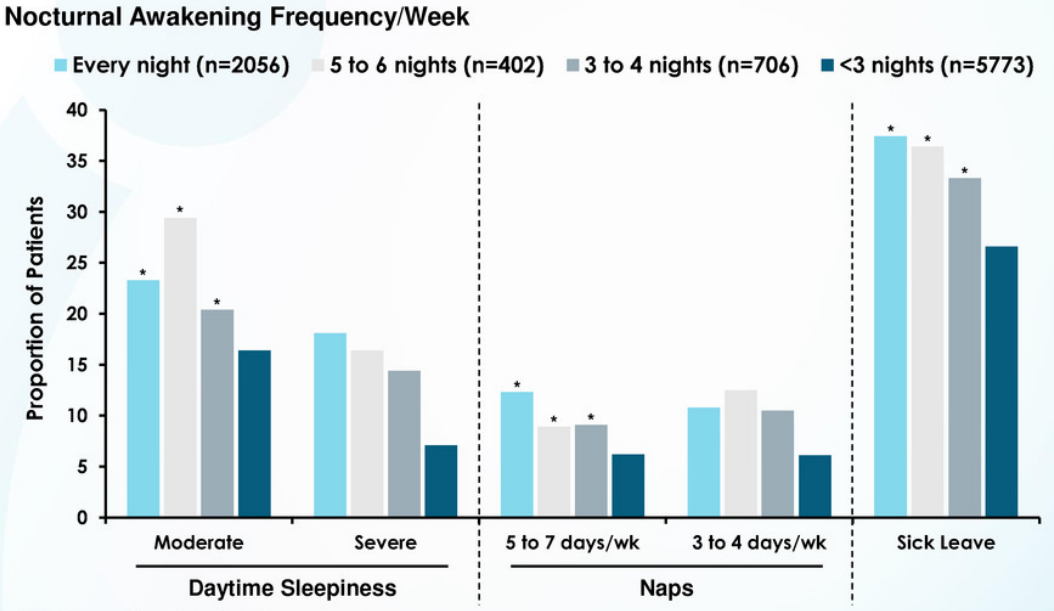

*P<0.001 vs awaking <3 nights/week.

1. Ohayon MM. Nocturnal awakenings and comorbid disorders in the American general population. *J Psychiatr Res.* 2008;43(1):48-54.

Nocturia affects daytime activity and work productivity[1]

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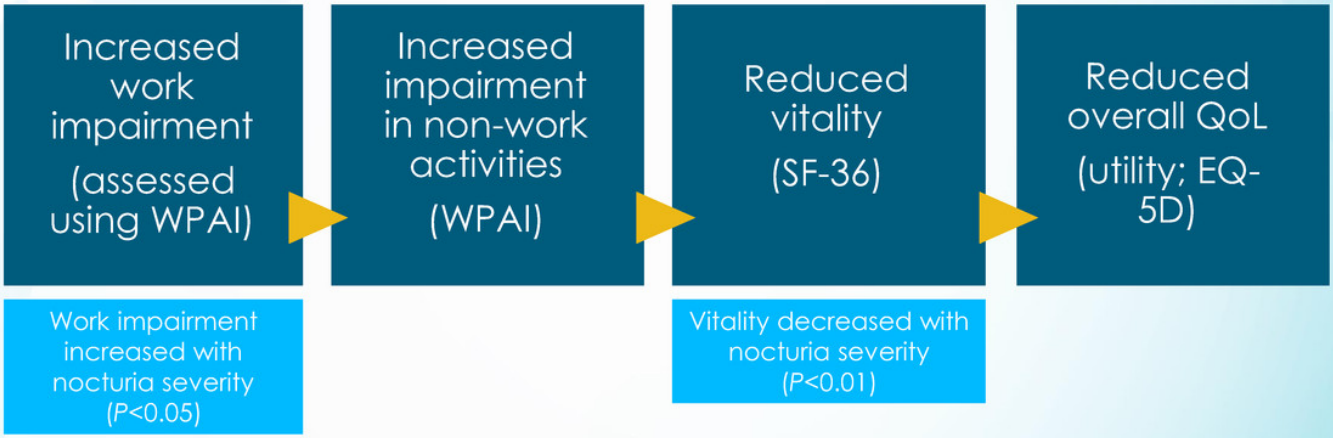
Compared with controls, patients with nocturia had significantly (*P*<0.001):



Productivity, vitality, and QoL were assessed in 203 professionally active adults in Sweden with ≥1 void/night.
WPAI: Work Productivity and Activity Impairment Questionnaire
EQ-5D: Euro Quality of Life Questionnaire

1. Kobelt G, Borgstrom F, Mattiasson A. Productivity, vitality and utility in a group of healthy professionally active individuals with nocturia. *BJU Int.* 2003;91(3):190-195.

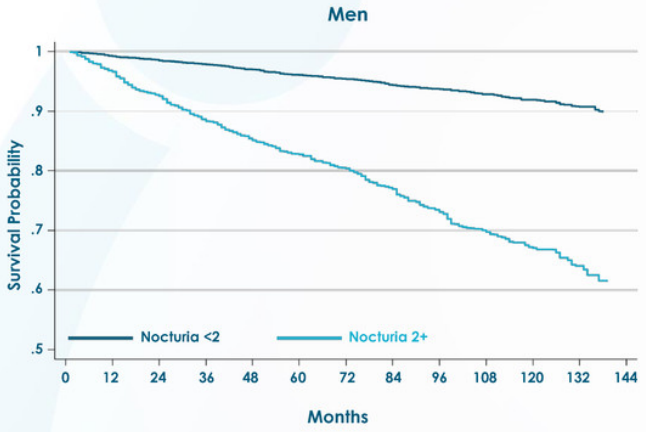
Nocturia: falls and hip fractures[1,2,3]

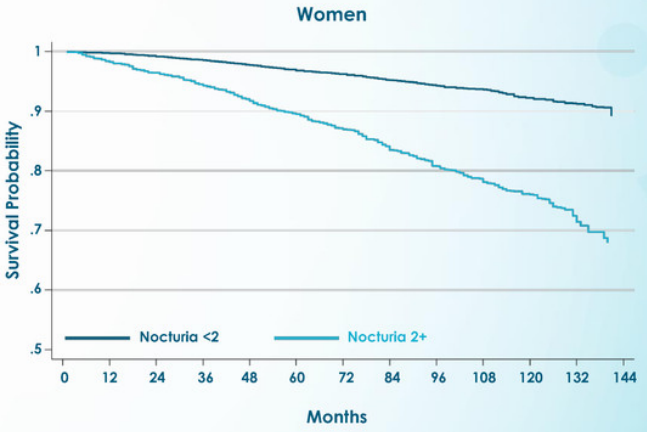
- Nocturia increases risk of a fall 25% over 3 years
- Odds Ratio (OR) for a fall increases from 1.84 (Nx2) to 2.15 (Nx3)
- OR for hip fracture
  - 1.36 in older men, N ≥ 2
  - 1.8 in older men, N ≥ 3

1. Stewart et al. J Am Ger Soc, 1992
2. Bliwise et al. Sleep Medicine, 2009
3. Temml et al. NeuroUrol Urodyn, 2009

Nocturia is a strong predictor of mortality[1]

US Data NHANES III





≥2 voids/night are associated with worse survival in a population-based sample of 7455 men and 8533 women

1. Kupelian V, Fitzgerald MP, Kaplan SA, Norgaard JP, Chiu GR, Rosen RC. Association of nocturia and mortality: results from the Third National Health and Nutrition Examination Survey. *J Urol.* 2011;185(2):571-577.

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Nocturia, Current Treatment

Roger Dmochowski, MD, MMHC, FACS

Professor of Urology and Gynecology
Vanderbilt University Medical Center

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"Improvements in nocturia contribute considerably to overall improvements in health-related quality of life."[1]

~Van Dijk, et al.

1. Van Dijk MM, Debruyne WH, Rosette DL, Michel MC. The role of nocturia in the quality of life of men with lower urinary tract symptoms. *BJU Int*. 2010;105(8):1141-1146.

Simple logic to decrease nocturia

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Decrease bladder activation on motor and/or sensory side of the micturition cycle (OAB, BPH, Combination)

Decrease significant residual urine volume and thereby improve nocturnal storage capacity (BPH)

Decrease nocturnal urine production

Nocturia therapies: outcome indicators

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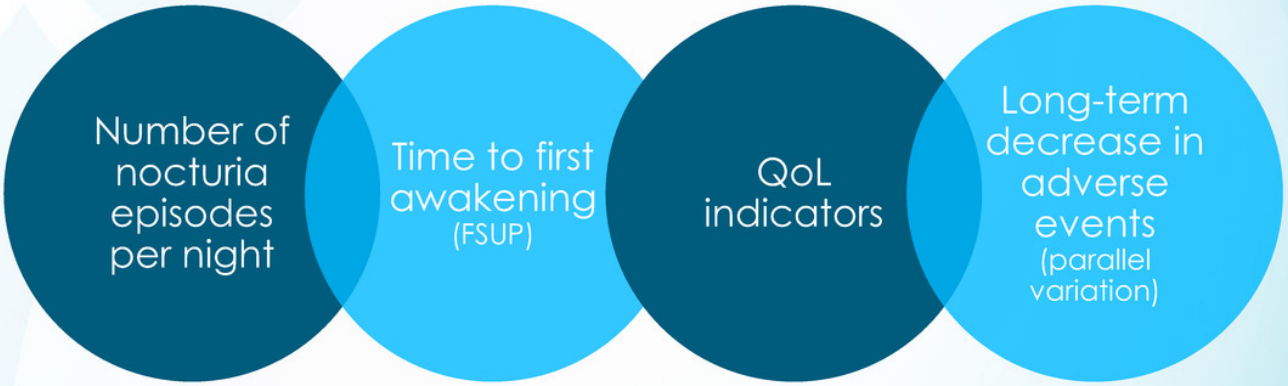

Nocturia treatment

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Behavior/lifestyle modifications

- Preemptive voiding
- Nocturnal and late afternoon dehydration
- Dietary restrictions (eg, caffeine, alcohol)
- Medication timing (late afternoon diuretic)
- Compression stockings
- Afternoon and evening leg elevation

Pharmacologic therapies

Target the most prominent symptoms or set of symptoms first

- Overactive bladder
- Prostatic enlargement/obstruction
- Nocturnal polyuria

But current treatment options do not effectively treat nocturia

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"Medications to treat LUTS in men…were not significantly better than placebo in short-term use."[1]

EAU Guidelines Committee

"Data on OAB medications generally had a female predominant population and were not significantly better than placebo in short-term use. It is an assumption that this would also apply in male only populations…"[1]

EAU Guidelines Committee

"…little response has been seen from anticholinergic agents and alpha-blockers."[2]

Drake, et al.

