



Corporate Presentation
September 2009

Forward Looking Statements

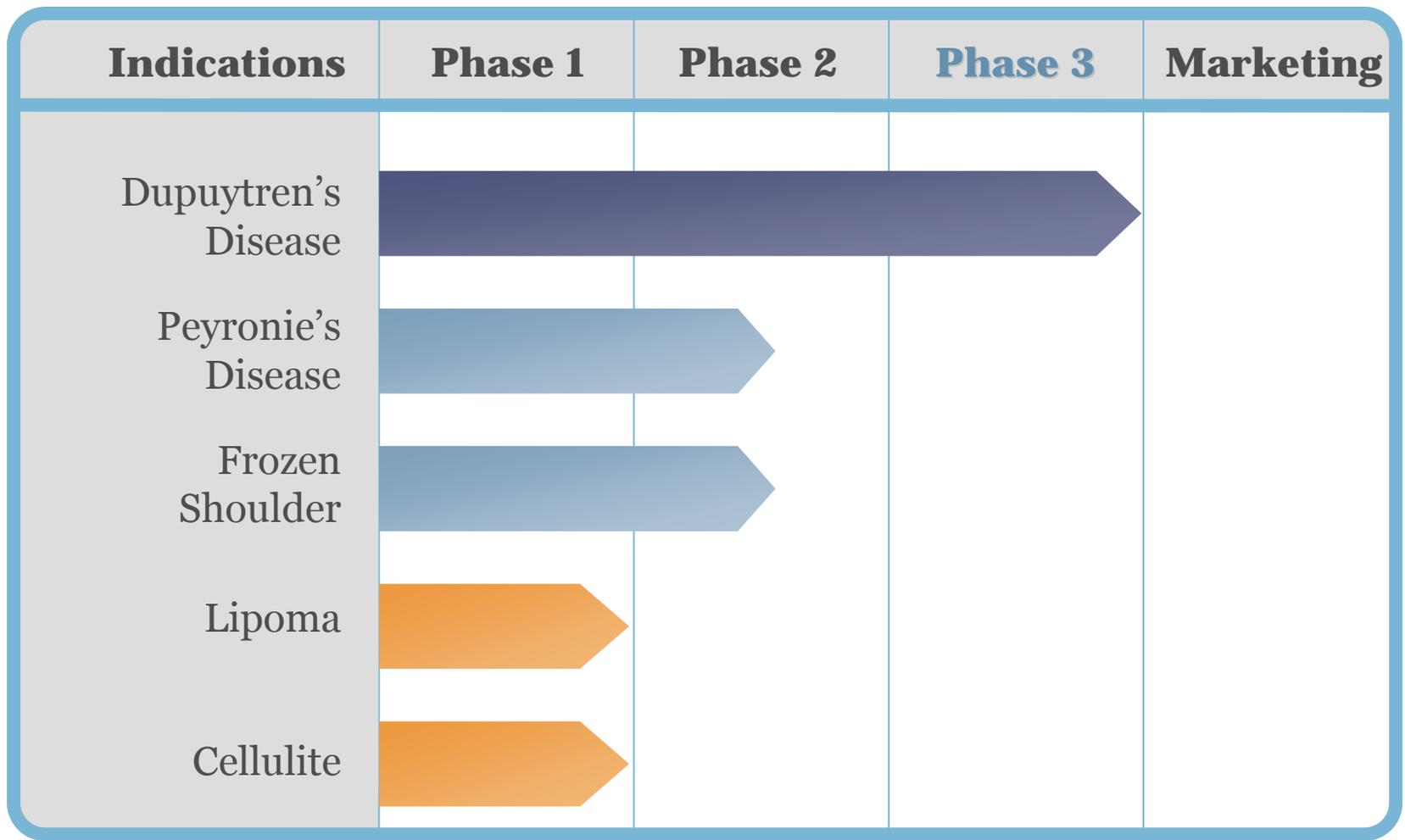
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Highlights

