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# Flexion: Buying Before And After ZILRETTA's PDUFA

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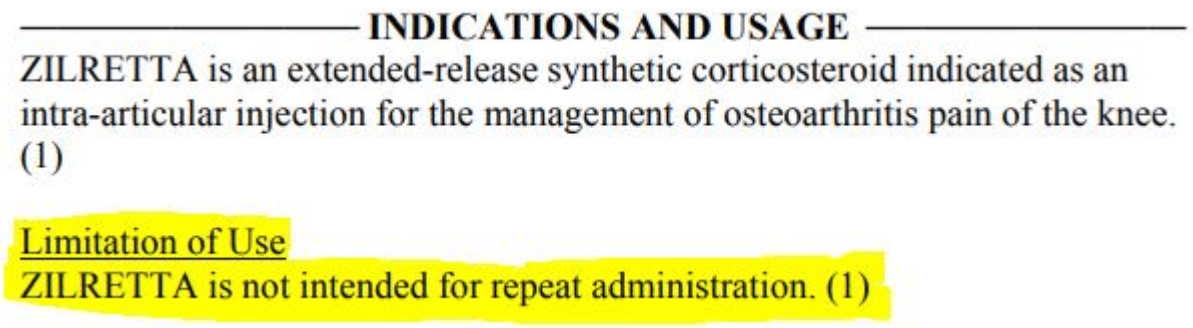
by: Biologics

## Summary


- Flexion Therapeutics had a strong Q2 with ZILRETTA pulling in $17M. I expect the company to hit the upper-end of their 2019 revenue guidance.
- The company has an upcoming PDUFA date on October 14th for repeat administration of ZILRETTA in OA knee.
- The company continues to record steady revenue growth since ZILRETTA's launch. I take a look at the current valuation to justify my decision to add to my speculative position.
- The stock has pulled up off the bottom but was rejected at a point of resistance. However, the pullback has been on low volume, so I am looking to add to my speculative position before and after a potential approval.


Flexion Therapeutics' (FLXN) flagship product, ZILRETTA, has an October 14th PDUFA date regarding an sNDA to allow repeat administration in OA of the knee. ZILRETTA has had some hiccups since its launch, but the Q2 numbers revealed the product has already gained some traction. As a result, I added to my speculative position following the Q2 earnings and I am debating on clicking the buy button prior to the FDA's decision.

Although the sNDA won't be a huge catalyst for the stock, it will remove the limited usage on ZILRETTA's label (Figure 1), which should lead to an uptick in orders.



**INDICATIONS AND USAGE**

ZILRETTA is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. (1)

Limitation of Use

ZILRETTA is not intended for repeat administration. (1)

*Figure 1: ZILRETTA Label (Source: FDA)*

I intend to review the data that supports the sNDA and why investors should remain vigilant around the PDUFA date. In addition, I take a look at FLXN's current valuation and what my plans are for my speculative position as we close out 2019.


*Source: FLXN*

## ZILRETTA Overview

On October 6th, 2017, the FDA approved ZILRETTA, as the first and only extended-release, intra-articular ("IA") injection, for the management of OA associated knee pain. ZILRETTA has a patented microsphere technology that can provide pain relief for greater than 12 weeks. ZILRETTA combines triamcinolone acetonide ("TA") with a poly lactic-co-glycolic acid ("PLGA") in a 32 mg dose to provide prolonged therapeutic concentrations in the joint along with an enduring analgesic effect.


*Source: FLXN*

If the sNDA is approved, repeat administrations will be added onto the long list of ZILRETTA's abilities (Figure 2).

