



*Building Canada's leading specialty pharmaceutical company*

**Strategic Partnership with TherapeuticsMD**

**Exclusive License Agreement for Canada and Israel**



# About TX-001HR and TX-004HR

*Two complementary late-stage women's health products*

- TX-004HR (17B-estradiol vaginal softgel capsule) is a differentiated treatment option for vulvovaginal atrophy (VVA)
  - Vaginal softgel capsule available in multiple strengths
  - Approved in the US on May 30, 2018 for the treatment of moderate-to-severe dyspareunia (vaginal pain associated with sexual activity), a symptom of VVA, due to menopause
  - The only product in its therapeutic class to offer a 4 mcg and 10 mcg dose, the 4 mcg representing the lowest approved dose of vaginal estradiol available
- TX-001HR (17B-estradiol and micronized progesterone oral capsule) is the only fixed-dose combination of bio-identical estrogen and progesterone for the treatment of vasomotor symptoms of menopause (VMS)
  - Oral softgel capsule available in multiple strengths of estradiol and progesterone
  - Once daily continuous dosing
  - Significant improvements in both frequency and severity of hot flashes at weeks 4 and 12
  - US PDUFA date of October 28, 2018



# TX-004HR

*Differentiated treatment option for vulvovaginal atrophy (VVA)*

- **Local, Hormonal VVA Market**
  - Total market in 2017 was \$61M and grew at a 4-year CAGR of 8%.
  - Total prescriptions were approx. 1M in 2017 and grew at a 4-year CAGR of 4%
  - The market is comprised of 4 products with 2017 sales of:
    - Vagifem: reached \$49.6M
    - Premarin: reached \$6.1M
    - Estring: reached \$4.1M
    - Estragyn Vaginal Cream: reached \$1.4M
- **Key Differentiation**
  - New lowest effective dose
  - Data showing onset of action at 2 weeks
  - Dosing flexibility with different strengths
  - Easy to administer/insert
  - Less discomfort given absence of applicator
  - Mess-free administration



# TX-001HR

*Only bio-identical fixed-dose combination for the treatment of VMS*

- **Hormone replacement therapy (HRT) Market**
  - Total market in 2017 was \$116M and declining at a 4-year CAGR of 1.3%.
  - Total prescriptions were approx. 4.1M in 2017 and declining at a 4-year CAGR of 3.7%
  - Market is comprised of oral and transdermal therapies with 2017 sales of:
    - Oral products accounted for ~\$85M [branded: \$54.5M; generic:\$30.6M]
    - Transdermal products accounted for ~\$31M [branded: \$29.7M; generic:\$1.1M]
- **Key Differentiation**
  - Single combination pill may improve compliance
  - Would be the only commercially available oral combination of “bio-identical” estrogen and progesterone
  - Fewer side effects associated with bio-identical progesterone than with synthetic progestins<sup>1</sup>

<sup>1</sup> Goletiani NV, Keith DR, Gorsky SJ. Progesterone: review of safety for clinical studies. *Exp Clin Psychopharmacol* 2007;15:427–44.



# Strategic Rationale

*Building on opportunology*

- Exclusive license agreement for two late-stage products that have demonstrated efficacy and safety
  - TX-004HR has already been approved by the FDA
  - TX-001HR has an upcoming PDUFA date of October 28, 2018
- Provides Knight with an anchor with 2 differentiated products into a new specialty that is of strategic interest
- Strategic partnership between the companies through an equity investment by Knight