- ▶ BioSpecifics develops and commercializes collagenase-based products
 - Collagenase is an enzyme that breaks down collagen
 - Over 2200 patients treated; tested in 11 indications
- ▶ Partnered with Auxilium for development of injectable collagenase (XIAFLEX™)*
 - Low double digit royalties; markup on COGS
 - Additional payments to come from Auxilium-Pfizer EU development and commercial partnership
- ▶ Lead indications for XIAFLEX™
 - **Dupuytren's Disease** – BLA accepted with priority review; September 16 FDA Advisory Committee date
 - **Peyronie's Disease** – Completed enrollment in Phase 2b
 - **Frozen shoulder** – Completed Phase 2a
- ▶ Expect sufficient cash to fund operations through first half of 2012

* Trademark of Auxilium Pharmaceuticals

Deep Product Pipeline



Auxilium XIAFLEX™ Development and Commercialization Partnership

- ▶ \$15.4 million received to date
- ▶ Future milestones for:
 - Additional indications
 - Regulatory submissions and approvals in US or EU
 - Percentage of sub-licensing fees
- ▶ Future low double digit royalties as % of worldwide net sales
 - Includes sub-licensees
 - Flat rate, no tiering
 - Additional markup on COGS

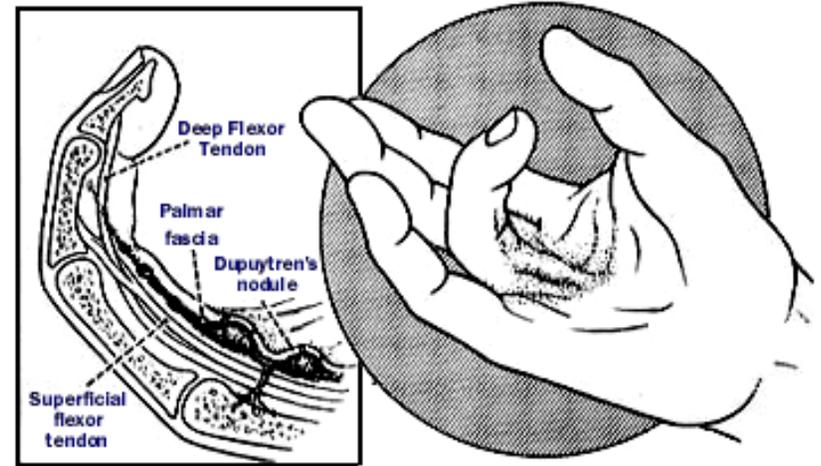
Auxilium – Pfizer Partnership for XIAFLEX™ in Europe

- ▶ Pfizer responsible for marketing XIAFLEX for Dupuytren's disease and Peyronie's disease in 27 member countries of European Union and 19 other European and Eurasian countries
- ▶ \$6.375 million upfront payment paid by Auxilium to BioSpecifics
- ▶ BioSpecifics to receive:
 - 8.5% of the \$410 million in additional potential future milestone payments paid to Auxilium
 - ▶ \$150 million regulatory, \$260 million sales
 - ▶ Additive to milestones due under Auxilium partnership
 - Low double digit royalties and COGS markup independent of indication, territory, sales volume and whether Pfizer or Auxilium sells product

