

Company Snapshot

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a primary focus on products for urology, endocrinology, and orthopaedics. Several of the Company's products will address a select segment of the primary care physician population as well. The only marketed product, Testim™, is a 1% testosterone gel for the treatment of hypogonadism. The most important pipeline product is Xiaflex™, a collagenase enzyme derived from Clostridium histolyticum. We expect a BLA (Biological License Application) for this product to be filed in early 2009, for the initial indication of Dupuytren's Contracture. Additional indications will include Peyronie's disease and Frozen Shoulder Syndrome. Further indications are possible, with payments of an additional "opt in" fee to Biospecifics Technology Corp. (BSTC.OB-OTC BB-\$15.00). AUXL's current burn rate is approximately \$45MM annually, and as of the most recent filing, the Company had \$48.8MM (approximately 1 year) in cash.

Key Statistics

Key Statistics pricing data reflects previous trading day's closing price. Other applicable data are trailing 12-months unless otherwise specified.

Market Overview

Price	\$27.55
Price Target	\$14.00
52 Week Price Range	\$42.75-20.11
Shares Outstanding	41.5 MM

Valuation

Market Cap (intraday):	1.14B
Shares Outstanding:	41.5MM
Float:	36.8MM
Short % shs out (25-Sep-08):	26.6%
Enterprise Value (14-Oct-08):	1.1B
Trailing P/E (ttm, intraday):	N/A
Forward P/E (fye 29-Sep-09):	N/A
PEG Ratio (5 yr expected):	N/A
Price/Sales (ttm):	9.57
Price/Book (mrq):	22.46
Enterprise Value/Revenue (ttm):	9.82

Revenue Estimates

Current Quarter - 09/08	Next Quarter - 12/08	Current Year - 12/08	Next Year - 12/09
32MM	34MM	124MM	150MM

Investment Thesis

Rating: Sell

The current valuation of AUXL appears to reflect much wider use of Xiaflex than we anticipate. We believe the current phase III data is flawed in several respects, and does not accurately reflect how treatment with Xiaflex compares with existing, effective treatment modalities.

Additionally, we are concerned about the safety of injecting a lytic enzyme into closed spaces filled with connective tissue, and believe the FDA will have similar concerns. While we currently estimate that there is a 50% chance of FDA approval in 2010, we believe that subsequent Xiaflex utilization will be limited by a restrictive label.

Finally, if Xiaflex is ultimately approved by the FDA, we anticipate a slow sales ramp. Major reimbursement hurdles will need to be overcome before the drug can achieve significant market penetration. We do not believe that these factors are properly reflected in the current market capitalization of AUXL, and therefore believe the stock should be sold.

12 Month Price Chart



Product Discussion

Testim™

- Testim 1% testosterone gel has demonstrated efficacy in 16 clinical trials involving 1800 patients. It was approved by the FDA in October 2002. The worldwide market for testosterone products is currently \$700MM, and 75% of sales are generated by gel products. Testim sales currently represent approximately 22% of the gel market. We anticipate this market will grow 20-25% annually. There are at least 25 topical testosterone products currently on the market. We believe they all adequately treat the condition of hypogonadism.
- While we accept that Testim treats hypogonadism effectively, we also have concerns that competitive pressures will ultimately result in price reductions. Price reductions effected in an attempt to maintain or grow market share would have a significant negative impact on associated margins and profitability.
- We note that in 2Q08, Testim sales were \$30.9MM and COGS was \$7.4MM, resulting in a gross margin of 76%. However, SG&A was \$22.2MM, and we believe a significant percentage of this amount is attributable to Testim sales. Therefore, the net profitability of Testim does not appear to be significant, and we believe our concerns about future margin pressures are warranted.