1. Sakalis VI, Karavitakis M, Bedretdinova D, et al. Medical treatment of nocturia in men with lower urinary tract symptoms: systematic review by the European Association of Urology Guidelines Panel for Male Lower Urinary Tract Symptoms. *Eur Urol*. 2017;72(5):757-769.
2. Kerrebroeck PV, Drake M, Rees J. Nocturia: what do we need to know in 2017? Identify the cause and tailoring the treatment. *Eur Med J Urol*. 2017;5(1):32-37.

OAB and BPH therapies do not address the true source of nocturia

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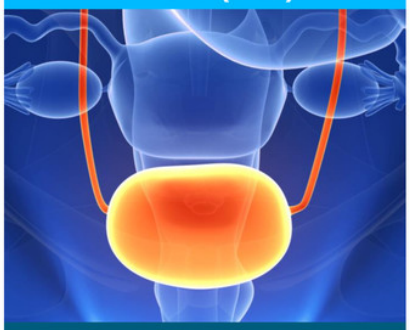
Benign prostatic hyperplasia (BPH)

Alpha blockers relax the muscle of the prostate and bladder neck, allowing urine to flow more easily[1]

Overactive bladder (OAB)



Anticholinergics target receptors in the bladder, improving capacity and reducing involuntary contractions, urgency, and frequency[2]

Nocturia due to nocturnal polyuria

Nocturia due to nocturnal polyuria results from overproduction of urine by the kidneys at night[3]

1. Asseldonk BV, Barkin J, Elterman DS. Medical therapy for benign prostatic hyperplasia: a review. *Can J Urol*. 2015;22(suppl 1):7-17.
2. Jayarajan J, Radomski SB. Pharmacotherapy of overactive bladder in adults: a review of efficacy, tolerability, and quality of life. *Res Rep Urol*. 2013;6:1-16.
3. Fine ND, Weiss JP, Wein AJ. Nocturia: consequences, classification, and management. F1000Res. 2017;6:1627.

Many patients are not satisfied with current treatment options[1-4]

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BPH/OAB therapies have limited effect on nocturia

Therapy	Reduction in voids vs placebo
Doxazosin + Finasteride[2]	0.2 voids
Solifenacin[3]	0.16 voids
Fesoterodine[4]	0.14 voids
Oxybutynin[4]	0.11 voids

1. Noctiva Quantitative Market Research Assessment Patient Final Report. April 16, 2014.
2. Johnson TM, Jones K, Williford WO, Kutner MH, Issa MM, Lepor H. Changes in nocturia from medical treatment of benign prostatic hyperplasia: secondary analysis of the Department of Veterans Affairs Cooperative Study Trial. *J Urol.* 2003;170(1):145-148.
3. Yamaguchi O, Marui E, Kakizaki H, Itoh N, Yokota T, Okada H. Randomized, double-blind, placebo- and propiverine-controlled trial of the once-daily antimuscarinic agent solifenacin in Japanese patients with overactive bladder. *BJU Int.* 2007;100(3):579-587.
4. Buser N, Ivic S, Kessler TM, Kessels AG, Bachmann LM. Efficacy and adverse events of antimuscarinics for treating overactive bladder: network meta-analysis. *Eur Urol.* 2012;62(6):1040-1060.

Nocturia treatment considerations

- BPH and OAB therapies do not adequately address the underlying cause of nocturia in a majority of patients: nocturnal polyuria
- Improvement in nocturia is therefore often minimal with BPH/OAB therapies
- Antidiuretic therapy with desmopressin targets nocturnal polyuria and is endorsed with the highest level of recommendation by ICS and EAU[1,2]

1. Marshall SD, Raskolnikov D, Blanker MH, et al. Nocturia: current levels of evidence and recommendations from the International Consultation on Male Lower Urinary Tract Symptoms. *Urology*. 2015;85(6):1291-1299.
2. Sakalis VI, Karavitakis M, Bedretdinova D, et al. Medical treatment of nocturia in men with lower urinary tract symptoms: systematic review by the European Association of Urology Guidelines Panel for male lower urinary tract symptoms. *Eur Urol*. 2017;72(5):757-769.

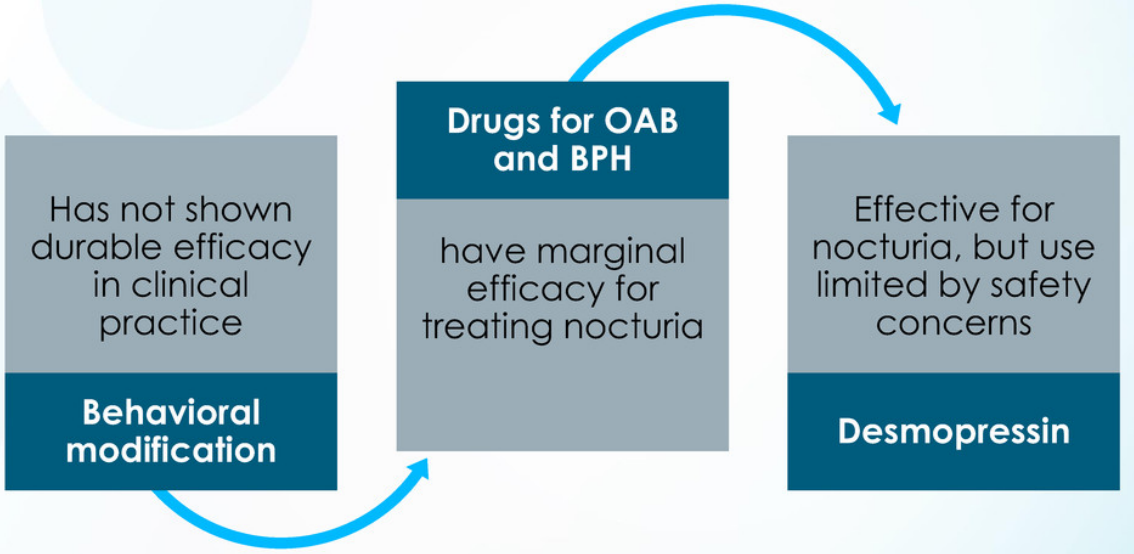
Desmopressin is effective for the treatment of nocturia[1]

Study	Effective dose	Route of delivery	Clinical response in treatment arm (%)	Clinical response in placebo arm (%)	Incidence of hyponatremia (%)
Mattiasson 2002	0.1, 0.2, 0.4 mg	Oral	**34**	3	8
Lose 2003	0.1, 0.2, 0.4 mg	Oral	**44**	4	12
Lose 2004	0.1, 0.2, 0.4 mg	Oral	**67**	NA	14
Van Kerrebroeck 2007	0.1, 0.2, 0.4 mg	Oral	**33**	11	3
Rembratt 2003	0.2 mg	Oral	**82**	NA	5
Kuo 2002	0.1 mg	Oral	**66.7**	NA	3
Wang 2011	0.1 mg	Oral	**61.4**	13.8	16

- Oral and sublingual formulations of desmopressin were associated with an increased risk of hyponatremia
- Desmopressin works at the source of nocturia by increasing urea reabsorption in the medullary collecting tubule

1. Friedman FM, Weiss JP. Desmopressin in the treatment of nocturia: clinical evidence and experience. *Ther Adv Urol*. 2013;5(6):310-317.

Current nocturia therapy has varying effectiveness



Conclusions

- Nocturia is an important medical condition associated with significant morbidity
- Nocturia increases the risk of falls and is a strong predictor of mortality
- Nocturia disrupts normal sleep, causes daytime fatigue and loss of productivity, and impairs ability to perform daily activities
- Behavior modifications do little to address nocturia, and pharmacologic options are limited by efficacy and safety concerns

Noctiva, the Invention

Samuel Herschkowtiz, MD

Chief Executive Officer, Serenity Pharmaceuticals, LLC

Noctiva is not yet available for prescription.

Noctiva™
(desmopressin acetate) Nasal Spray

The challenge:

To limit the duration of antidiuretic action of desmopressin to **4 to 6 hours** at night in order to achieve efficacy and improve the safety profile (minimize risk of hyponatremia)

Noctiva (desmopressin acetate) product overview

Noctiva™ (desmopressin acetate) Nasal Spray

First-in-class product[1]

For the treatment of nocturia due to nocturnal polyuria in adults who awaken 2 or more times per night to void[2]

- No therapeutic equivalent[3]
- Patented spray technology to maximize drug delivery[4]
- Very low-dose desmopressin in a metered-dose nasal spray[5]
- 1 spray 30 minutes before bed[2]; works on first use[4]

FDA-approved March 3, 2017[1]

Avadel secured exclusive rights September 2017[7]

- Rapid absorption and lasts for ~4 to 6 hours after administration[2]
- Works in the kidneys to decrease urine production[2]
- Decreases the number of nighttime voids[2]
- Approval based on more stringent efficacy threshold than other desmopressin studies (response defined as 50% reduction in nocturic episodes [vs 33%])[2,6]

1. US Food and Drug Administration. FDA approves first treatment for frequent urination at night due to overproduction of urine. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm544877.htm. Published March 3, 2017.
2. Noctiva [package insert]. Chesterfield, MO: Avadel Specialty Pharmaceuticals, LLC; 2017.
3. US Food and Drug Administration. Drugs@FDA: FDA-approved drug products. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201656. 2017.
4. Data on file. Avadel Specialty Pharmaceuticals, LLC.
5. Kaminetsky J, Fein S, Dmochowski R, et al. Efficacy and safety of SER120 nasal spray in nocturia patients: pooled analysis of 2 randomized, double-blind, placebo-controlled phase 3 trials. *J Urol*. 2017 [in preparation].
6. US Food and Drug Administration. Nocdurna briefing document. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM429354.pdf. Published December 3, 2014.
7. Avadel Pharmaceuticals press release.

