Prepared for Denver Metro Chamber of Commerce

Mark Spiecker – President, STAQ Pharma
Jerrod Milton – VP Operations, Children’s Hospital Colorado
Agenda

• Introductions
• STAQ Pharma team
• Market / Product Set
• STAQ Mission and Facility
• Questions
Introduction

- We are STAQ Pharma. We previously operated the largest 503A Hospice Infusion Pharmacy headquartered in the Front Range of Colorado serving approximately 1,500 patients per day with sterile, compounded medications.

- We are building a **new 503B outsourcing facility**, not converting a 503A, in accordance with cGMP Quality design and operating requirements. **Visante** is guiding us on the execution of our mission.

- Our 503B will operate with a **unique mission we call STAQ**.
  - Safety, Transparency, Availability and Quality
  - We will serve large hospitals and hospital systems by automating a very large cleanroom facility in Denver.

- We seek to be a business partner with our clients and solve / manage pharmaceutical issues together (stocking, availability, chain of custody, safety, disposal, etc...).
• **Management**
  - CEO – Joe Bagan
  - COO / Chief Pharmacist – Jeff Hval
  - President – Mark Spiecker
  - CMO – Dr. Mark Twite, Children’s Hospital Colorado
  - VP of Operations – Grayson Heller
  - Director of Quality – Melinda Sogo
  - Director of Operations – Jack Barker
  - Key Advisors, Greg Burger and Fred Massoomi (Visante)

• **Board Members**
  - Chair Joe Bagan
  - Jeff Hval
  - Mark Spiecker
  - Dan Seff (Managing Partner CBIZ MHM Audit, Tax and Business Advisory)
  - Jerrod Milton (Executive at Children’s Hospital Colorado)
  - Donna Lynne (former Kaiser Permanente Group President, Current Lt. Governor of Colorado, CEO of Columbia Health System Physicians, COO of Columbia Health)
  - Open
Market/Products

- We have spent the last few months speaking to potential Customers:

- Goals and needs in working with a 503B
  - Reduction in Recalls, Shortages, and Shipping Delays
  - Improvement in Communication
  - Standardization for the Pediatric Space
  - Simplification in Outsourcing / Compliance with USP 795/797 and 800

- Desired products, product types, and concentrations
  - Consistency in Supply at Pediatric Concentrations and Availability
  - Extended Stability (60-90 days) at Room Temperature
  - Ready to Use Pre-filled Syringes
  - PCA’s

- Safety, Transparency, Availability and Quality are Key!
Why 503B Outsourcing?

- In recent years, researchers have discovered benefits (reduced medication error rates and better utilization) from manufactured and prefilled O.R. syringes.
- Peer-reviewed literature supports a switch to prefilled O.R. syringes for 3 benefits:

  1. **Decreased healthcare cost** (pre-filled syringes, non-sterile to sterile, can often cost less than syringes filled either by Anesthesiologists or in high volume, long-dated anticipatory compounding by Hospital Pharmacy)

  2. **Decreased waste** – One Study found cost of over $185,000 in annual preventable waste at one hospital\(^1\)

  3. **Reduction in adverse events** - Easily-read labels on prefilled syringes streamline processes and reduce confusion during stressful situations

Our Mission

- We will build a facility that is singularly focused on (STAQ):
  - Safety, Transparency, Availability, and Quality

- Safety
  - Provide patients with the Right Drug, Right Concentration, Right Volume, in a package that can be used safely and effectively at the Right Time.
  - Reduce the Opioid burden by providing Right Volume in Right Concentration.

- Transparency
  - Build an Inspection Room in our facility to include a video wall with video feeds throughout our facility and all documentation needed for anyone to inspect us.
  - Build continuous improvement management techniques into the Quality Management Systems and Procedures
  - Post 483’s for all to see (i.e. put them on our website) and our actions to address the 483’s
Our Mission

• **Availability**
  - **Shield our clients from shortages** through our own ability to produce non-sterile to sterile and store finished product specifically for our clients needs.
  - Ensure the Quality Management Systems prevent recalls. Find issues before they leave the door.
  - Use sophisticated Manufacturing Planning systems to **produce what our clients need before they need it**. Connect our planning systems to Customers’ ordering systems and reduce lead times for our clients.