Dupuytren's Disease

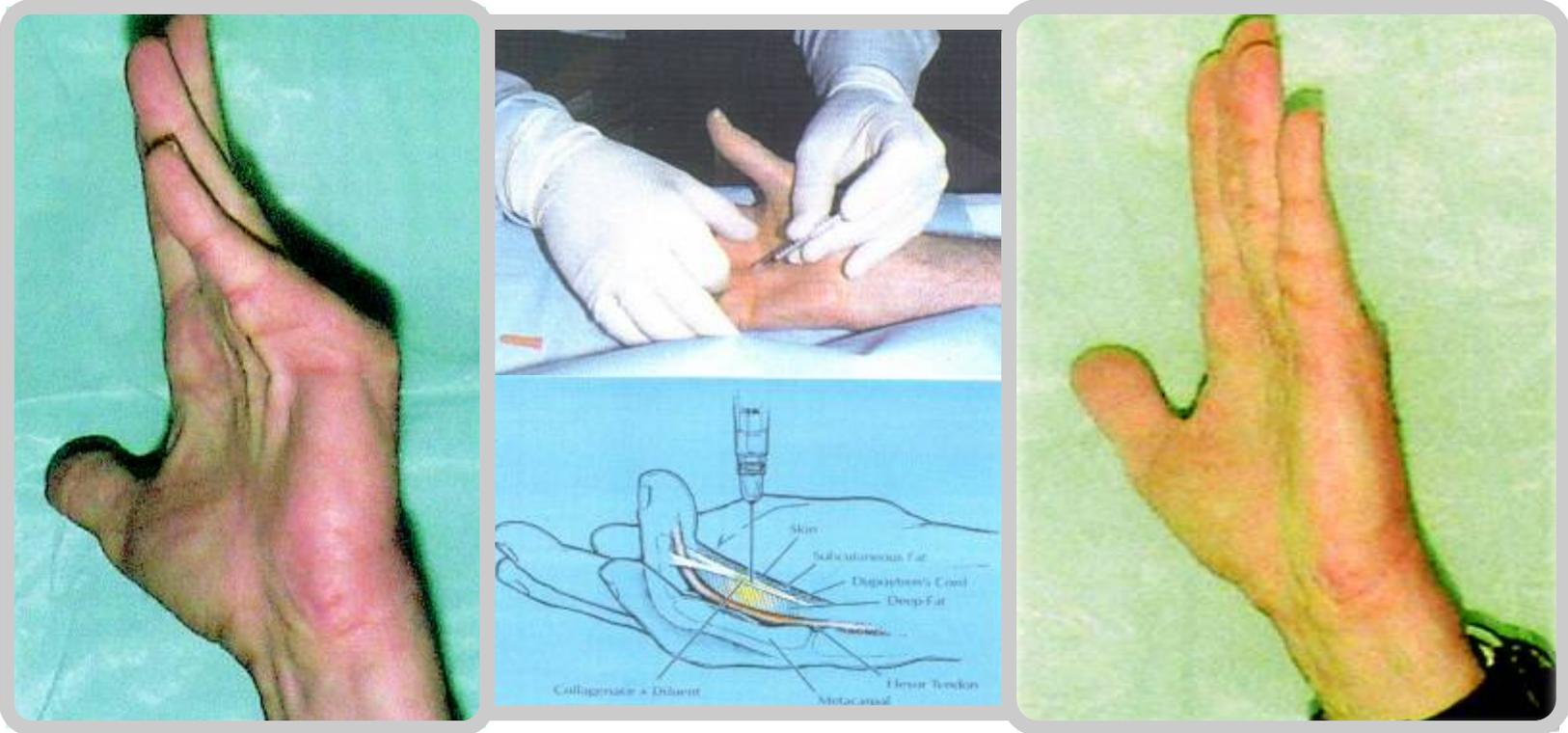
Dupuytren's Disease

- ▶ Formation of a collagen cord in the palm that contracts and limits range of motion of fingers
 - May cause dysfunction
- ▶ Surgery is current treatment, but unattractive option
 - Painful
 - General anesthesia required
 - Unpredictable results and complications
 - ▶ One month recovery
 - ▶ High recurrence rate