Xiaflex™

- Xiaflex was originally licensed from BSTC in 2004. BSTC will receive approximately 13% of pretax net sales for each indication. The only FDA approved collagenase product currently on the market is topical Santyl™, originally developed by BSTC, and sold to DFB Biotech for approximately \$8MM plus earn out payments. Abbott Laboratories (ABT-NYSE-\$54.78) currently compounds the Active Pharmaceutical Ingredient (API) into an ointment. This product is also derived from Clostridium histolyticum, and it is used to debride the necrotic tissue from wounds.
- Collagenase is the only protease that can hydrolyze the triple helical region of collagen under physiological conditions. Collagen is the main constituent of scar tissue, skin, tendon, and cartilage, as well as the organic component of teeth and bone. The body produces endogenous collagenases to remove dead tissue and regulate matrix remodeling and tissue turnover. The Clostridial collagenase is more efficient than the human variety because it can cleave the collagen molecule at multiple sites along the triple helix. The efficacy of this collagenase is greatly responsible for the serious and invasive nature of certain Clostridial infections in humans, including gas gangrene.
- We note that the most significant warning on the label for “topical” Santyl™ is to monitor for systemic infections (sepsis). Collagen is a major constituent of the extracellular matrix, and it provides structural integrity as well as providing a physical barrier to adjacent tissue. The destruction of this collagen matrix has the potential to facilitate the rapid transit of bacteria through the interstitial space and into the bloodstream. The resultant systemic infection can be life threatening. Xiaflex has been granted Orphan drug status by the FDA for both Dupuytren’s Contracture and Peyronie’s Disease.

Xiaflex Indications

- **Depuytren's Contracture** is an uncommon (source: MayoClinic.com) hand deformity in which the connective tissue under the skin of the palm contracts and toughens over time. Knots of tissue eventually form a thick cord under the skin, and pull a finger into a flexed position. The affected fingers continue to flex normally, but cannot be fully extended. The disorder is rarely painful. The ring finger and pinky are most commonly affected, and the thumb and index finger are rarely involved. The precise cause of the disease is unknown, although family history, diabetes (type I and II), smoking and alcohol all appear to increase the frequency of the disease. It is more common in males and people over 40. The disease can make it difficult to grasp large objects, but usually does not affect fine motor activities such as writing. The course of the disease is variable, with occasional spontaneous resolutions, but generally, it progresses slowly. The efficacy of therapy is generally inversely related to the severity of the deformity.
- There are several non-surgical options for treating the deformity. These include steroid injection, radiation therapy, and needle aponeurotomy (percutaneous needle fasciotomy). We will only discuss needle aponeurotomy and surgery.
- Needle aponeurotomy (NA) is a minimally invasive procedure where a needle is inserted and manipulated to break the restricting cord. It was proposed as therapy in 1832 by Guillaume Dupuytren himself. It has few associated complications, but requires a physician experienced in the technique. It is also relatively inexpensive, fairly painless, takes very little time, creates minimal scarring, and can be repeated. The success rate of NA is high. The Lermusiaux study with 992 hands, reported in 1996, documented success rates of 92% for stage I, 78% for stage II, 71% for stage III, and 57% for stage IV, (Staging of the disease is usually done using Tubiana's simplified criteria as follows: Stage I, 0 to 45 degrees, Stage II, 46-90 degrees, Stage III, 91 to 135 degrees, and Stage IV, 136-180 degrees.).
- Surgery is generally reserved for patients with disability from the disease. There are approximately 30K procedures annually. While surgery generally restores function, it does not prevent recurrence. Partial fasciectomy is the most common surgical procedure for late stage contracture. Diseased tissue is not easy to identify, and residual diseased tissue probably contributes to a relatively high recurrence rate.
- Variable recurrence rates have been reported for both surgery and NA. The largest study we found, (DIAS and Braybrokke-1996), involving surgery on 1,037 patients, demonstrated a recurrence rate of 15% at 27 months. While the recurrence rate with surgery may be lower than with NA, NA has the distinct advantage of being easily repeated while offering approximately an 85% success rate for flexion contractures of less than 90 degrees.
- (See discussion of the Xiaflex phase III clinical data below)