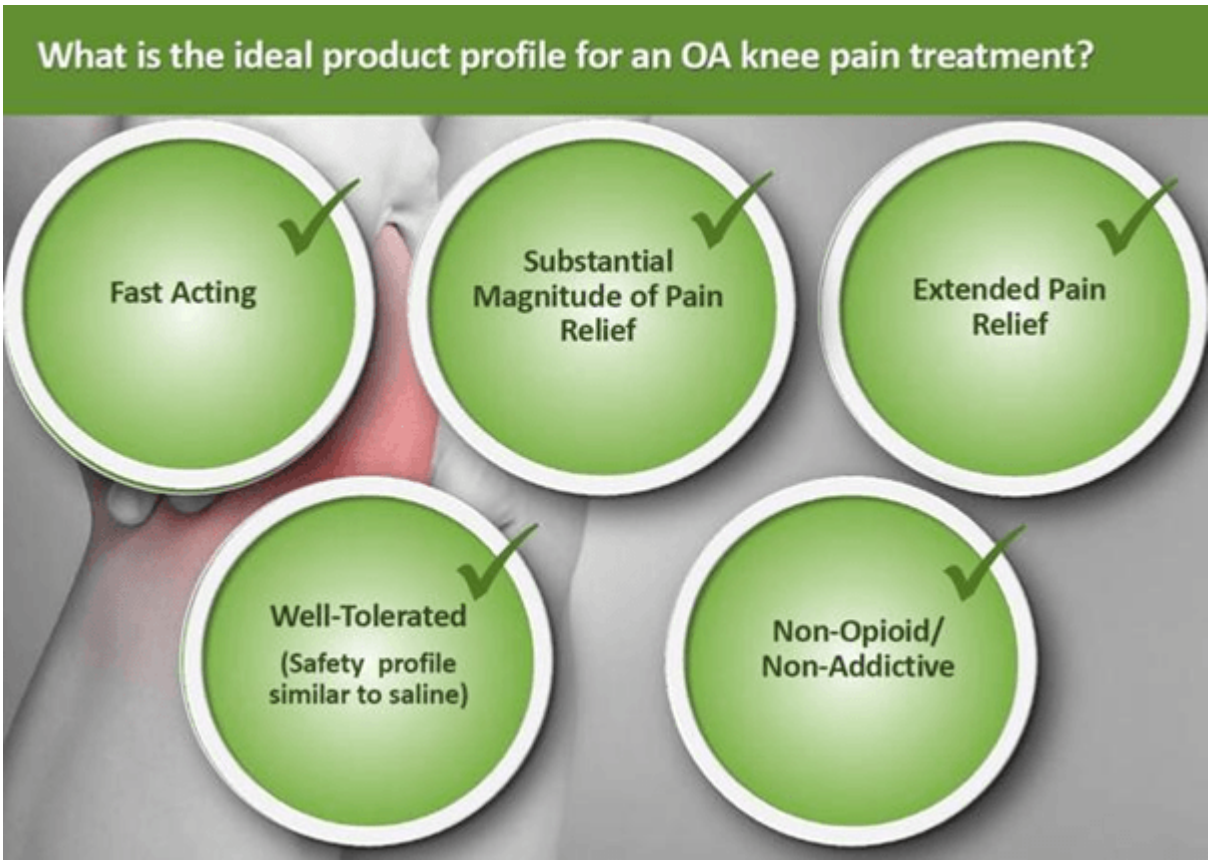



*Figure 2: ZILRETTA's Profile (Source: FLXN)*

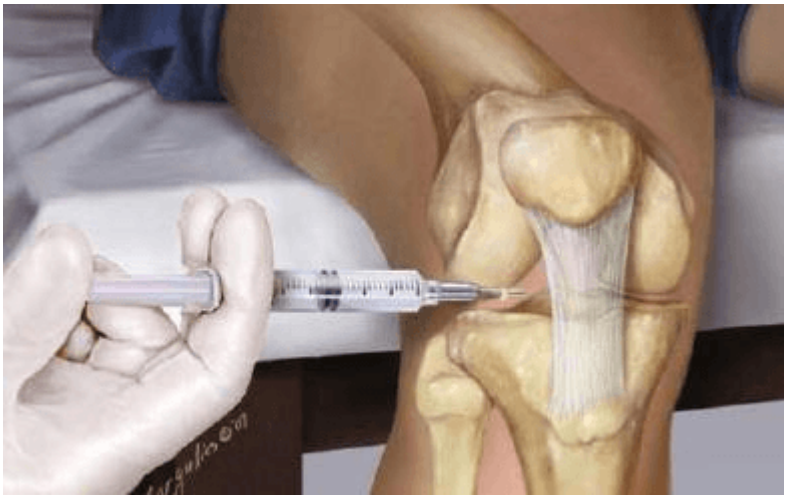
It is these characteristics that could support ZILRETTA as the next standard-of-care for its OA indications.