Dupuytren's Disease

Collagenase: Restores Normal Motion

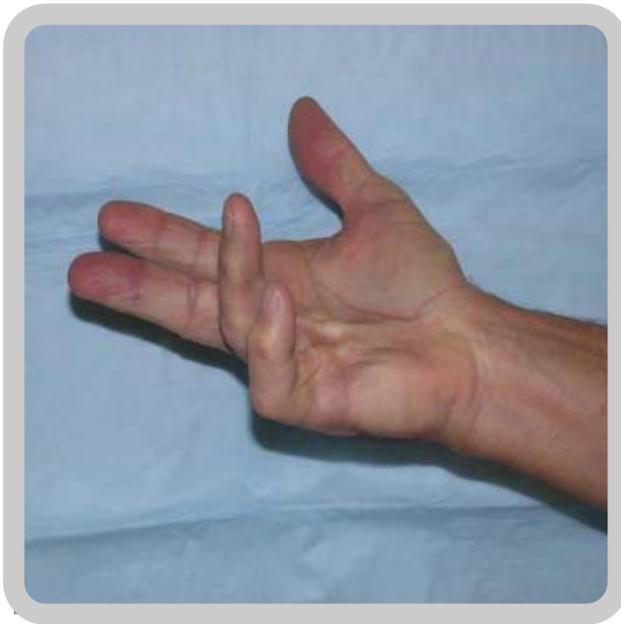


Dupuytren's Disease

Collagenase: Treatment Advantages

- ▶ No anesthesia required
- ▶ Minimally invasive
- ▶ Office procedure

Pre-treatment



Post-treatment



Dupuytren's Disease Commercial Potential

- ▶ Market Size
 - Prevalence in US and Europe:
 - ▶ 3-6% of population ~ 13.5-27 million
 - Patients seeking treatment: 1 million
 - Potential annual candidates: 240,000
- ▶ Surgeons highly receptive
 - Physician surveys show potential use in 76% of medical/surgical candidates
- ▶ Price competitive with surgery (approximately \$5,000 in U.S. – equates to \$1,600 per vial)

Source: Auxilium Pharmaceuticals

Dupuytren's Disease BioSpecifics Phase 3 Study Results

	Injectable Collagenase	Placebo	P - value
Primary Endpoint	21/23 (91%)	0/12	< .001
▶ MP Joint	12/14 (86%)	0/7	< .001
▶ PIP Joint	9/9 (100%)	0/5	< .001
Secondary Joint	5/6 (83%)	0/3	.035
Median Time to Success	8 days	N/A	

Sources: Auxilium Pharmaceuticals
Badalamente, M. et al. *Journal of Hand Surgery*, 2007, 32A: 767-774

Dupuytren's Disease BioSpecifics Phase 3 Study – Other Findings

- ▶ Adverse events
 - No serious adverse events reported
 - Adverse events were mild to moderate, mostly local reactions
 - ▶ Resolved within a mean of 3 weeks
 - No reports of loss of sensation or infections; no skin grafts required
- ▶ 87% (54/62) joints achieved clinical success in the study and its open label extension
- ▶ Recurrence rates
 - 3 of 54 joints followed for 1 year (6%)
 - 5 of 27 joints followed for 2 years (18%)
 - 27 – 80% for surgery

Sources: Auxilium Pharmaceuticals
Badalamente, M. et al. *Journal of Hand Surgery*, 2007, 32A: 767-774

Dupuytren's Disease Auxilium's Phase 3 Top-Line Results

► Overview

- Primary endpoint: reduction in contracture to within 0-5° of normal
- Primary and secondary endpoints were met with high statistical significance in Phase 3 trials

► Results

- Cord I* (**306** patients) in 16 US centers;
 - 203 patients received XIAFLEX and 103 received placebo
 - **64%** of XIAFLEX patients met primary endpoint vs. **6.8%** for placebo; $p < 0.001$
- Cord II (**66** patients) 5 Australian centers
 - 45 patients received XIAFLEX and 21 received placebo
 - **44%** of XIAFLEX patients met primary endpoint vs. **4.8%** for placebo; $p < 0.001$

► BLA accepted with Priority Review

Sources: Auxilium Pharmaceuticals
New England Journal of Medicine (N. Engl. J. Med. 2009;361:968-79.)