- **Peyronie's disease** is characterized by the presence of a fibrous plaque on the shaft of the penis. Specifically, the fibrosing process occurs in the tunica albuginea, the fibrous envelope surrounding the corpora cavernosa (muscle tissue). This plaque distorts the penis and may make intercourse painful or difficult. Patients with Peyronie's disease have an increased likelihood of having Dupuytren's contractures. The underlying cause is thought to be penile trauma, usually incurred through sexual activity.
- Without treatment, approximately 12-13% will spontaneously improve, 40-50% will get worse, and the rest will remain relatively stable. There is anecdotal evidence that vacuum erection devices will produce remodeling through the exertion of longitudinal force. In 2007, Dr. Laurence Levine reported that a traction device reduced curvature by an average of 33%. Multiple medications have been tried with mixed results. Surgery is considered a last resort, and a penile prosthesis may be necessary in advanced cases.
- Xiaflex phase II trials in Peyronie's disease included a total of 35 patients. A success was considered to be a reduction in curvature of 25%. In the first phase II, involving 25 patients, the patients received 3 injections over 7-10 days followed by an additional 3 injections 12 weeks later. The initial average deviation was 52.8 degrees, and after 6 months only 53% of patients had clinical success. The second phase II study had slightly better results, but required three series of three injections and only involved 10 patients.
- We have several issues with these studies, not the least of which is their small size. Most importantly, we question whether patients will opt for repeated penile injections to achieve a 50-60% chance of a 25% reduction in deviation angle, without first attempting less invasive methods (some of which appear to produce equivalent or superior results).
- Additionally, there was no mention of initial patient disability, or the treatment effect on the disability. In cases where the disease is primarily cosmetic, we would anticipate difficulty in obtaining reimbursement. We also have serious clinical concerns about the safety of repeated blind injection of a lytic enzyme into the penis.
- **Frozen Shoulder Syndrome**, or adhesive capsulitis, is characterized by stiffness and pain in the shoulder joint, with a concomitant decrease in range of motion. The capsule surrounding the joint becomes inflamed. This process may result in the production of adhesions, or fibrous cords that restrict motion. The exact cause is unknown, but diabetes, age over 40, and prolonged shoulder immobilization all increase the risk.
- Physiotherapy is a mainstay of treatment. Nonsteroidal anti-inflammatory drugs (NSAIDS) and steroids often decrease the symptoms. Transcutaneous electrical nerve stimulation (TENS) can be used to control pain. Arthroscopic surgery is rarely employed to excise scar tissue.
- An early phase II trial involved 60 patients and was randomized and placebo controlled. Three doses of Xiaflex were tested, and while the announced results do not mention statistical significance, there was a "meaningful return to normal shoulder motion and function with drug treatment compared to placebo".
- While we find this data interesting, it is far from specific. Additionally, steroid injection and physiotherapy often produce dramatic positive results. We continue to have clinical concerns over the blind injection of collagenase into the shoulder, but believe this location is far more

innocuous than either the penis or the hand. Once again, we have concerns about the potential for reimbursement while inexpensive alternative treatment modalities are available.

Pipeline Products

- AUXL has a developmental pipeline that includes an oral transmucosal drug delivery system. The technology was licensed from Formulation Technologies, Inc. There are three products in development; one to treat overactive bladder and two product candidates to treat pain. The Company also has the right to develop six additional pain products and products for hormone replacement and urologic disease. The basis of this technology is a small film that adheres to the upper gum. The overactive bladder product is currently in phase I testing. This pipeline is early stage.

Depuytren’s Contracture Phase III Data

- Xiaflex’s efficacy in Depuytren’s Contracture has been demonstrated in CORD I and CORD II phase III clinical trials. We present the data, as it was presented by AUXL on 6/3/08.

