

Nasdaq: NYMX

"... working to introduce a new, safe, efficacious and long-lasting therapy to the millions of men suffering from an enlarged prostate gland (BPH)".

Normal Prostate



**Enlarged Prostate** 



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#### **TODAY'S PRESENTATION OUTLINE:**

- 1) THE PROMISE AND THE OPPORTUNITY, WHO WE ARE
- 2) RECENT HISTORY OF THE COMPANY
- 3) CLINICAL DATA HIGHLIGHTS
- 4) THE FUTURE



#### NYMOX' MISSION

NYMOX IS DEVELOPING A NOVEL, PROPRIETARY TREATMENT FOR A CHRONIC CONDITION THAT NEGATIVELY IMPACTS THE LIVES OF MOST AGEING MEN ABOVE 60 AROUND THE WORLD:



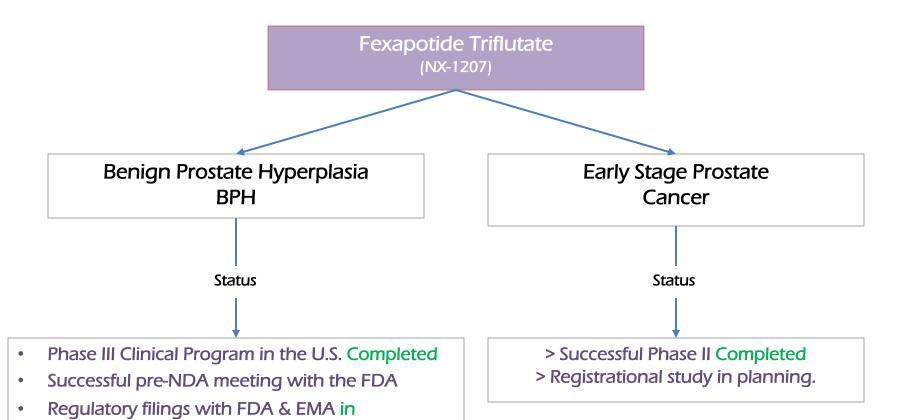
#### BENIGN PROSTATIC HYPERPLASIA (BPH)\*)





<sup>\*)</sup> Worldwide incidence of >100M men today.

#### **Main Assets**



preparation

Successful production scale-up achieved.



# THE NYMOX TREATMENT for BPH

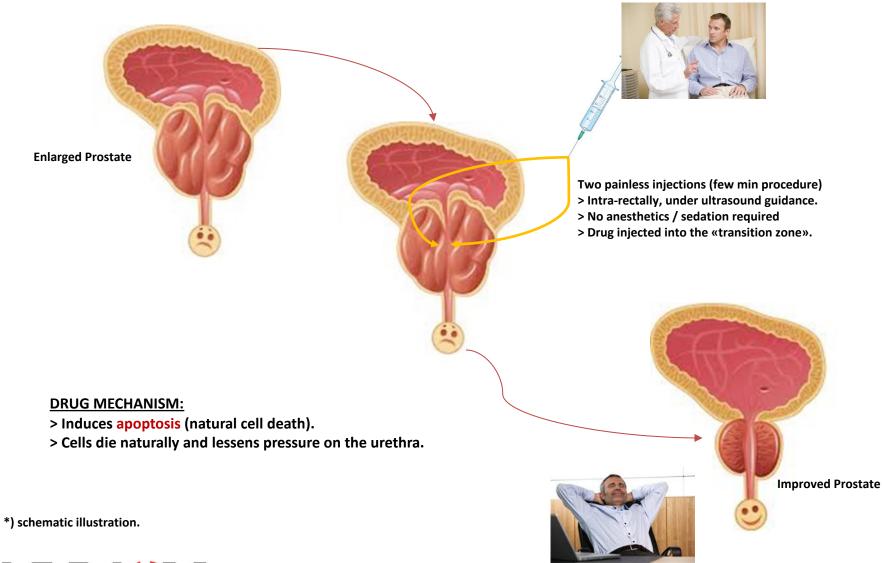


### Drug Name: Fexapotide Triflutate (FT)

(formerly NX-1207)



#### Transrectal Injection Into the Prostate





#### Status of Clinical Program in BPH:

- Two large Phase III Trials in the United States: COMPLETED
- More than 70 clinical sites across the U.S. involved.
- More than 970 men treated in the Phase III Program.
- Up to five-year clinical follow-up on study-participants.

#### **Nymox Comments:**

- ✓ No uncertainty about future clinical study results.
- ✓ Treatment effect is now well established and documented.



#### Demonstrated Long-term Clinical Benefits:

- Long-lasting BPH Symptom Relief (>7 years), based on one treatment. Treatment
  can be safely repeated with additional therapeutic benefit.
- FT Treatment provides 2-3x symptom relief effect seen with oral medication, which has side-effects.
- Excellent Safety: No drug related adverse side-effects. Improved sexual function.
- Statistically significantly reduced incidence of prostate cancer over the long-term.
- Statistically significant reduced need for surgical intervention long-term.
- All alternative treatment options (oral medication, minimally invasive procedures and surgery) are all associated with clinically meaningful adverse side-effect profiles.