Dupuytren's Disease Auxilium's Phase 3 Safety Data

- ▶ Data based on 2,600 XIAFLEX injections in approximately 1,082 subjects
- ▶ 7 SAEs (0.27%) reported by Auxilium
 - 3 out of 7 reported in connection with tendon injuries
 - 1 ligament injury
 - 1 Deep Vein Thrombosis
 - 1 Complex Regional Pain Syndrome
 - 1 Unconfirmed Proliferation of Dupuytren's Disease

Source: Auxilium Pharmaceuticals

Dupuytren's Disease Development Pathway and Pre-Launch Activities

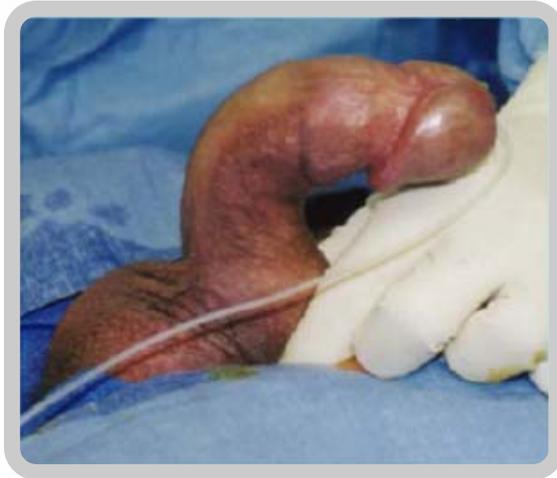
- ▶ Anticipated development milestones
 - FDA Advisory Committee date of September 16, 2009
 - Potential MAA filing by Pfizer in EU in 2010
- ▶ Auxilium pre-launch activities
 - Gearing up for U.S. launch 60 days post-approval

Source: Auxilium Pharmaceuticals

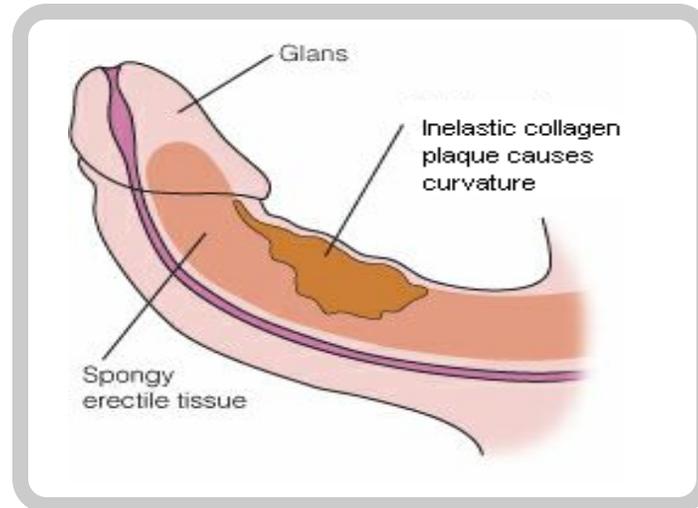
Peyronie's Disease

Peyronie's Disease

- ▶ Excess of inelastic collagen causes penis curvature; distorts erection
- ▶ Affects over one million individuals worldwide
- ▶ Sexual dysfunction may result
- ▶ No current effective pharmaceutical therapies



Erect penis with Peyronie's



Peyronie's Disease – Current Surgical Treatment

- ▶ Painful
- ▶ General anesthesia required
- ▶ Mixed results
- ▶ Penis shortens
- ▶ Resistance by surgeons and patients

Peyronie's Disease Market Size

- ▶ 475,000 patients seeking treatment annually in the US and Europe
- ▶ 210,000 potential candidates annually
- ▶ Market research shows 90% of US based urologists would use collagenase injection to avoid or delay surgery

Source: Auxilium Pharmaceuticals

Peyronie's Disease

BioSpecifics Phase 2a Clinical Study

- ▶ Study design
 - 49 patients assigned to placebo or one of the three dosages depending upon disease severity
 - One treatment
- ▶ Statistically significant reduction of angle of penile curvature
 - $p < 0.007$ for 3 pooled arms of study

Peyronie's Disease Open Label Study Results (Protocol 1030)

- ▶ N=25
- ▶ 1st series of 3 injections given over 7-10 days
- ▶ Promising results
 - 52% rated as very much improved or much improved by investigator at 9 months post 2nd series
 - 61% improvement in VAS question on sex life
 - 52% met criteria for decrease in plaque length $p=.0073$ (Paired T Test)
- ▶ Adverse events include bruising and tear of tunica
- ▶ Results published in January 2008 *Journal of Sexual Medicine*

