2018 CATEGORY WINNER: PROJECT EXECUTION
Agenda

• Introductions to BioMarin and Speakers
• Intro to Project
  • Project Execution Plan
  • Overview of Overall Deliverable
• Execution Process
  • Design and Construction Approach
  • Concurrent Schedule
  • Contractors/Vendors truly part of a team
• Lessons Learned
  • Keys to Success
  • Improvement Opportunities
• Q&A
BioMarin Pharmaceutical Inc.

Founded: 1997

Corporate Headquarters:
San Rafael, California USA

Employees: ~ 2700 Worldwide

Commercial Operations: > 70 Countries

Focus:
Rare (Orphan) Genetic Diseases

Products address markets for which no products are currently available, or current products have major deficiencies
Proven Capabilities For Biologic Production

7 Approved Products

Distributed in 70 Countries

2 Licensed Biologic Facilities

Generating $1.5B in Worldwide Sales

>70 GMP/GLP/GCP Inspections by
FDA, EMA, MHRA, HPRA, AGES, ANVISA, PMDA, and TMMDA
Leading the Industry in Rapid and Creative Innovation for Treatment of Devastating Diseases

**First Ever Treatment for MPS Disease**

**First Sulfatase Treatment For MPS Disease**

**First Chaperone Treatment for PKU**

**First Treatment for MPS IVA Disease**

**First Enzyme Chronically Delivered by ICV Route**

**First Bacterial Enzyme Chronically Delivered by SQ Route**

**Time From Phase I to Approval**

1 Year

5 Years

10 Years

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**Aldurazyme®** (Laronidase)

**Naglazyme®** (Galsulfase)

**Vimizim™** (elosulfase alfa)

**Brineura™** (cerliponase alfa)

**Palynziq™** (pegvaliase-pqpz) Injection
About the Speakers

Carl Albertson
Project Director

Logan Kelley
Senior Project Manager
Design and Construction
June-2016: PEP Workshop – Objectives and Milestones

**MILESTONES**

- **15 JUL 16**: GURS - FROZEN SCOPE/LAYOUT
- **30 SEP 16**: BOD/PAQ/DP APPROVED
- **15 OCT 16**: GMP CM/GC
- **30 OCT 16**: FULL FUNDING
  - BOM FINALIZED
- **8 AUG 16**: BOD MTS: UPDATES FOR TIME/COST
- **15 OCT 16**: BOD MTS
- **28 FEB 17**: PEHE POWER-ON (TRANSFORMER)
  - HIRED - SOQ ON BOARD
- **16 MAY 17**: CLEAN UTILITIES (CIV/COMP/FOOD)
- **30 JUN 17**: HVAC START-UP
  - EQUIPMENT QUALIFICATION (RESOURCES)
- **31 DEC 17**: GMP MATERIAL RELEASED VIAL
35 Leveroni Project History

- Site Selection Evaluation; 35 Leveroni Selected
- Project Kick-Off, Start Demo of Office/Warehouse
- Structural and Underground Complete
- Mechanically Complete
- Engineering Run
- 1st Filled & Tested Vial

2016
- Rec’d Project approval by Board of Directors on 6/7/16

2017
- Design/Construction/IOPQ – 12-Months
- 3X Clean / Gowning; PD Run
- Facility Released for Use; GMP Run #1
- GMP Run #2
- GMP Run #3
August 4th, 2016 (2-days after project kick-off)
August 2016 – 35L Demo Underway
September 2016 – Underground Full Swing
November 2016 – Underground Complete / Structural Reinforcement
January 2017 – Hanging Duct
January 2017 – Erecting Walls
February 2017 – Ceiling Up
May 2017 – Nearly Complete
August 2017 - Ribbon Cutting
## Design Approach

<table>
<thead>
<tr>
<th>TIME</th>
<th>Design Packages</th>
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<tbody>
<tr>
<td>Demo</td>
<td>Manufacturing space Layout</td>
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<td></td>
<td>Layout Lock</td>
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<td>MEP &amp; Process Equipment Sizing</td>
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<td>MEP &amp; Process Equipment Layout</td>
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<td>Utility systems point of use identification</td>
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<td>Cost and Scope alignment (VE)</td>
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<td>Long lead MEP &amp; Process Equipment Specifications &amp; Procurement</td>
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<td></td>
<td>Cost and Scope alignment</td>
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<td>Basis of Design Lock</td>
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<td>Utility Yard</td>
<td>Design Specifications</td>
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<td>Utility Yard, MEP &amp; Process systems detailed design</td>
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<td>Process Lock</td>
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<tr>
<td>Interiors</td>
<td>Interiors and site detailed design</td>
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### Design / Spec
- Architectural
- Civil
- Structural
- Plumbing
- Mechanical
- Electrical

### Design Build
- Design / Spec
- Civil
- Structural
- Plumbing
- Mechanical
- Electrical

### Design Assist
- Process
Construction Zones

- Utility Yard Structure
- Structural Work
- Underground drains
- Roof top Equipment
- Mechanical Mezzanine
- Manufacturing Suites
- Utility Systems

BUILDING CORE

BUILDING SYSTEMS and INTERIORS
Design / Construction Overlap – 65%

Equipment procurement / Design Overlap – 100%

Facility Start up / Process Development Run overlap – 50%

GMP Runs/ C & Q documentation review – 90%
Gene Therapy Manufacturing Facility Team Breakdown

+ 50 BioMarin Employees dedicated to the project

~ 70 Design and Engineering personnel across 5 firms

Over 200 Construction contractors from ~ 40 construction companies

~ 30 Commissioning and Qualification engineers from 3 firms
# Owner / Vendor / Contractor Integrated Teams

Integrated Owner, Design, Construction leadership team

- **Teams Organized by discipline – not by contract**
- Team 1
- Team 2
- Team 3

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<thead>
<tr>
<th>Facilities / Manufacturing Operations</th>
<th>Team 1</th>
<th>Team 2</th>
<th>Team 3</th>
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<tr>
<td>Facilities / Manufacturing Engineering &amp; EHS&amp;S</td>
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<tr>
<td>Architectural &amp; Engineering firm</td>
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<td>General Contractors</td>
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<td>Design / Build Engineers</td>
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<td>ASC / MEP Construction teams</td>
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Winter 2017 Exterior Construction
Foundational Elements for Success

- BEAM
- Clear Objectives / Defined PEP
- Dedicated/Co-Located Project Team
- Excellent Alternatives Analysis
- Well defined Basis of Design
- Robust Contract Strategy with proven partners (DB-DA)
- BMRN Resource Support
- Single Unilateral Vision from Senior Leadership
- Good communication & Coordination
- Early Start/Well Planned OPR/TT
- Maintaining Motivation

Improvement Opportunities

- Project Team challenges
  - Senior Planner
  - C&Q Planning & PM alignment
  - Document Manager
- Fit-for-Purpose Schedule
- Procurement Workarounds
- Document Management
- Turnover Management
- MC-IV / Shakedown C-OV / CCC
Motivation – Patients
THANK YOU