Mark Schoenberg, Chief Medical Officer, Urogen Pharma, New York, United States

- **Investment Rational**
  Urogen Pharma is a clinical stage biotechnology company developing non-surgical therapies for urothelial cancers. Our proprietary technology is designed to allow local delivery of therapeutic agents, and potentially improving efficacy through prolonged exposure. The company’s lead investigational mitomycin gel product, UGN-101, which has been granted orphan, fast track and breakthrough designations, is the subject of a rolling NDA that was initiated in December, 2018. Completion is expected in 2H, 2019. The company’s experienced management team is led by Liz Barrett, CEO who joined Urogen after holding significant leadership roles at Novartis, Johnson & Johnson, Cephalon and Pfizer.

- **Business Strategy**
  Urogen Pharma plans to commercialize UGN-101 in the U.S. market after anticipated FDA-approval in 1H 2020. The commercial team is already in place and hiring the relevant sales force.

- **Core Technology**
  The company’s proprietary technology is RTGel™, a reverse thermal gel that is designed to permit local delivery of therapeutic agents. The platform is designed to deliver molecules of diverse size and chemical composition over extended periods (6-8 hrs).

- **Product Profile/Pipeline**
  The company is developing three investigational drugs: UGN-101 (Phase 3, rolling NDA initiated for non-surgical treatment of low upper tract urothelial cancer ~6K patients annually), UGN-102 (Phase 2b enrolling for low-grade non-muscle invasive bladder cancer ~40K patients annually) and UGN-201 (Phase 1 start 2H 2019 for high grade NMIBC). Urogen has a licensing agreement with Allergan which is developing a combination of RTGel with Botox for the treatment of overactive bladder (OAB).

- **What’s Next?**
  Urogen will complete the NDA submission for UGN-101 in 2H 2019. Additional information regarding the UGN-102 and UGN-201 programs will be forthcoming.