The solution: Noctiva

Noctiva™ (desmopressin acetate) Nasal Spray

- **A** Very low dose of desmopressin[1]
- **B** Engineered to achieve highly consistent absorption from dose to dose and from patient to patient[1]
- **C** Pharmacokinetic coefficient of variation is comparable to subcutaneous administration[2]
- **D** Patented permeation enhancer (CPD) results in higher bioavailability and rapid absorption, resulting in peak blood levels within 20 to 45 minutes[2,3]
- **E** Almost no depot effect: all the desmopressin that will be absorbed into the blood is absorbed quickly[2]

1. Kaminetsky J, Fein S, Dmochowski R, et al. Efficacy and safety of SER120 nasal spray in nocturia patients: pooled analysis of 2 randomized, double-blind, placebo-controlled phase 3 trials. *J Urol*. 2017 [in preparation].
2. Data on file. Avadel Specialty Pharmaceuticals, LLC.
3. Noctiva [package insert]. Chesterfield, MO: Avadel Specialty Pharmaceuticals, LLC; 2017.

Noctiva was designed specifically for the patient with nocturia*

Noctiva™ (desmopressin acetate) Nasal Spray

- The novel and patented Noctiva formulation produces:

High bioavailability[1] (~8%)

Peak plasma concentration <10 pg/mL[2]

Short duration of action[2] (4-6 hours)

Unique spray pattern[3] (centrifugal, donut-shaped droplet distribution, which deposits more drug on nasal turbinates)

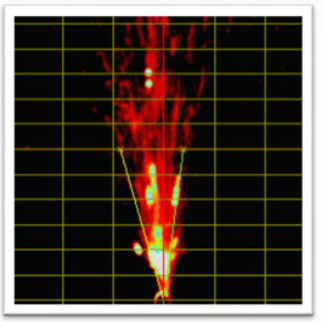
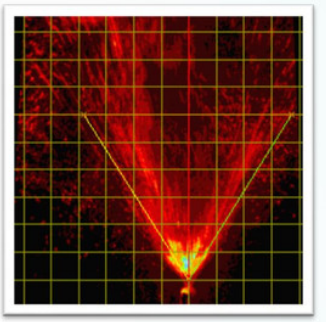
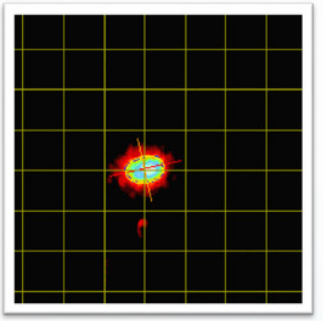
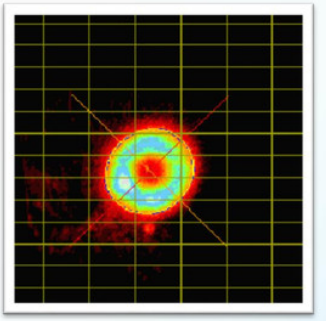
These features optimize blood levels and duration of action, which minimize the incidence of hyponatremia

*Due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

1. Cohn JA, Kowalik CG, Reynolds WS, et al. Desmopressin acetate nasal spray for adults with nocturia. Exp Rev Clin Pharmacol. 2017. doi:10.1080/17512433.2017.1394185.
2. Noctiva [package insert]. Chesterfield, MO; Avadel Specialty Pharmaceuticals, LLC; 2017.
3. Data on file. Avadel Specialty Pharmaceuticals, LLC.

Noctiva vs aqueous-based nasal spray[1]

Noctiva™ (desmopressin acetate) Nasal Spray

	Aqueous base	Noctiva
Plume geometry		
Spray pattern		

1. Data on file. Avadel Specialty Pharmaceuticals, LLC.

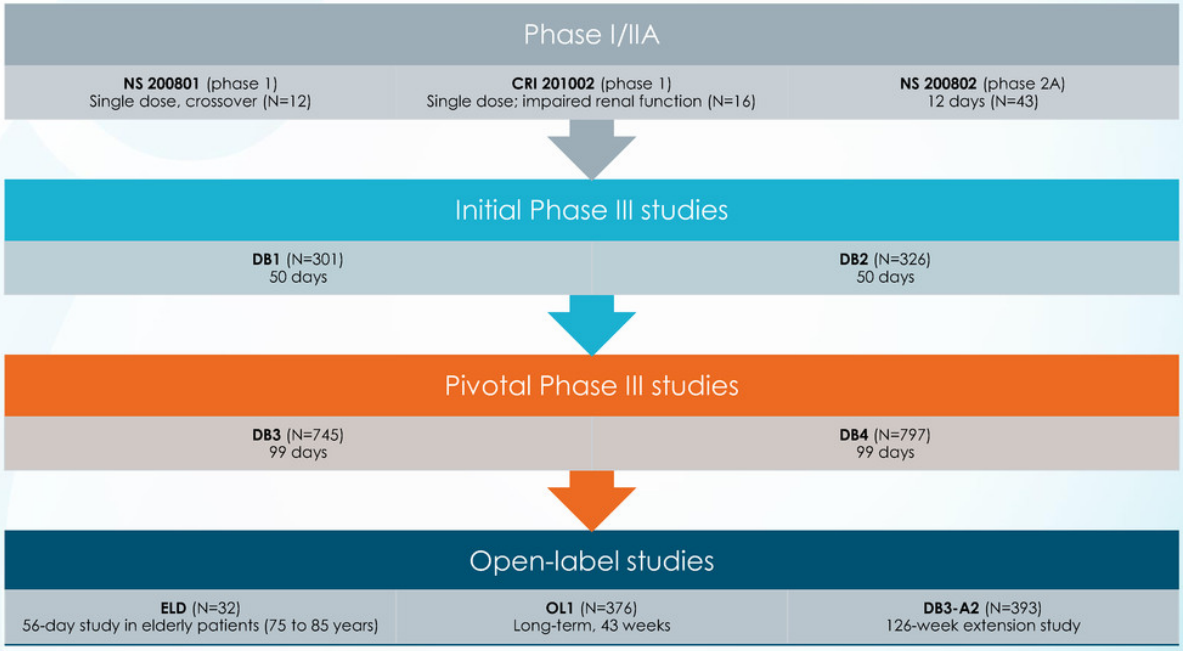
Noctiva™
(desmopressin acetate) Nasal Spray

Overview of Clinical Data

Seymour Fein, MD
Chief Medical Officer, Serenity Pharmaceuticals, LLC

Noctiva is not yet available for prescription.

Noctiva has been studied in clinical trials in over 2300 patients



Noctiva™ (desmopressin acetate) Nasal Spray

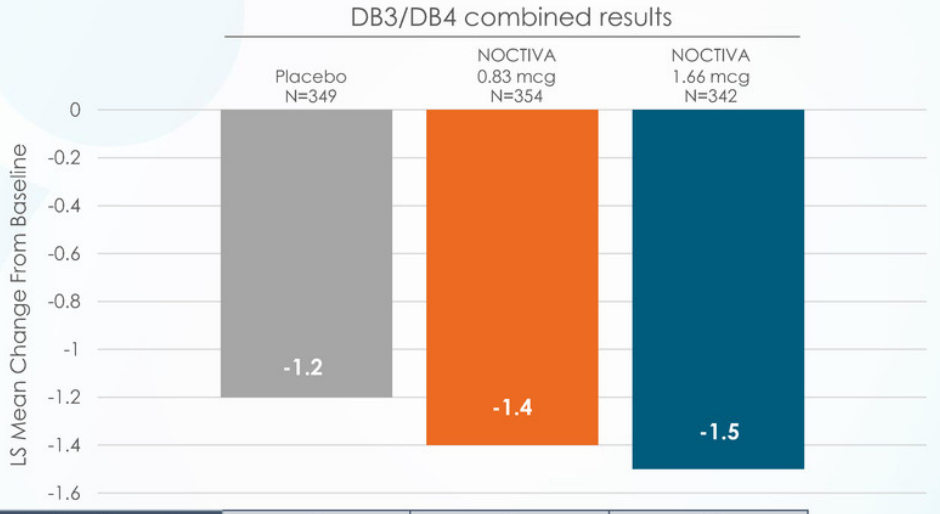
Overview of Pivotal Clinical Study Data

2 Phase III randomized, double-blind, placebo-controlled, parallel-group, multicenter, clinical studies (DB3 and DB4)

Noctiva is not yet available for prescription.

Change in mean number of nocturic episodes per night[1]

Co-primary Efficacy Endpoint



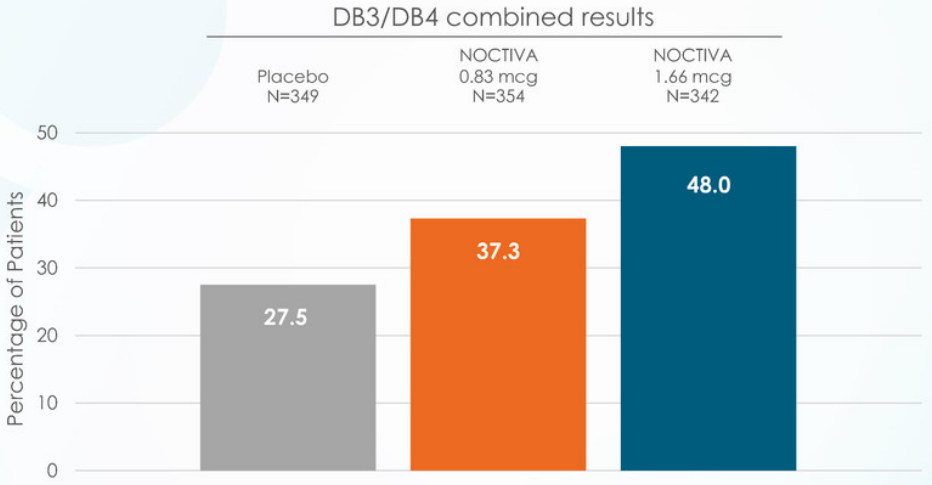
Baseline (LS mean)	3.3	3.4	3.3
Difference from placebo	–	-0.2	-0.3
***P* value vs placebo**	–	<.0001	<.0001

ITT population with nocturia due to nocturnal polyuria.