Top-line Efficacy Results of CORD I and CORD II

	XIAFLEX arm	Placebo arm	p-value
CORD I:			
Number of evaluable subjects	203	103	
Percentage of contractures achieving greater than or equal to 5° of normal	64% (130/203)	6.8% (7/103)	< 0.001
Average percent improvement in contracture from baseline	79.3% (50.2°/12.2°)	8.6% (49.1°/45.7°)	< 0.001
Percentage of contractures achieving less than or equal to 50% reduction	84.7% (172/203)	11.7% (12/103)	< 0.001
CORD II:			
Number of evaluable subjects	45	21	
Percentage of contractures achieving greater than or equal to 5° of normal	44.4% (20/45)	4.8% (1/21)	< 0.001
Average percent improvement in contracture from baseline	70.5% (53.2°/16.7°)	13.6% (50.0°/44.3°)	< 0.001
Percentage of contractures achieving less than or equal to 50% reduction	77.8% (35/45)	14.3% (3/21)	< 0.001

- We note that through the end of May 2008, over 850 patients have been injected, with 7 serious adverse events (SAE's), including 5 tendon or ligament injuries, a venous thrombosis, and a complex regional pain syndrome. Other adverse events include pain, swelling, bruising, and pruritis at the injection site, as well as transient lymph node swelling and pain.

Data Discussion

- CORD I enrolled 306 evaluable patients across 16 sites in the U.S. 203 received Xiaflex and 103 received placebo. The joints were stratified 2:1, MP (Metacarpal Phalangeal): PIP (Proximal Interphalangeal). The primary endpoint of a resultant contracture within 5 degrees of normal was achieved in 64% (130/203) patients treated with Xiaflex, and in 6.8% (7/103) of placebo patients.
- Moreover, the CORD I Xiaflex treated patients improved an average of 38 degrees from baseline and the CORD II patients improved an average of 36.5 degrees from baseline. The residual flexion in these patients averaged 12.2 degrees and 16.7 degrees respectively. We note that all patients started with approximately 50 degrees of flexion contracture.
- CORD II enrolled 66 patients and stratified 1:1 (MP: PIP). 44.4% (20/45) achieved the clinical endpoint of contracture reduction to within 5 degrees of normal, while only 4.8% (1/21) of the placebo group met the endpoint.

Data Concerns

- We have several issues with this data. The first is the definition of evaluable patients. We would like to know how many patients were initially enrolled, how many received at least one injection, and how many dropped out and for what reasons. We assume that this data will be provided to the FDA, but we note that an earlier press release indicated that 216 patients would be treated in CORD I. If a significant number of these 13 missing patients experienced adverse reactions to the medication, we believe that the FDA will have serious safety concerns. Additionally, the exclusion of 13 patients from such a small study has the potential to significantly change the response rates. We prefer data that uses an "intent to treat" basis for statistical analysis.
- Secondly, we believe the comparator arm is misleading. Surgery or needle aponeurotomy is the correct comparator, not placebo. As previously mentioned, NA can be very effective and inexpensive, and is most effective in stage I and II disease. Specifically, we would like to see the results of a trial that directly compares Xiaflex to NA (not placebo). A head to head trial is required to accurately reflect the comparative efficacy and recurrence rates.

While the upcoming release of recurrence rates at 12 months for 100 patients in CORD I (expected 2009) may initially indicate that Xiaflex appears equivalent or superior to NA (clinical studies have demonstrated highly variable recurrence rates), we believe the cost benefit

analysis will be dramatically in favor of NA. The cost of repeated treatments with a \$5000 drug, especially in early stage disease, is likely to be prohibitive. We believe the current data set fails to provide sufficient evidence that Xiaflex is superior to NA in either efficacy or recurrence rates. We note that recurrence rates with NA can be extremely low, and success rates are usually extremely high, especially in early stage disease.

- We have additional concerns regarding the severity of the disease being evaluated in CORD I and CORD II. It is widely acknowledged that earlier stage disease responds more favorably to all treatment modalities. A response rate of 50% in the stage III and IV population would be impressive, and simultaneously serve to demonstrate the viability of the drug as an alternative to surgery. However, the patients in these trials had relatively mild disease, with average angulations of approximately 50 degrees.