## Repeat Usage ZILRETTA

Back in December of 2018, the company publicized it had submitted the sNDA for ZILRETTA. Today, ZILRETTA's label has a limitation of usage ("LOU") and is suggested to be only administered once to an OA patient. Clearly, this has an impact on ZILRETTA adoption by physicians and the willingness for offices to commit to larger orders. If the FDA approves the sNDA and removes the LOU language, we ought to assume we will see a growth in product usage.

The company believes the data from an open-label Phase IIIb clinical trial demonstrates ZILRETTA is safe for repeat administration in OA knee patients. In this study, 95% of patients reported clinical benefit after an initial injection of ZILRETTA and 92% of these patients were administered a second injection on or after Week 12. In addition, the data

also indicated the magnitude and duration of pain relief experienced by patients after both the first and second injections were similar to results from ZILRETTA's pivotal Phase III trial.



*Source: FLXN*

Back in July, Flexion announced detailed data from their Phase IIIb repeat administration trial of ZILRETTA in OA knee pain. The data from patients with symptomatic knee OA ranging in grades 2-4 showed that ZILRETTA was able to reduce OA knee pain for 12 weeks after each injection. In terms of safety, “there were no indications of chondrolysis, osteonecrosis, subchondral insufficiency fractures, or clinically significant subchondral bone changes in any subgroup.” So, it appears that ZILRETTA is reliable and even works on grade 4 patients, which is the most severe form of OA. In fact, roughly 60% of grade 4 patients “reported no to mild pain at Week 12” succeeding initial and repeat injections.

Based on these results, I must believe the FDA is going to give the green light on sNDA and remove limited usage on the label. The repeat usage label should have an abrupt impact on sales. The sales force would be able to market the repeat administration, which should encourage accounts to order larger quantities of ZILRETTA to have on hand for the patient’s next injection.

## Downside Risk from a CRL

If the FDA provides a CRL, we can expect the market to punish the stock and some downgrades by Street analysts. In addition, we have to anticipate the shoulder and hip indication will be limited to a single-use. If ZILRETTA is going to be limited to a single-use product, we have to anticipate a decrease in estimated peak sales.

## Why Am I Looking to Add Before and After the PDUFA?

Flexion reported $10.6M in ZILRETTA net sales in Q1 and that they already had $5.1M in net sales in April. Flexion went on to have a strong May and June to report $17M in Q2 net sales. This puts the company on track to hit their 2019 full-year revenue guidance of $65-80M.