1. Sussman D, Kaminetsky J, Efros M, et al. SER120 nasal spray is effective for the treatment of nocturia in patients regardless of etiology: A pooled analysis of two randomized, placebo-controlled phase 3 trials. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

Percentage of patients achieving ≥50% reduction in nocturic episodes[1]

Co-primary Efficacy Endpoint



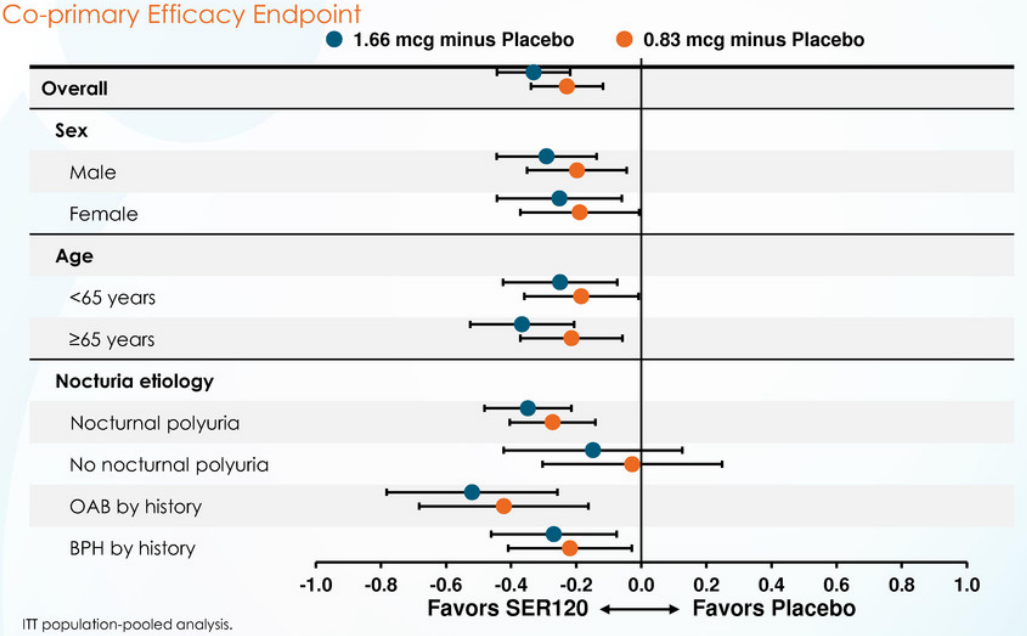
Difference from placebo (%)	–	9.8	20.5
P value vs placebo		.0055	<.0001

ITT population with nocturia due to nocturnal polyuria.

1. Sussman D, Kaminetsky J, Efros M, et al. SER120 nasal spray is effective for the treatment of nocturia in patients regardless of etiology: a pooled analysis of two randomized, placebo-controlled phase 3 trials. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

Reduction in mean number of nocturic episodes per night by gender, age, and nocturia etiology[1]

Co-primary Efficacy Endpoint



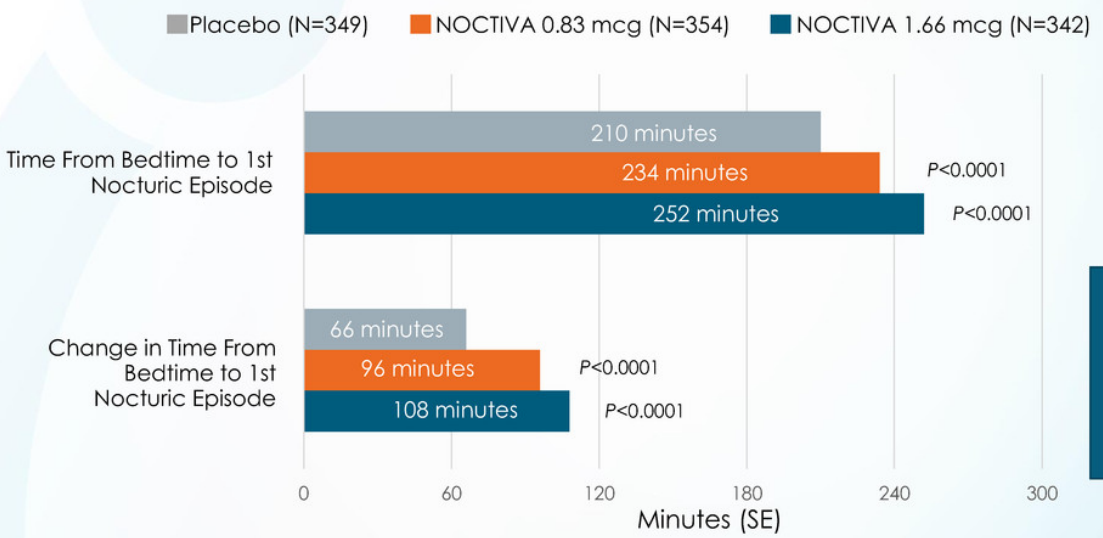
Noctiva was effective regardless of sex, age, or etiology

ITT population-pooled analysis.

1. Data on file. Avadel Specialty Pharmaceuticals, LLC.

Change in time from bedtime to first nocturic episode[1]

Secondary Efficacy Endpoint



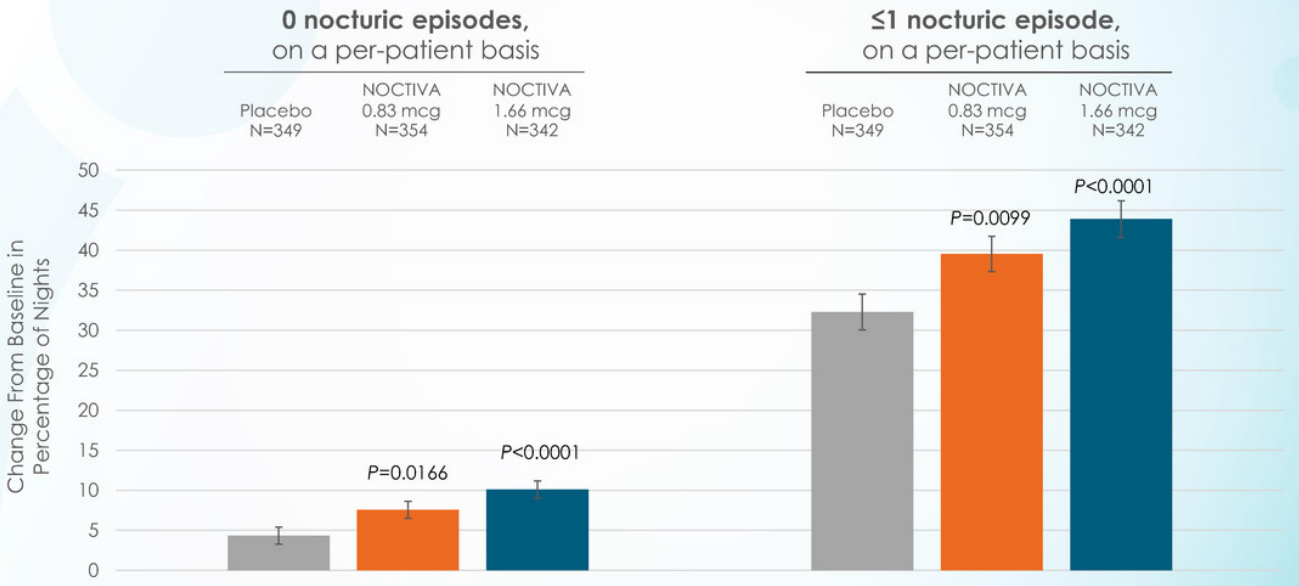
Patients using Noctiva were able to stay asleep longer

ITT population with nocturia due to nocturnal polyuria.
Data reported as LSM (least squares mean) ± SE (standard error) unless otherwise indicated.

1. Sussman D, Kaminetsky J, Efros M, et al. SER120 nasal spray is effective for the treatment of nocturia in patients regardless of etiology: a pooled analysis of two randomized, placebo-controlled phase 3 trials. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

Change in percentage of nights with 0 or ≤1 nocturic episode[1]

Secondary Efficacy Endpoint

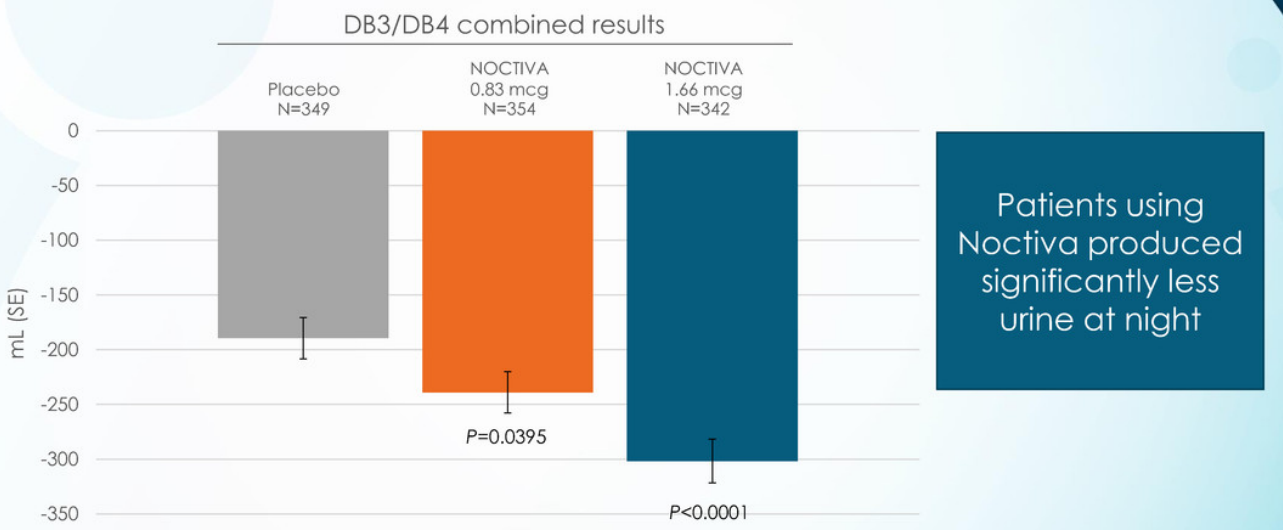


ITT population with nocturia due to nocturnal polyuria.

