# Expanding continuous pharmaceutical manufacturing into the American market

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## **Continuous Manufacturing Overview**

#### Continuous Manufacturing is Lean

- · Fast lead time of days
- Simple API formulation and drug product manufactured in one process
   Higher guality - streamlined requirements

#### Traditional Manufacturing is Rigid

- Slow lead time of months
   Complex API formulation and manufacturing across geographies
   Lower quality - recall and regulatory risks
- Lower quality recall and regulatory risks



## **Retail and Generics Supply Chain**

#### **Retail Supply Chain**

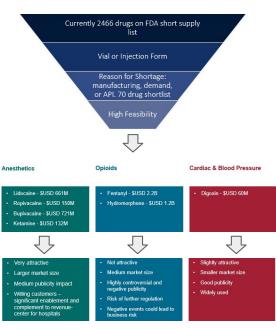
- Complex supply chain with many stakeholders
- Few players dominate with strong negotiation power
  Opaque contracts and high

regulatory barriers

#### Generic Supply Chain

- \$85B sales, \$104B by 2024
- 89% of all US prescriptions
- Transparent but lower price points and margins in market
- Race to lowest cost results in poor quality, outsourced production, supply chain disruption, drug shortages

# Short Supply Drug Market Entry



# Peptides Market Entry

## **Peptides Overview**

- Peptides are sequences of amino acids that do not require folding for function
- 45% of FDA-approved peptides are synthesized by liquid phase synthesis technique which should integrate well with CP capabilities
- 80% of peptides are finished in vial or injectable form and are administered through parenteral injection
- Multiple startups and companies in the Boston area are exploring *in-silico* peptide drug development and Continuus is well positioned to be their CDMO partner
- Small batch sizes and iterative process for drug design play to CP's strengths

## **Generics Peptides Market Attractiveness**

- USD 16.7 Billion overall peptides market Size (2022)
- 5.7% Market Growth (CAGR 2022-2030)
- · Metabolic disorders represent 35% of revenue,
- including diabetics, liver disease, NASH, etc.
- Generics have 40% revenue share of overall market
- Anumber of peptides are on the FDA short supply list, and either soon-to-be off-patent or already offpatent without a generic

- Large and growing market size
- Rise in chronic diseases fueling overall market growth, particularly in the US
- Loss of patents for many branded drugs key driver for generics growth
- Represents a strategic
   opportunity for new market entry

## **Generics Peptides Candidates**

Peptide Generic Name	Brand Name	Primary indication	US Patent Expiry	Generics on market?	Short Supply?	Est. 2022 US sales (USD Million)
Enfuvirtide	Fuzeon	HIV infection	yes	no	no	4
Ziconotide	Prialt	Pain	2024	no	no	21
Exenatide	Byetta	Type 2 Diabetes	yes	pending	no	54
Dulaglutide	Trulicity	Type 2 Diabetes, Stroke	2027	no	yes	5,800
Eptifibatide	Integrilin	Myocardial Infarction	yes	yes	yes	N/A
Octreotide Acetate	Octreolin	Hormonal Disorders	yes	yes	yes	22
Semaglutide	Ozempic	Type 2 Diabetes	2031	no	yes	6,500
Tirzepatide	Mounjaro	Type 2 Diabetes,	2036	по	yes	N/A