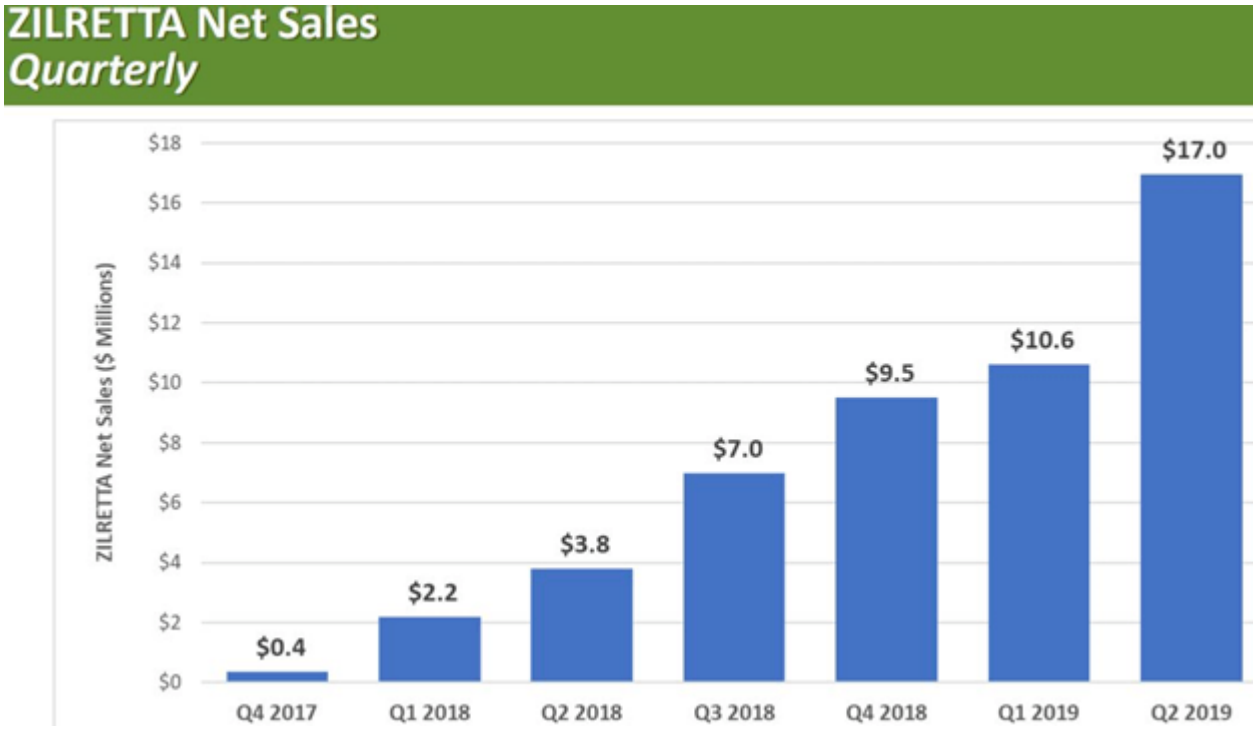



*Figure 3: ZILRETTA Quarterly Net Sales (Source: FLXN)*

It looks as if the company's commercial strategy for ZILRETTA is working and is showing improvement in every metric (Figure 4).

- ZILRETTA® net sales of $17.0 million in the second quarter of 2019
- We have called on almost all of our 4,400 target accounts
- 2,733 accounts have purchased ZILRETTA, as of June 30, 2019; up from 2,247, as of March 31, 2019
- 2,004 accounts have re-ordered ZILRETTA (73% of accounts that had purchased), as of June 30, 2019; up from 1,601 accounts that had re-ordered ZILRETTA (71% of accounts that had purchased) as of March 31, 2019

*Figure 4: FLXN Commercial Metrics (Source: FLXN)*

The company has solid growth in the number of accounts since launch, with 2,733 out of 4,400 of target accounts purchasing ZILRETTA (Figure 2). The majority of the ZILRETTA units are going to existing accounts, which have purchased about 80K units of ZILRETTA since launch (Figure 5).