Therefore, we believe the CORD I and II trials fail to validate Xiaflex as effective therapy for severe disease, or as an equivalent alternative to surgery for severe disease. Consequently, we have concerns about the potentially restrictive label, should the drug be approved for any indication. We expect additional clinical trials with Xiaflex will demonstrate that earlier stage disease responds the best, as is the case with all other treatment modalities. While surgery is time consuming and patients often require a significant amount of rehabilitation, we believe that relative efficacy, recurrence rates, and cost are the most important parameters to evaluate when deciding on treatment alternatives for Depuytren's Contracture.

Once again we would like to see a head to head comparison of Xiaflex to surgery for stage III and IV disease. Without such a study in severe disease, we believe AUXL will be unable to substantiate any claim of superior efficacy or a decreased recurrence rate compared to surgical intervention. Based on the currently available data, we believe any claim to that effect would be misleading.

- The inability to convince physicians of equivalence or superiority to surgery in the severe disease population will put Xiaflex at a marketing disadvantage. Similarly, the inability to demonstrate equivalence or superiority may interfere with reimbursement approval. These two factors would exert a significant negative impact on the adoption rate.
- We are quite surprised by a response rate of nearly 7% in the CORD I placebo patients. We ascribe that placebo response to the early stage of the disease being treated (or the inaccuracy of diagnosis). Additionally, if we assume that 6.8% of the treated patients would have recovered spontaneously, the success rate was really 57.2% in CORD I. We are not certain how the FDA will interpret these findings, but believe that it statistically lowers the relative success rate achieved in this trial.
- The study size appears small. CORD I and CORD II enrolled 372 patients, and only 248 received the drug. AUXL contends that 395K patients in the U.S. get prescriptions for Depuytren's contracture, and that the addressable market in the U.S. is 150K. If that is in fact the case, we believe larger studies are warranted. In fact, the Company is conducting additional phase III open-label trials (JOINT I and II) in 600 patients, in addition to the open-label extensions of

CORD I and II. We think this additional data will be required before the FDA approves Xiaflex. If the FDA requests additional data, the potential approval of Xiaflex could be significantly delayed.

- Additionally, we are concerned that a significant majority of patients have residual contracture. Despite the fact that a majority of treated patients appear to have their contracture reduced by over 50%, the residual scar tissue provides a nidus for additional scar formation. This can lead to a worsening of the disease. We believe this residual scar tissue will lead to increased recurrence rates.

Earlier trials indicate recurrence rates with Xiaflex of 18% after 24 months. We believe that number could be significantly higher in current phase III trials. As the recurrence rates rise, Xiaflex treatment becomes less competitive with alternative treatments. As mentioned previously, we believe insurers may find the cost of retreatment prohibitive. A lack of reimbursement for retreatment will have a significant negative impact on utilization.

- Importantly, we have an issue with safety. Although SAE's were seen in a small percentage of patients in these studies, they included tendon ruptures and venous thromboses. Xiaflex was administered by hand experts, with years of experience in the treatment of adhesions and Dupuytren's Contracture. The hand is considered a confined space, with a vast amount of collagen, in the form of tendons, tendon sheathes, cartilage, and connective tissue.

The consequences of injecting a collagenase blindly into a confined collagen filled space can be dire. We are extremely concerned about the sequela of improper administration, and believe, if approved, the use of Xiaflex will be closely monitored. We do not believe this drug should be administered by any physician who lacks the appropriate expertise.

We therefore would expect a slow, controlled, closely supervised, launch to hand experts. Accordingly, we anticipate a relatively slow revenue ramp. The consequences of a rapid, unsupervised, unrestricted launch could be disastrous. We believe a broad-based launch would be associated with large numbers of SAE's. If Xiaflex utilization became associated with large numbers of SAE's, we believe that the FDA would intervene.