### Efficacy Results Summary From U.S. Phase III Study Change From Baseline = Benefit to Patient

- **5.7 points improvement** at 3.6 years after single injection
- **6.6 points improvement** in first-line patients (**treatment naïve**) at 3.6 years after single injection.
- > 8 points improvement after 2 injections.

#### **Comment:**

Patients have substantial symptom improvement as soon as 10 days after treatment. Long-term a second injection confers on average over 8 points IPSS improvement from baseline.

Sounds "too good to be true?"



#### Fexapotide Triflutate Data Has Been Scrutinized

- Nymox Phase III clinical trial results have been presented multiple times by leading U.S. urologists at regional and national AUA meetings in 2017 and 2018.
- Study results published and discussed in:
  - World Journal of Urology (January 2018)
  - Therapeutic Advances in Urology (January 2019)



World Journal of Urology https://doi.org/10.1007/s00345-018-2185-v

Fexapotide triflutate: results of long-term safety and efficacy trials of a novel injectable therapy for symptomatic prostate enlargement

Neal Shore 1 ○ · Ronald Tutrone 2 · Mitchell Efros 3 · Mohamed Bidair 4 · Barton Wachs 5 · Susan Kalota 6 · Sheldon Freedman James Bailen Schichard Levin Stephen Richardson Schalbert Stephen Richardson Scholars Sallen Scholars Scholar Scholars Sc Barry Shepard 13 · Kenneth Goldberg 14 · Alan Hay 15 · Steven Gange 16 · Ivan Grunberger 17



#### Nymox: Development History

- Phase 3 study results showed the 12 months post treatment primary endpoint failed in November 2014 and therefore longer-term follow-up study was required to determine drug efficacy.
- The company performed additional long-term extension study protocols and outcome analysis up to 6 years post-treatment.
- In 2015, the company announced that the long-term follow up data met the primary endpoint long- term and there was statistically significant treatment benefit in FT treated patients versus placebo.



#### Multiple Long-term Treatment Benefits of FT:

- Cancer Benefit (June 2016): Company reported significantly lower incidence of prostate cancer in FT treated men in its Phase III Study Program for BPH.

  Median follow up time: 5 years. FT Cancer Incidence: 1.3%, Placebo: 6.3%.
- Less Need for Surgery (August 2016): For patients in the Phase III BPH trial who initially received placebo and subsequently crossed over to either FT or conventional therapies, there was an 82-95% reduction in the eventual need for surgery in the FT treated group.
- Repeat FT Treatment (October 2016) is safe and induces long-term BPH symptom relief up to 6 years after initial treatment.
- Superior results (symptom relief) both short- and long-term in treatment naïve men (November 2016).
- Improved sexual function in FT treated group (May 2017)



#### Strong Clinical Data has allowed Company to Recover

- Access to significant capital in spring 2018; USD 18M.
- Adequately financed to complete regulatory process.
- Clean, straight equity at a 10% discount to the market.
- Strong, supportive shareholders that invest in our BP.
- Insiders participated in the financing.
- New capital has allowed company to significantly upgrade and expand regulatory advisory teams, both in the United States and Europe.
- Successful pre-NDA meeting with the FDA (January 2018).
- Successful CMC Meeting with the FDA (April 2019)



#### Fexapotide Therapy Summary / Profile:

At least twice as efficacious as currently used oral therapies.

No side-effects – currently prescribed therapies have significant side-effects profiles.

Durable treatment effect. Easy for patient to comply with therapy.

Cancer inhibitory properties.

Quick, painless procedure in the doctor's office.

Improved sexual function, no incontinence and no effect on testosterone levels. Maintained quality of life.



#### **Corporate Summary**

- Block-buster market opportunity; >100M potential patients WW.
- No competition. Very attractive COGS.
- Potentially Disease Modifying Treatment:
  - Almost twice as efficacious as current non-surgical treatment modalities
  - Demonstrated reduced incidence of surgery in treated patients.
  - Demonstrated reduced incidence of urinary retention in treated patients.
  - Demonstrated reduced long-term incidence in prostate cancer in treated patients.
  - No side-effects. Treatment is extremely safe.
  - Improved sexual function; no treatment induced damage to nerves.
  - Treatment can be safely repeated.
- Company owns 100% commercial rights worldwide.
- Strong IP: Several new, recently issued patents.



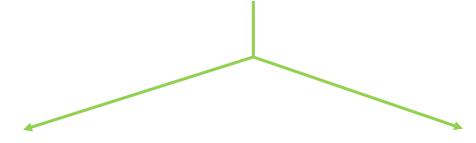
#### **Corporate Summary**

- Well financed (Q1-2019: \$11.3M) through to to completion of regulatory process.
- Shares outstanding: approx. 70M.
- Clean capital structure, no debt.
- No warrant overhang.
- No larger lingering expenses. All trials have been paid for. Only regulatory.



#### What does Nymox Represent:

## Significant Opportunity Risk / Reward



Current Market Cap: <\$120M

Blockbuster sales potential.

... many significant milestones in next year



#### Upcoming Corporate Milestones Next 12-18 Months.

- File for Regulatory Approval in the United States and Europe.
- Clinical advancement of Fexapotide Triflutate for early stage prostate cancer.
- Continue to augment and enhance management team.
- Prepare for commercialization.
- Potential Commercial Partnerships.
- Additional Clinical Publications.
- Obtain regulatory clearance for FT in BPH.





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Thank you for your attention!

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