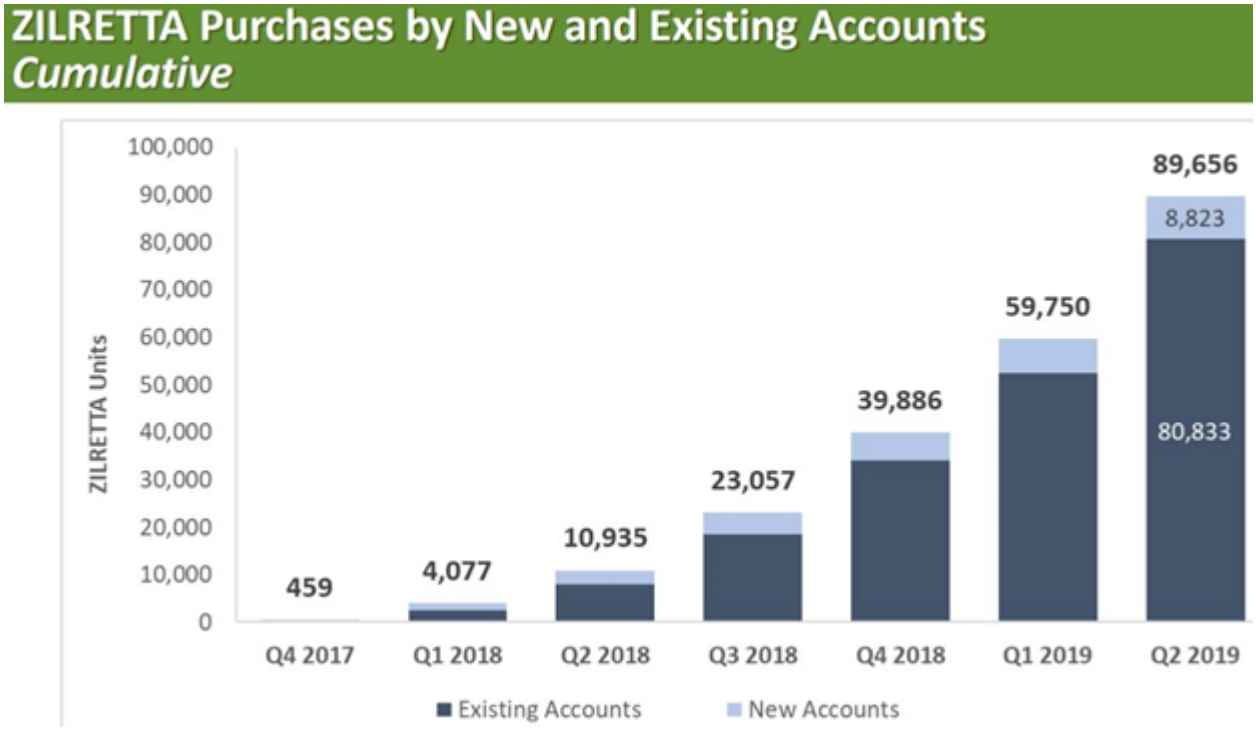



*Figure 5: ZILRETTA New vs Existing Accounts (Source: FLXN)*

What is more, it appears most of these repeat customers have ordered over 50 units of ZILRETTA (Figure 6).