1. Sussman D, Kaminetsky J, Efros M, et al. SER120 nasal spray is effective for the treatment of nocturia in patients regardless of etiology: A pooled analysis of two randomized, placebo-controlled phase 3 trials. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

Reduction in nocturnal urine volume[1]

Secondary Efficacy Endpoint



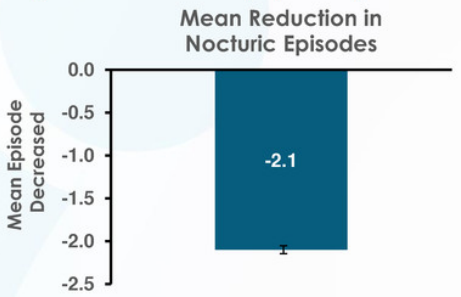
Patients using Noctiva produced significantly less urine at night

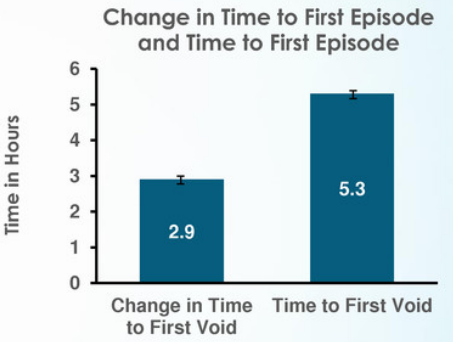
ITT population with nocturia due to nocturnal polyuria.
Data reported as LSM (least squares mean) ± SE (standard error) unless otherwise indicated.

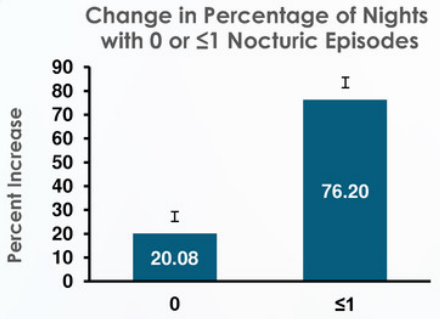
1. Sussman D, Kaminetsky J, Efros M, et al. SER120 nasal spray is effective for the treatment of nocturia in patients regardless of etiology: a pooled analysis of two randomized, placebo-controlled phase 3 trials. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

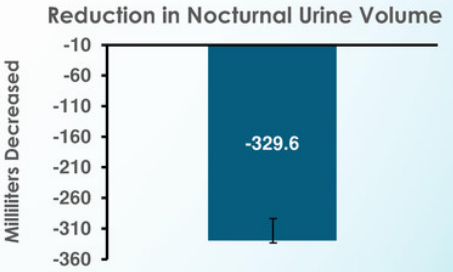
Magnitude of change in responders for various efficacy variables[1]

1.5 mcg Treatment Group (N=214)





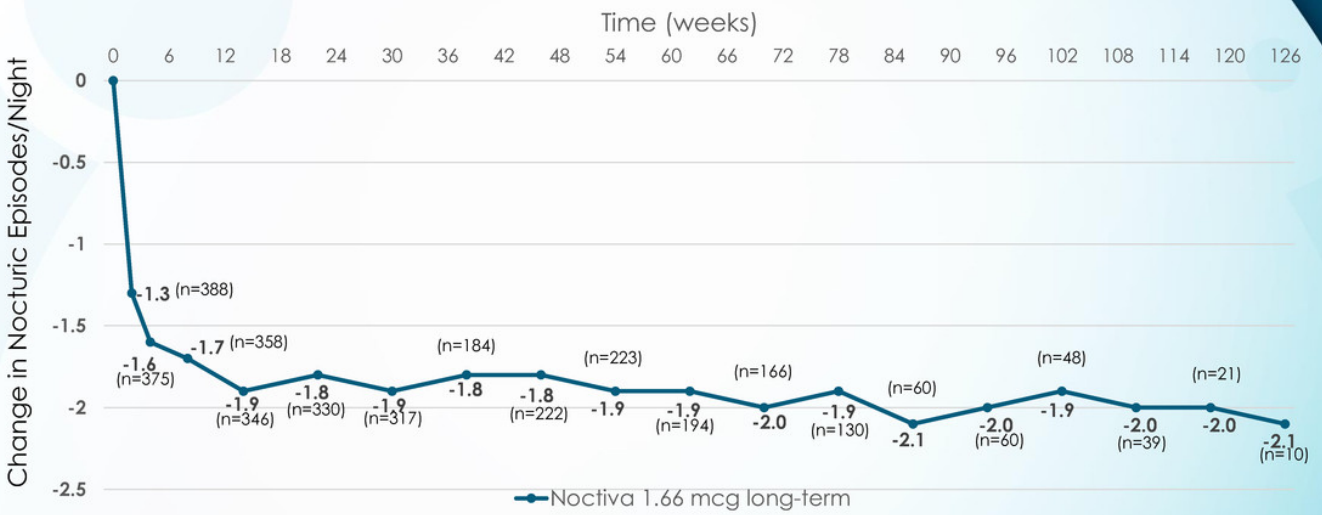




1. Data on file. Avadel Specialty Pharmaceuticals, LLC.

Durability: reduction in mean nocturic episodes per night[1]

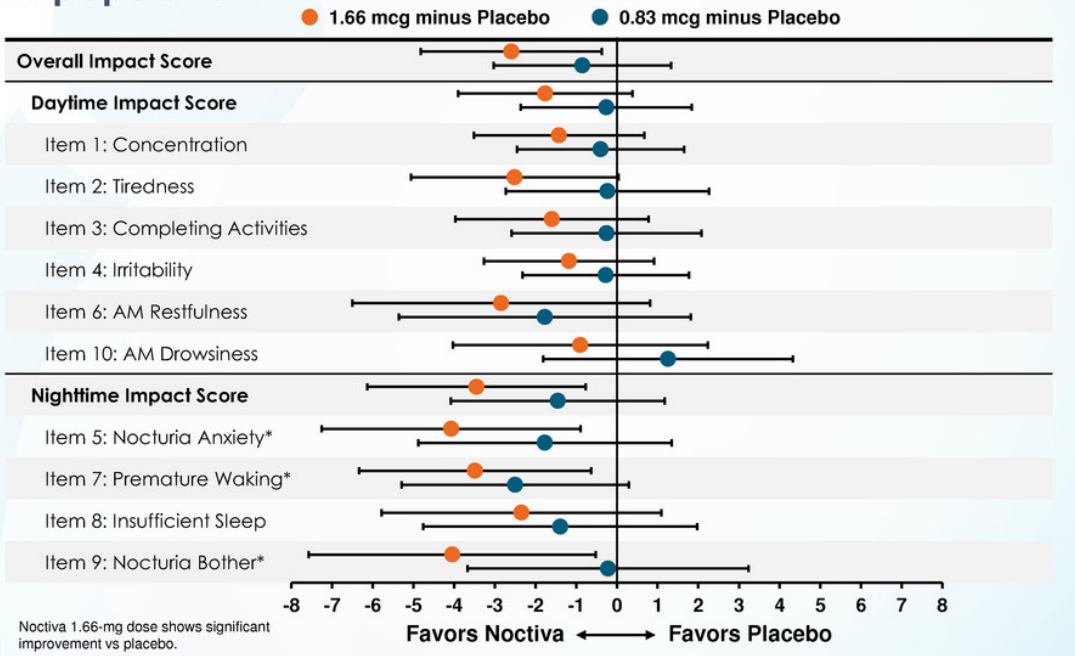
Open-Label, Long-Term Extension Trial—Up to 126 Weeks



Time interval assessment (n) = Time of diary assessment (number of patients).

1. MacDiarmid S, Nicandro JP, Cheng M, et al. Long-term efficacy and safety of ser120 1.66 mcg in patients with nocturia: results from a 2-year open-label extension study. Poster presented at: Annual Meeting of the American Urological Association (AUA); May 12-16, 2017; Boston, MA.

INTU items: placebo-subtracted mean change scores ITT population[1]

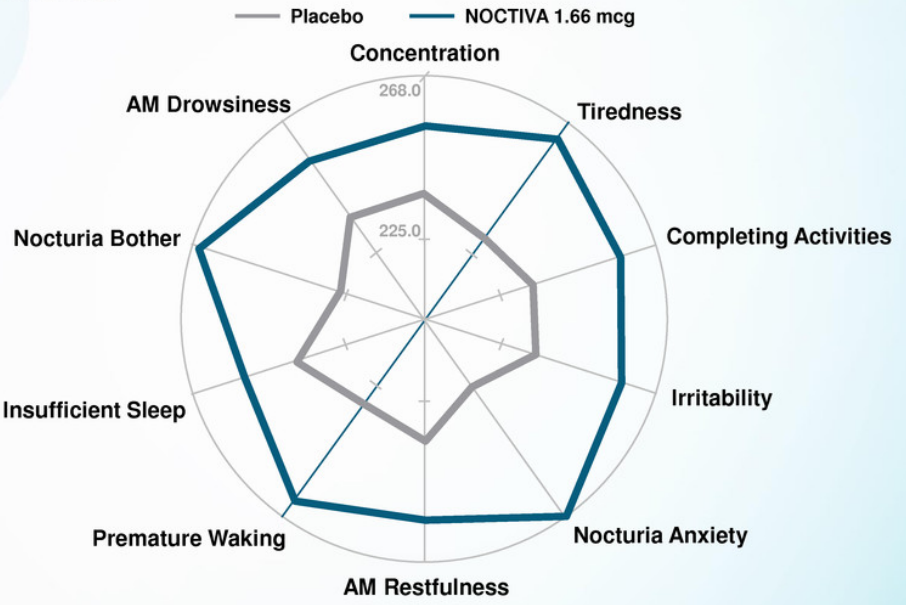


Noctiva 1.66-mg dose shows significant improvement vs placebo.

INTU consists of 10 items and is a reliable and validated patient-reported outcome that measures impact of nocturia

1. Rovner E, Bennett J, Abrams S, et al. Improvement in patient-reported treatment benefit and health-related quality of life following treatment with ser-120 among patients with nocturia. Poster presented at: Society for Urodynamics and Female Urology (SUFU); February 28-March 4, 2017; Scottsdale, AZ.

O'Brien multivariate rank analysis for INTU items: change from screening to treatment[1]



Axis Length is Mean Rank. The highest rank represents the greatest reduction among all change values of an outcome variable in the pooled set of 2 samples.

ITT population-pooled analysis.