- Our belief that the existing data set fails to demonstrate equivalence or superiority to existing treatment modalities has potential reimbursement ramifications. The Company has stated that the price for treatment will be about the same as surgery. Each patient has an average of 2.2 joints that require treatment, and early indications are that 1.4 vials will be required per joint. Thus, 3.1 vials per average patient (2.2 joints x 1.4 vials/joint) will cost about \$5000 (\$3500 in the EU).

We would anticipate some coverage in younger individuals (uncommon) who demonstrate a significant disability. In older individuals (most common), who have a predominantly cosmetic deformity, however, we believe the procedure will be considered elective, and coverage will not be provided. Additionally, we question whether preliminary treatment attempts with alternatives (i.e., NA) will be required by insurers before a patient qualifies for reimbursement. Further, we question whether retreatment will be reimbursed at all. Due to its high cost, reimbursement for Xiaflex is of paramount importance, and may be the major determinant of utilization. Without data that demonstrates clear superiority to less expensive alternatives, we

believe insurers will be reticent to provide widespread reimbursement. Lack of widespread reimbursement will exert a negative effect on Xiaflex utilization. We have already stated our contention that current phase III data fails to provide accurate comparisons, on a staging basis, to alternative treatments.

- Finally, we briefly address the issue of off-label use, such as in carpal tunnel syndrome. Carpal tunnel syndrome results from a nerve compression at the wrist, unlike Depuytren's Contracture. This nerve compression is generally the result of flexor sheath impingement on the nerve. We believe that the off-label use of a lytic agent in the wrist, without concrete safety and efficacy data based on long-term phase III double blinded, placebo controlled trials, would be tantamount to malpractice. Further, we believe any physician who administers this agent in an off-label indication and incurs an SAE, should be subjected to Regulatory sanctions. Additionally, there is unlikely to be any reimbursement for off-label indications without validating studies. Consequently, we ascribe zero revenue to off-label use of Xiaflex in this, and most other, off-label indications.

Price Target/ Valuation

- We anticipate a BLA submission in early 2009 and currently assign (based on currently available data) a 50% chance of FDA approval by early 2010. Upon approval, we would expect a launch in early 2010. If our prediction of restrictive labeling is correct, we would anticipate that approximately 5% of the potential population would receive treatment in the first 12 months after launch. This estimate may be optimistic, as without reimbursement, we believe that number would be much lower.
- Thus, we ascribe a 5% penetration year 1, with an annual growth rate of 15-20%. This translates to 7500 patients in the first 12 months, and gross revenues of \$37.5 MM and \$45 MM in 2010 and 2011 respectively. Additional positive safety and efficacy data, as well as European approval, will cause us to increase these estimates. Conversely, a delay or rejection at the FDA will cause us to dramatically reduce these estimates. However, we do not anticipate any modifications to these estimates in the near-term.
- We believe Testim revenues will continue to grow approximately 20-30% annually. Thus, we anticipate sales in 2009-2011 of about \$150MM, \$185MM, and \$222MM respectively. Due to low profit margins, we do not expect Testim to meaningfully contribute to profitability in the near-term.
- To account for estimate errors, we have doubled our Xiaflex sales estimates for 2011 to \$90MM. We will also assume a 75% gross margin and then subtract 13% for the payment to BSTC. The net sales, before R&D and taxes would therefore be \$58.75MM. R&D will continue to be a significant expense, as additional studies with Xiaflex and pipeline products will be continuing.
- As net income will likely continue to be negative through 2011, a simple P/E calculation is inappropriate. Instead, we ascribe a multiple of 1x 2011 sales to Testim (as margins are currently small and competitive pressures could diminish them further) and assign a multiple of 5x potential 2011 sales to Xiaflex.
- Our combined 2011 valuation is therefore \$777MM. We discount back only 10% annually to determine our current fair value of \$567MM. We add an additional \$14MM for the very early stage pipeline products, and arrive at our current price target of \$14.

Disclosures

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