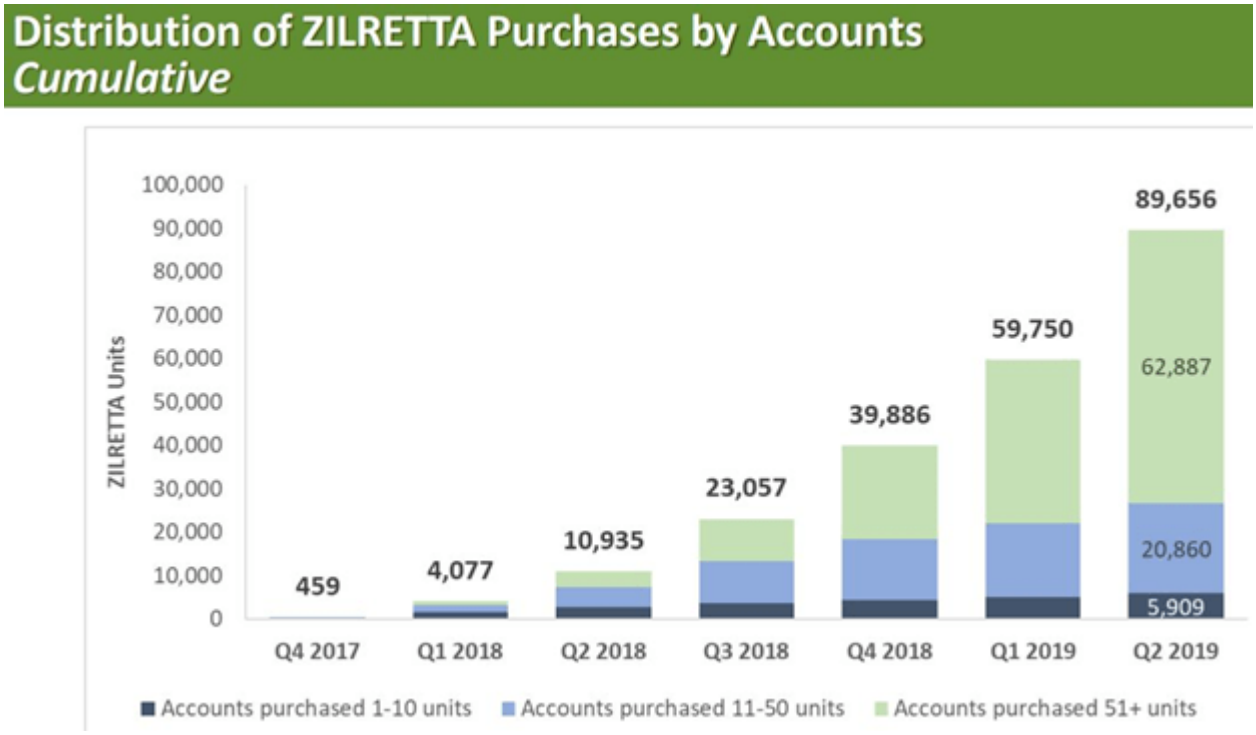



*Figure 6: ZILRETTA Number of Accounts (Source: FLXN)*

Certainly, the company still has the second half of its target accounts to work on, but the company appears to have made the right decisions in their commercial operations to realize these improvements over Q1. Now, the company must take aim and capture a larger percentage of the projected 7.8M OA knee patients who receive IA injections (Figure 7).