1. Data on file. Avadel Specialty Pharmaceuticals, LLC.

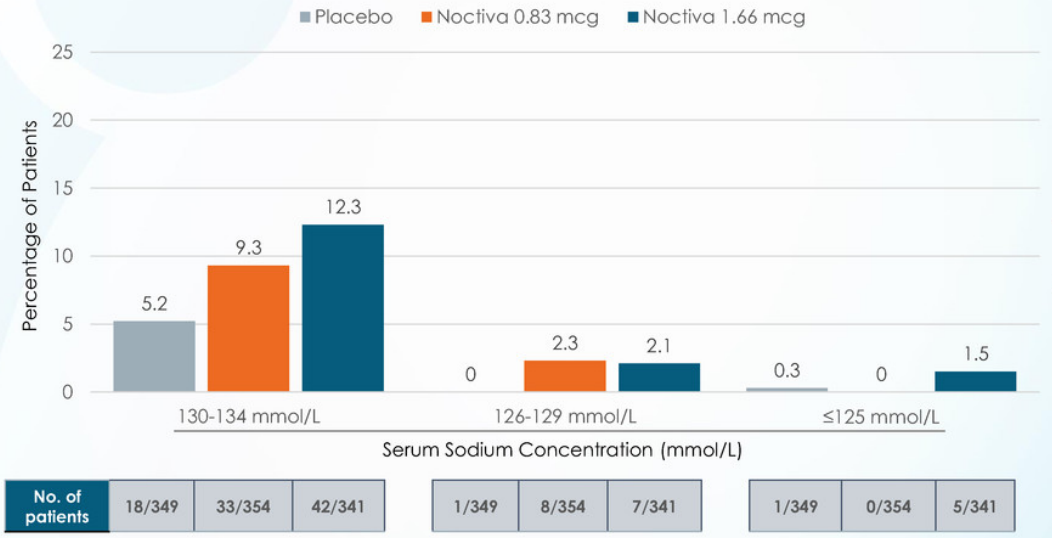
Noctiva™
(desmopressin acetate) Nasal Spray

Integrated Summary of Safety

Overview of hyponatremia data

Incidence of serum sodium concentration below normal range[1]

DB3/DB4 Studies



No. of patients	18/349	33/354	42/341	1/349	8/354	7/341	1/349	0/354	5/341

- Patients ≥65 had a higher risk of hyponatremia
- Rate of hyponatremia was similar in men and women

1. Noctiva [package insert]. Chesterfield, MO: Avadel Specialty Pharmaceuticals, LLC; 2017.

Incidence of patients with nadir serum sodium post baseline by serum sodium range[1]

ISS ELD/OL1/DB3-A2 Studies, Safety Population

Serum Sodium Range (mmol/L)	Noctiva 1.66 mcg N=358 n (%)	Noctiva 0.83 mcg N=238 n (%)
130-134	43 (12.0)	13 (5.5)
126-129	1 (0.3)	0
≤125	0	0

- In a 2-year, open-label extension study, no patient using 1.66 mcg Noctiva reported an occurrence of hyponatremia

Note: The N (%) from 0.75-mcg group is based on the number of patients from the ELD and OL1 studies. Treatment period for the ELD study was 8 weeks while the treatment period for the OL1 study was 43 weeks.

1. Data on file. Avadel Specialty Pharmaceuticals, LLC.

Noctiva™ (desmopressin acetate) Indication and Boxed Warning

- **INDICATIONS AND USAGE**: Noctiva is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
  - Limitation of Use: Not studied in patients younger than 50 years of age.

WARNING: HYPONATREMIA

Noctiva can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest or death.

Noctiva is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.

Ensure serum sodium concentrations are normal before starting or resuming Noctiva. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.

If hyponatremia occurs, Noctiva may need to be temporarily or permanently discontinued.

Please see the full Prescribing Information for Noctiva at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201656lbl.pdf

Noctiva Important Safety Information (continued)

- **CONTRAINDICATIONS:** Hyponatremia or a history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate below 50 mL/min/1.73 m^2, Syndrome of inappropriate antidiuretic hormone secretion (SIADH, during illnesses that can cause fluid or electrolyte imbalance, New York Heart Association (NYHA) Class II-IV congestive heart failure, uncontrolled hypertension
- **WARNINGS AND PRECAUTIONS**
  - **Fluid retention:** Not recommended in patients at risk of increased intracranial pressure or history of urinary retention. Monitor volume status in patients with NYHA Class I congestive heart failure.
  - **Nasal conditions:** Discontinue in patients with concurrent nasal conditions that may increase absorption, until resolved.
- **ADVERSE REACTIONS:** Common adverse reactions in clinical trials (incidence >2%) included nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension / blood pressure increased, back pain, epistaxis, bronchitis and dizziness.
- **DRUG INTERACTIONS:** Monitor serum sodium more frequently when Noctiva is concomitantly used with drugs that may cause water retention and increase the risk for hyponatremia (e.g., tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine, opiate analgesics, nonsteroidal anti-inflammatories, lamotrigine and carbamazepine).
- **USE IN SPECIFIC POPULATIONS**
  - **Pregnancy:** Use of Noctiva is not recommended.
  - **Pediatric:** Do not use Noctiva for primary nocturnal enuresis in children.

Please see the full Prescribing Information for Noctiva at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201656lbl.pdf

Noctiva™
(desmopressin acetate) Nasal Spray

A Clinician's Perspective

Steve A. Kaplan, MD

Professor of Urology, Icahn School of Medicine at Mount Sinai

Director, Benign Urologic Diseases and The Men's Health Program, Mount Sinai Health System

Noctiva is not yet available for prescription.

Summary point 1

Noctiva™ (desmopressin acetate) Nasal Spray

Nocturia is an under-recognized condition

- Out of an estimated 40 million Americans with nocturia, only approximately 11 million have been diagnosed[1-4]
- Prevalence increases with age[5]
- Nocturnal polyuria impacts 4 out of 5 people with nocturia[6-8]

1. QuintilesIMS Secondary Research.
2. Lee LK, Goren A, Zou KH, et al. Potential benefits of diagnosis and treatment on health outcomes among elderly people with symptoms of overactive bladder. *Int J Clin Pract*. 2016;70(1):66-81.
3. Decision Resources. Treatment Algorithm in OAB.
4. Vuichoud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. *J Urol*. 2015;22(51):1-6.
5. Markland AD, Richter HE, Fwu CW, Eggers P, Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. *J Urol*. 2011;186(2):589-593.
6. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn*. 2004;23(4):322-330.
7. Chang SC, Lin AT, Chen KK, Chang LS. Multifactorial nature of male nocturia. *Urology*. 2006;67(3):541-544.
8. Weiss JP. Prevalence of nocturnal polyuria in nocturia. *J Urol*. 2009;181(4):538.

Summary point 2

Noctiva™ (desmopressin acetate) Nasal Spray

Nocturia has important consequences for health, lifestyle, and work

- Nocturia sufferers may have an elevated risk of diabetes, hypertension, coronary heart disease, and death[1]
- Nocturia significantly impacts daily functioning[2,3]
- Those who awoke at least 3 nights per week to void had a statistically significant increase of daytime sleepiness, naps, and sick leave[4]
- Nocturia is a strong predictor of falls and mortality[5-9]

1. Lightner DJ, Krambeck AE, Jacobson DJ, et al. Nocturia is associated with an increased risk of coronary heart disease and death. *BJU Int.* 2012;110(6):848-853.
2. Tikkinen KA, Johnson TM, Tammela TL, et al. Nocturia frequency, bother, and quality of life: how often is too often? A population-based study in Finland. *Eur Urol.* 2010;57(3):488-496.
3. Sintonen H. The 15D instrument of health-related quality of life: properties and applications. *Ann Med.* 2001;33(5):328-336.
4. Ohayon MM. Nocturnal awakenings and comorbid disorders in the American general population. *J Psychiatr Res.* 2008;43(1):48-54.
5. Stewart RB, Moore MT, May FE, Marks RG, Hale WE. Nocturia: a risk factor for falls in the elderly. *J Am Geriatr Soc.* 1992;40(12):1217-1220.
6. Bliwise DL, Foley DJ, Vitiello MV, Ansari FP, Ancoli-Israel S, Walsh JK. Nocturia and disturbed sleep in the elderly. *Sleep Med.* 2009;10(5):540-548.
7. Ponholzer A, Temml C, Wehrberger C, Marszalek M, Madersbacher S. The association between vascular risk factors and lower urinary tract symptoms in both sexes. *Eur Urol.* 2006;50(3):581-586.
8. Parsons JK, Mougey J, Lambert L, et al. Lower urinary tract symptoms increase the risk of falls in older men. *BJU Int.* 2009;104(1):63-68.
9. Kupelian V, Fitzgerald MP, Kaplan SA, Norgaard JP, Chiu GR, Rosen RC. Association of nocturia and mortality: results from the Third National Health and Nutrition Examination Survey. *J Urol.* 2011;185(2):571-577.

Summary point 3

Noctiva™ (desmopressin acetate) Nasal Spray

We finally have a safe and effective nocturia* therapy for both men and women

- Noctiva is the first and only FDA-approved treatment for nocturia[1]*
- Noctiva effectively treats nocturia using 1/100th of the desmopressin dosage of other formulations[2,3]
- Noctiva decreased nocturic episodes, lengthened the time to first void, and decreased nighttime urine volume[4]
- Noctiva significantly improved quality of life in patients with nocturia[2]
- Risk of hyponatremia was low, with a similar incidence in men and women[2]

*Due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

1. US Food and Drug Administration. FDA approves first treatment for frequent urination at night due to overproduction of urine. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm544877.htm. Published March 3, 2017.
2. Noctiva [package insert]. Chesterfield, MO: Avadel Specialty Pharmaceuticals, LLC; 2017.
3. DDAVP nasal spray [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC.
4. Cohn JA, Kowalik CG, Reynolds WS, et al. Desmopressin acetate nasal spray for adults with nocturia. *Exp Rev Clin Pharmacol*. 2017. doi:10.1080/17512433.2017.1394185

Noctiva™
(desmopressin acetate) Nasal Spray

Commercial Strategy and Launch Update

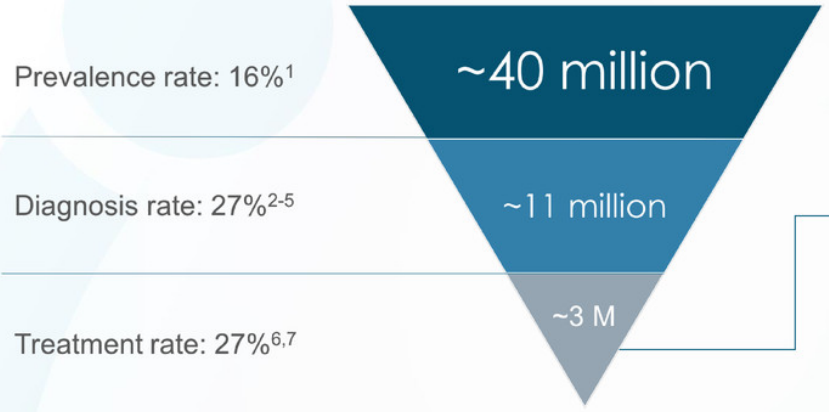
Greg Divis, Executive Vice President and
Chief Commercial Officer
Avadel