• **Quality**
  - **Use independent testing** to ensure Sterility, Potency, Stability, and lack of Endotoxin
  - Meet all cGMP requirements, USP 800/797/795, through smart design, build, and Quality Management System operations
  - Provide independent Certificate of Analysis with every batch
  - Provide a **Customer credit on future orders** for our customers for their expired medications
Market / Products

- STAQ Pharma Design Principles – Why we are different
  - Highly Automated / Minimal # of human touches
  - Designed as a cGMP facility that produces compounded medications – NOT a converted 503A

- Located in Denver, CO – 20 minutes from the airport with direct access to the rest of the country
- 18,400 sq.ft.
- Over 5,000 sq.ft. of cleanroom
- Non-Sterile to Sterile / Sterile to Sterile
- Initial capability to produce 10,000 syringes per day, capability up to 30,000
- Starting with 3-5 products, will expand as systems come on line
<table>
<thead>
<tr>
<th>API</th>
<th>Concentration</th>
<th>Fill Volume</th>
<th>Syringe size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>50 mcg/ml</td>
<td>2 ml</td>
<td>3 ml</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>50 mcg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>0.2 mg/ml</td>
<td>2 ml</td>
<td>3 ml</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>0.2 mg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Morphine</td>
<td>1 mg/ml</td>
<td>2 ml</td>
<td>3 ml</td>
</tr>
<tr>
<td>Morphine</td>
<td>1 mg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Ketamine</td>
<td>10 mg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Midazolam</td>
<td>1 mg/ml</td>
<td>2 ml</td>
<td>3 ml</td>
</tr>
</tbody>
</table>

Note: These products may either be made from Bulk API or Repackaged depending on the current Product Shortage list, Commercial Availability, and the then current regulatory rules and requirements.
### Potential Other Products

<table>
<thead>
<tr>
<th>API</th>
<th>Concentration</th>
<th>Fill Volume</th>
<th>Syringe size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>10 mcg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Customer directed</td>
<td>Customer directed</td>
<td>Customer directed</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>1% and 2%</td>
<td>Various</td>
<td>Various</td>
</tr>
<tr>
<td>Ropivacaine</td>
<td>Various</td>
<td>Ambulatory Pump Fill (e.g. On-Q)</td>
<td>Ambulatory Pump Fill (e.g. On-Q)</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>Various</td>
<td>20 mg/ml</td>
<td>10 ml</td>
</tr>
<tr>
<td>Succinylcholine</td>
<td>0.2 mg/ml; 0.5 mg/ml; 1 mg/ml</td>
<td>Various</td>
<td>Various</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>100 mg/ml</td>
<td>5 ml</td>
<td>5 ml</td>
</tr>
<tr>
<td>Phenylephrine HCL</td>
<td>10 mcg/ml</td>
<td>10 ml</td>
<td>10 ml</td>
</tr>
<tr>
<td>Morphine</td>
<td>10 mg/ml</td>
<td>5 ml</td>
<td>10 ml</td>
</tr>
<tr>
<td>Rocuronium Bromide</td>
<td>Customer directed</td>
<td>Customer directed</td>
<td>Customer directed</td>
</tr>
</tbody>
</table>

Note: These products may either be made from Bulk API or Repackaged depending on the current Product Shortage list, Commercial Availability, and the then current regulatory rules and requirements.
Inside View
Cargin System
Why STAQ Pharma?

- Current 503Bs try to do “everything for everybody” and are built from 503A up to 503B level- We will be focused on fewer, select clients and start with a smaller catalogue using CMO’s to build out a robust offering

- STAQ Pharma is FOCUSED on and DEDICATED to cGMP compliance. Our facility is designed and will be built for it.

- STAQ Pharma plans to involve the FDA upfront in our business plan, design and workflows. We will minimize human touch during production.

- STAQ Pharma Design Principles
  - Highly Automated / Designed as a cGMP Facility
  - Minimal # of human touches

- Questions?