Peyronie's Disease

Open Label Study Results

(Protocol 1035)

▶ Parameters

- N=10
- 1st series of 3 injections administered over one week
- 2nd and 3rd series administered 6 weeks apart
- Baseline deviation angle average 50.2 degrees

▶ Promising results

- 9 month post 1st series 25% or greater reduction in deviation angle achieved in 89% (8/9 patients) of patients who completed the follow up schedule
- 67% (6/9 patients) rated as very much improved or much improved at 9 month follow-up

Source: Auxilium Pharmaceuticals

Peyronie's Disease Phase 2b Clinical Study

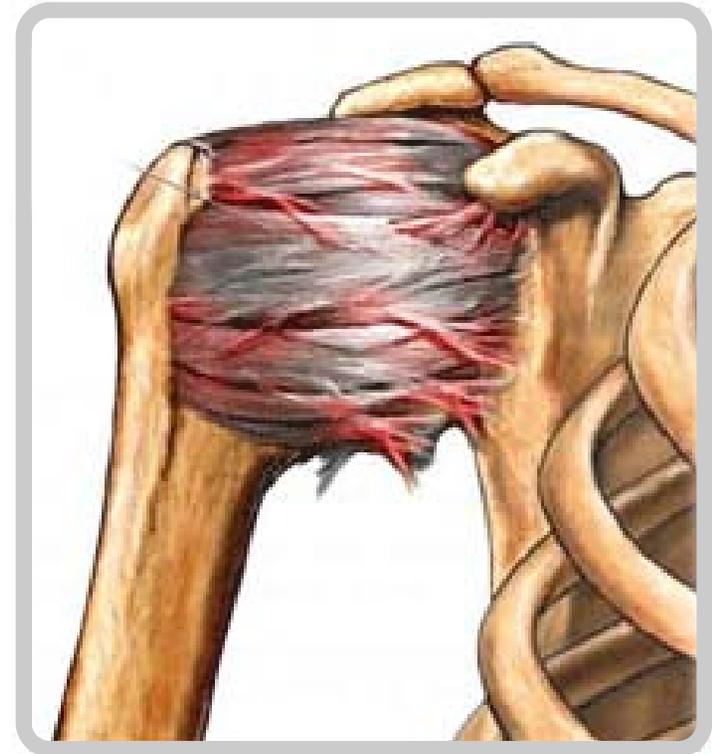
- ▶ Enrollment complete
- ▶ Study design
 - 120+ patients assigned to 3:1 XIAFLEX™ to placebo
 - 1:1 remodeling or none
 - 11 US sites
 - 2 injections weekly every 6 weeks
 - Max of 6 injections
 - Validation of methodology for assessment
- ▶ Top-line results expected by the end of 2009