Highlights

- Market overview
- Situation analysis—recent key learnings
  - Prescriber
  - Patient
  - Payer
- Brand strategic plan
- Launch update and timing
- Physician segmentation and field force update
- Key financial highlights
- Summary

Nocturia market overview

Noctiva™ (desmopressin acetate) Nasal Spray

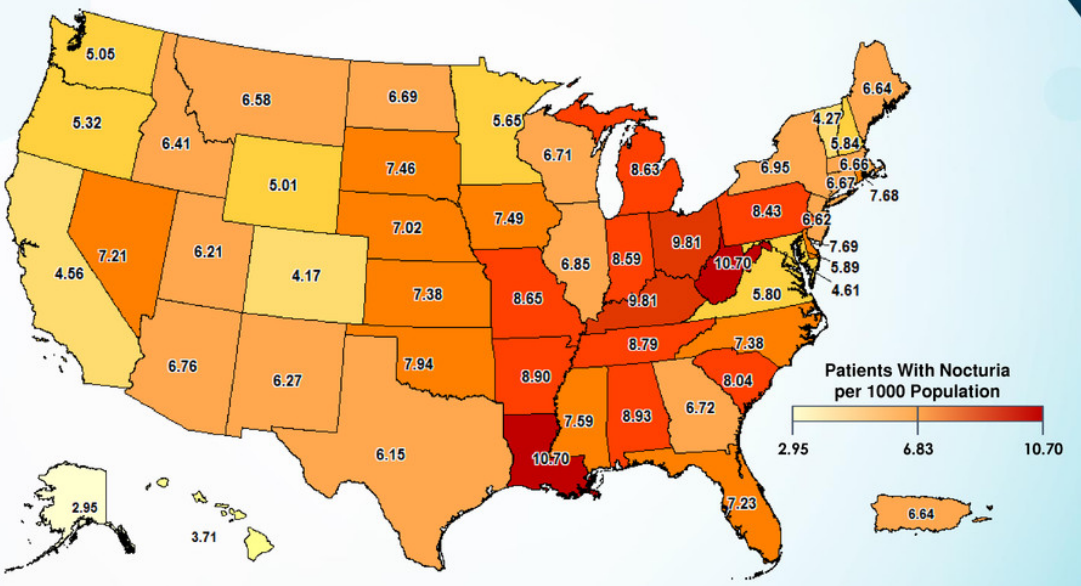


- ~50% Dx nocturia alone
- ~50% Dx nocturia with other (OAB/BPH)
- 6 to 12 million[8] annual TRxs
- $2B+[8] current annual market value

Attractive existing market with significant upside for market expansion

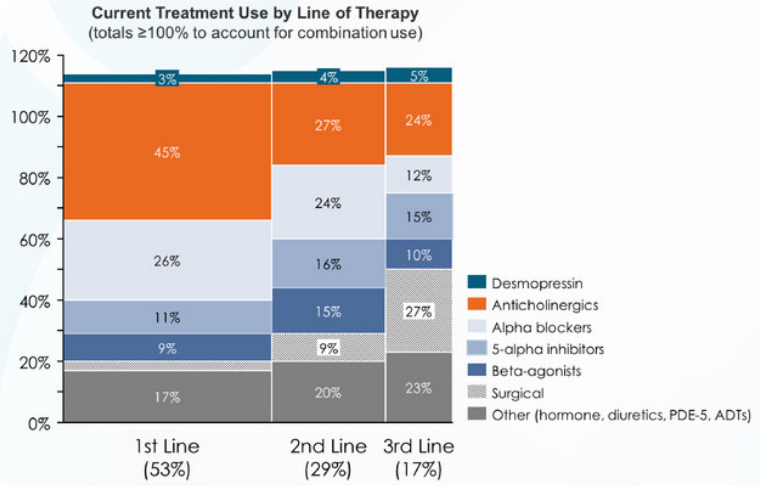
1. Bosch JLH, Weiss JP. The prevalence and causes of nocturia. *J Urol*. 2010;184(2):440-446.
2. QuintilesIMS Secondary Research.
3. Lee LK, Goren A, Zou KH, et al. Potential benefits of diagnosis and treatment on health outcomes among elderly people with symptoms of overactive bladder. *Int J Clin Pract*. 2016;70(1):66-81.
4. Decision Resources. *Treatment Algorithm in OAB*.
5. Vuichoud C, Loughlin KR. Benign prostatic hyperplasia: epidemiology, economics and evaluation. *J Urol*. 2015;22(51):1-6.
6. Helfand BT, Evans RM, McVary KT. A comparison of the frequencies of medical therapies for overactive bladder in men and women: analysis of more than 7.2 million aging patients. *Eur Urol*. 2010;57(4):586-591.
7. Goldman HB, Anger JT, Esinduy CB, et al. Real-world patterns of care for the overactive bladder syndrome in the United States. *Urology*. 2016;87:64-69.
8. Data on file.

At a state level, the highest nocturia prevalence rates tend to occur in the Midwest and South Central states



Source: QI Nocturia Predictive Modeling October 2017 based on Xponent and Claims Databases, MAT July 2017. US Census projected population data 2016.

Anticholinergics and alpha-blockers are the most common treatments for nocturia due to OAB and BPH overlap



Physicians will treat patients based upon the presentation and etiology of nocturia

- Patients with other comorbidities, such as diabetes, hypertension, or infections, will be treated for those conditions first unless nocturia is a primary patient complaint
- Older desmopressin formulations currently used primarily when no other underlying conditions appear with nocturia

Sources: Physician interviews, physician survey. July 2017.

Current branded treatments and price points

Product	WAC	Package Size
VESIcare Oral Tablet 10 mg or 5 mg (same price)	$314.77	30 tablets
Detrol LA Oral Capsule Extended Release 24 Hour 2 mg	$365.00	30 capsules
Ditropan XL – Ditropan XL Oral Tablet Extended Release 24 Hour 10 mg	$636.12	100 tablets
Myrbetriq Oral Tablet Extended Release 24 Hour 25 mg	$323.45	30 tablets
Flomax Oral Capsule 0.4 mg	$731.45	100 capsules
DDAVP Nasal Solution 0.01%	$439.36	5 mL

Average daily costs range between ~$10-$15/day

Source: PriceRx database query conducted by IQVIA on 11/9/2017.

Situation and insights

Comprehensive, ongoing market research with HCPs, patients, and payers

400+
interviews with urologists, OB/GYNs, UroGYNs, PCPs, NPs, and PAs

400+
patients included in qualitative and quantitative studies

40+
interviews with P&T committee members within large national and regional MCOs

HCPs' ability to offer patients symptomatic relief from nocturia is variable

Most doctors acknowledge that current treatments don't work well on nighttime symptoms

- Nocturia is typically **discovered** during routine H&P or "review of systems" and tends to be more frequently talked about directly with patients by urologists and OB/GYNs

- HCPs look at nocturia as a **symptom** and do their best to identify and address the underlying cause, whether it is (1) a medical condition like BPH, (2) behavioral/ lifestyle choices, or (3) medication-related (eg, loop diuretics)

- While their **results vary** in addressing patients' nocturia, depending upon the cause, it is generally understood that medical treatments (eg, anti-cholinergics) do not work well on nighttime symptoms[1]

Source: Physician interviews. October 2017.

1. Van Kerrebroeck P, et al. Nocturia research: current status and future perspectives. *Neurourol Urodyn.* 2010;29(4):623-628.

HCPs believe the way to highlight the importance of addressing nocturia is to point out that it can substantially impact QoL

They recommend emphasizing individual QoL benefits

- Rather than focus on one particular effect of nocturia, HCPs told us that **improving the patient's QoL is the paramount goal** in addressing nocturia: helping the patient to enjoy an uninterrupted night's sleep will yield multiple QoL and health-related dividends

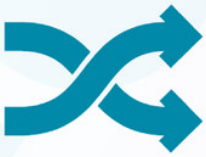
- While not a sleep story, per se, HCPs feel that the value of addressing nocturia is promoting a more "sustained, restorative" sleep, which in turn yields differential benefits, depending upon the patient type (eg, more productivity for those who are working, safety for older patients) and expected associated benefits of improved sleep

- In seeking to encourage a greater focus on nocturia, HCPs emphasize that while offering symptomatic relief is an important goal, looking for the underlying cause of the nocturia remains their medical responsibility

Source: Physician interviews. October 2017.

Impact of nocturia on patients is variable: for most, it is frustrating but viewed as a natural consequence of aging

Most people experiencing nocturia are unaware that this condition even has a name



Variability is driven by:

- Frequency of sleep disruptions
- Ease of falling back to sleep
- Ability to accommodate sleep disruptions
  - Impacts working patients more
- Other comorbid health issues
- Impact on partner sleep

Nocturia is seen by most as a natural consequence of aging:

- Onset is gradual
- It is often not discussed with the HCP
- May be associated with other urinary conditions (eg, BPH, OAB)
- Not seen as treatable

There are different segments of patients experiencing nocturia

- Variation is driven by
  - Bother
  - Ability to fall back to sleep
  - Age
  - Work status
  - Comorbidity

Source: Patient interviews. October 2017.

Patients face barriers in talking to doctors about their nocturia—they don't (yet) have a name for it

Why It Gets Raised	Why It Does Not Get Raised or Addressed
• Patient has other urinary symptoms, particularly daytime symptoms (OAB, BPH) • The patient's nocturia is very bothersome (multiple voids a night, inability to fall back to sleep) ○ It is significantly impacting the patient's ability to function during the day, esp. function on the job	• A natural part of the aging process • Lack of awareness of potential treatment options • The onset is gradual that it's often hard to notice that there is a problem • Symptoms are often forgotten about during the day • Belief that a "weak bladder" is a natural condition after having children • Belief that symptoms are not (or are) a "red flag" of a potentially serious underlying medical condition

Physician and patient education early and often is key

Source: Patient interviews. October 2017.

Payers do not actively manage or monitor nocturia as it is a low-cost area for plans and lower priority overall

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Current Market Access Environment

Management	• **Low priority is placed on nocturia because it is a low-cost, low-burden lifestyle disease** • Coverage is mostly dependent on cost of the product and generic availability
Formulary Positioning	• At launch, majority of branded products will be placed on tier 3 for both commercial and Medicare plans • **Contracting and rebates are needed for preferred tiering (especially Part D)**
Restrictions	• "Me too" products run the risk of restrictions and non-coverage, particularly on Medicare plans • Step edits are common for high-cost products or branded products with generic availability

*"We don't have any case management [for nocturia]; it's really not on our radar screen. If you think about what we call basically urinary incontinence, **that borders on a lifestyle-type disease state and therefore we don't put a lot of emphasis on that.** Health plans are dealing with expensive orphan or oncology drugs, so this is really way down the line for us."*

- MCO Payer

*"**Tiering is based on price, cost, and contracting.** For new agents where contracting isn't good, we put them on tier 3. For example, Myrbetriq is currently non-preferred with step edits."*

- MCO Payer

Source: Payer interviews. July 2017.


Today
No specific treatment for nocturia; payers are focused elsewhere; HCPs and patients are frustrated
Future
Noctiva – a treatment of choice for nocturia for payers, HCPs, and patients


Today
No specific treatment for nocturia; payers are focused elsewhere; HCPs and patients are frustrated
Our approach
Pre-Launch
Energize
the market early and often
Specialist-Focused
Establish
leading market position among specialists quickly
Market Expansion
Expand
to drive broad market adoption
Future
Noctiva - a treatment of choice for nocturia for payers, HCPs, and patients

Overarching launch plan

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Energize
the market early and often

- ***Shape market by educating*** *high-value HCPs and payers*
- ***Ensure positive first experiences for target HCPs and their patients*** to drive early adoption
- ***Integrate and educate patients*** to self-identify and "get in line" for new treatment

Establish
leading market position among specialists quickly

- ***Target key prescribers of currently treated patients and create advocates*** to drive rapid uptake
- ***Drive patients with unresolved symptoms to demand*** the first and only FDA-approved treatment

Expand
to drive broad market adoption

- ***Expand prescriber base to diagnose and treat with Noctiva*** as their first-line choice
- ***Build broad consumer awareness*** *to drive diagnosis and treatment with Noctiva*

Launch update and timing

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Q4'17	Q1'18	Q2'18	Q3'18	Q4'18

Phase 1: Foundation building

Objectives:

- Secure top talent for key positions
- Prepare Noctiva for specialty-focused launch, including full campaign
- Develop relationships with key opinion leaders and professional organizations
- Develop economic and clinical value proposition for Noctiva, and begin payer outreach to prioritized accounts

Phase 2: Disease-state education and early experience

Objectives:

- Raise awareness with HCPs with a focused disease-state educational campaign
- Ensure positive early experiences with a targeted patient access and assistance program
- Implement early access program(s) through "soft launch" with controlled distribution
- Payer and market access engagement

Phase 3: Full commercial specialty-focused launch

Objectives:

- Maximize the value of Noctiva with high nocturia-treating specialists
- Partner with large group practices to drive efficiencies while ensuring broad reach through sales team
- Employ disruptive patient identification and engagement programs
- Execute coordinated medical publication strategy to ensure a continuous flow of clinical data
- Expand payer coverage reach and Part D contracting

Organizational build update

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Market Access

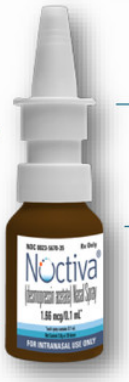
4 National Account Managers + contracted team

1 Patient Access and Reimbursement Lead

Medical & Clinical

8 MSLs, contracted

1 Medical Lead, contracted part-time



Marketing

1 Head of Urology

2 Brand Team Members

Sales Management

1 Head of Sales

8 District Managers

Sales Team

80 Reps covering ~10,000 high-volume prescribers

Contracted through leading CSO

All teams (except sales reps) to be on board by December 2017.
Sales team by January 2018

Sales force size and structure

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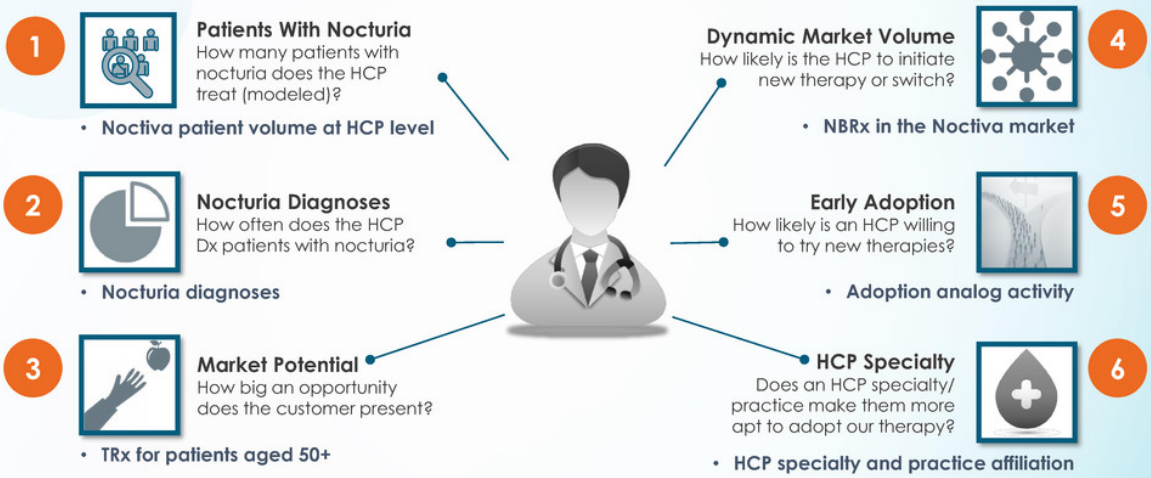

HCP segmentation and valuation framework is primarily based on 6 key dimensions

Source: Avadel/QI - Sales Force Design for Noctiva – HCP Segmentation.

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As might be expected, top nocturia market writers tend to cluster in metropolitan areas

Source: QI Nocturia Segmentation and Predictive Modeling October 2017 based on Xponent and Claims Databases, MAT July 2017.

80 optimized territories cover ~81% of targeted HCPs and ~90% of all current nocturia diagnosis claims

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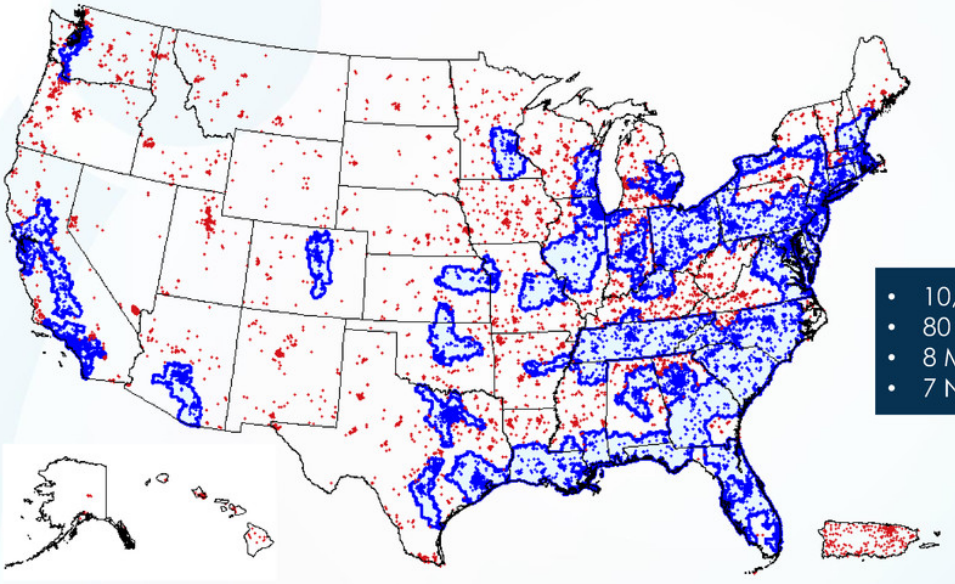

- 10,000+ specialty targets for year 1
- 80 Reps making up 8 total districts
- 8 MSLs aligned against districts
- 7 NAMs against prioritized payers

Source: QI Nocturia Segmentation and Predictive Modeling October 2017 based on Xponent and Claims Databases, MAT July 2017.00.

Key financial updates

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Transformational opportunity requires significant and disciplined investment

2018 launch investment of $50M+	• ~50% on new teams • ~20% on promotional campaign • ~20% on educational campaign • ~10% on other (data, research, PMR, etc)
Market uptake	• Expected to be impacted in the first couple of years due to market education and activation investments coupled with time to secure Part D preferred access
Pricing assumption	• Competitive to most commonly used branded agents currently prescribed

Revenue opportunity

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Specialist-focused launch

$250M-400M peak revenue opportunity

Assumes **6% to 10%** penetration of currently treated pool at peak

Maximizing the specialist opportunity will lead to expanding our treater base and building broader condition and Noctiva awareness.

Expanded launch opportunity

$500M-750M+ revenue opportunity

Assumes **11% to 15+%** penetration and a 20% growth in the treated patient pool at peak

Summary

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- A Transformational opportunity for Avadel
- B Innovative and differentiated product
- C First and only FDA-approved medication in highly prevalent condition
- D Documented serious health-related consequences of no or ineffective treatments
- E Strong IP position (2030) with exclusive state-of-the-art manufacturing facility

Noctiva provides significant growth catalyst and potential value creation opportunity for our shareholders

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Q&A

Closing remarks

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Past 1990-2012	Present 2012-2017	Future 2018 and beyond…
• ***Focused on drug delivery and life-cycle plays for large pharma*** with no internal pipeline or long-term growth strategy • ***Unprofitable with only one product approval.*** No *organizational direction or growth plan*	• ***Profitable with internal pipeline development:*** enabling *growth organically and through business development*	• ***5-year plan:*** *Growing specialty pharma company* • *$500+ million in sales* • *>$1B market cap* • *Distinctive product offerings for patients and providers*

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Thank You