Source: Auxilium Pharmaceuticals

Frozen Shoulder

Frozen Shoulder

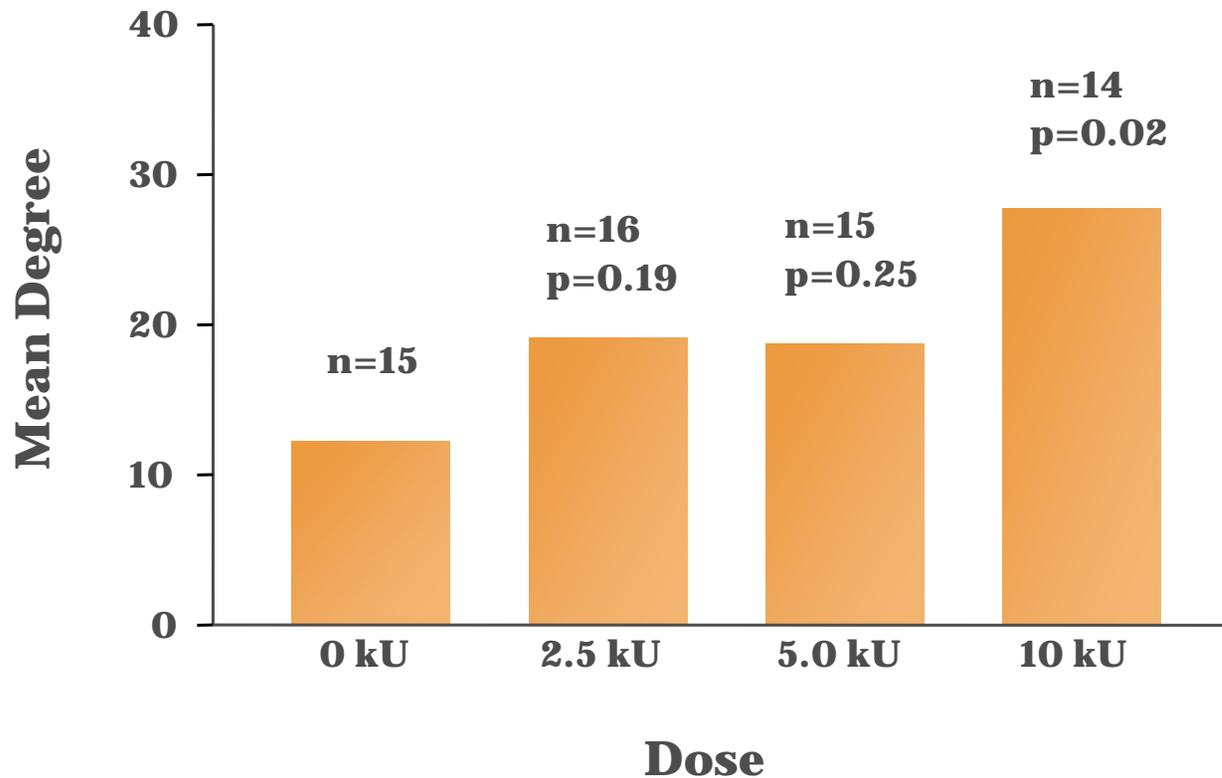
- ▶ Inflammation and thickening of the shoulder capsule
- ▶ Trauma or unknown causes
- ▶ Affects between 20-50 million worldwide
- ▶ 700,000 patients visit doctors annually in U.S.
- ▶ Occurs in patients ages 40-70
- ▶ About 15% patients bilateral
- ▶ Current therapies include manipulation: painful and requires general anesthesia



Source: Auxilium Pharmaceuticals

Frozen Shoulder Phase 2 Dose Response Study Results

Active elevation change from
baseline at the 30-day visit



Frozen Shoulder Pre/Post Treatment



Pre-treatment



Post-treatment

Corporate Summary

Intellectual Property

- ▶ Peyronie's and Dupuytren's Diseases have Orphan Drug designation status
 - 7 year exclusivity after commercialization
- ▶ 10 year exclusivity in EU anticipated by Auxilium
- ▶ Manufacturing and composition patent pending, if issued royalties until 2027
- ▶ Royalty stream protected by pending patent claim
- ▶ BioSpecifics owns or controls patents covering:
 - Peyronie's Disease
 - Dupuytren's Disease
 - Wound healing
 - Improved debridement
 - Removal of adipose tissue
 - Other patents pending

Financial Highlights

- ▶ \$9.3 million in cash as of 6/30/09
 - \$6.375 million received on 1/30/09
- ▶ 2008 net income of \$3.7 million or \$0.55 per diluted share.
- ▶ 2Q 2009 net loss of \$88,000 or \$0.01 per basic and diluted share.

Upcoming Milestones

▶ Dupuytren's Disease

- ✔ BLA accepted with Priority Review
- ✔ 12 month Dupuytren's safety data
 - ❑ FDA Advisory Panel September 16, 2009
 - ❑ U.S. Commercial launch 60 days after approval

▶ Peyronie's Disease

- ❑ Announce top-line results of Phase 2b study in 4Q09
- ❑ Begin global Phase 3 trial(s) in 2010

Source: Auxilium Pharmaceuticals

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