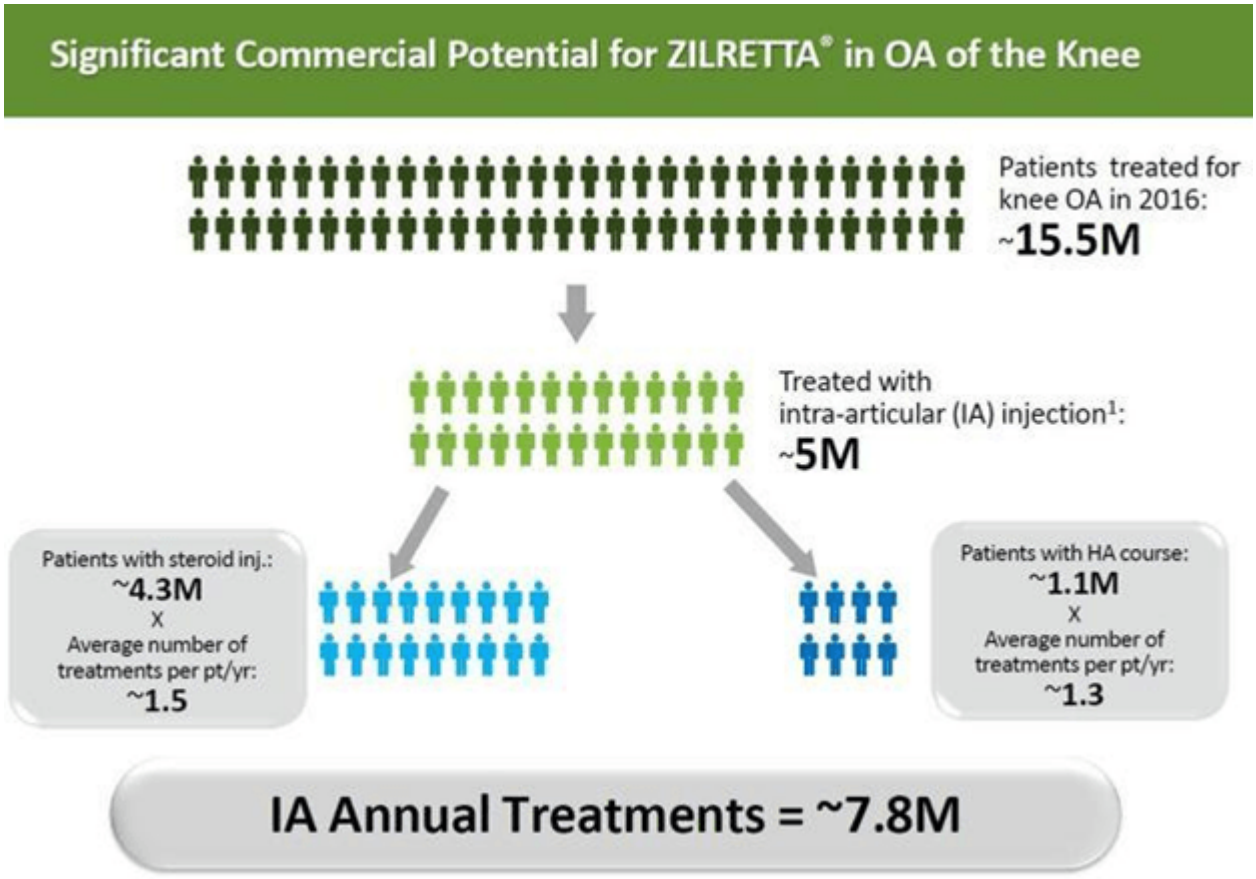



*Figure 7: ZILRETTA Market (Source: FLXN)*

If Flexion can improve on Q2's ZILRETTA numbers, we could see the company come close to hitting the upper end of their 2019 revenue guidance of around $80M. If the company hits $80M, it will surpass the highest revenue estimate in figure 8, which should trigger analyst upgrades and hopefully some institutional buying in the coming quarters. Even if the annual revenue was in line with the Street's estimates, it would still be a 211% year-over-year growth.

| Fiscal Period Ending | Revenue Estimate | YoY Growth | FWD Price/Sales | Low | High | # of Analysts |
|---|---|---|---|---|---|---|
| Dec 2019 | 70.12M | 211.31% | 7.38 | 65.00M | 73.61M | 9 |
| Dec 2020 | 138.85M | 98.01% | 3.73 | 127.00M | 169.00M | 9 |
| Dec 2021 | 230.47M | 65.99% | 2.25 | 191.00M | 296.50M | 7 |
| Dec 2022 | 332.15M | 44.12% | 1.56 | 278.70M | 439.40M | 6 |
| Dec 2023 | 444.38M | 33.79% | 1.16 | 359.00M | 551.00M | 5 |
| Dec 2024 | 527.10M | 18.61% | 0.98 | 437.80M | 667.00M | 4 |
| Dec 2025 | 606.75M | 15.11% | 0.85 | 516.60M | 787.30M | 4 |
| Dec 2026 | 692.70M | 14.17% | 0.75 | 620.80M | 903.20M | 4 |
| Dec 2027 | 760.08M | 9.73% | 0.68 | 684.30M | 944.30M | 4 |
| Dec 2028 | 760.17M | 0.01% | 0.68 | 713.40M | 785.30M | 3 |

*Figure 8: FLXN Annual Revenue Estimates (Source: Seeking Alpha)*

That growth is expected to continue for the next eight years and top-off around $760M in 2028. That would be 0.68x forward price-to-sales, which indicates the company would record a higher revenue than its current market cap.

This estimated revenue growth should eventually lead to a positive EPS at some point in 2022 (Figure 9).

| Fiscal Period Ending | EPS Estimate | YoY Growth | Forward PE | Low | High | # of Analysts |
|---|---|---|---|---|---|---|
| Dec 2019 | -3.90 | 16.47% | - | -4.13 | -3.72 | 8 |
| Dec 2020 | -2.38 | 38.89% | - | -2.70 | -2.04 | 8 |
| Dec 2021 | -0.40 | 83.35% | - | -1.11 | 0.76 | 6 |
| Dec 2022 | 1.47 | NM | 9.27 | 0.65 | 2.85 | 4 |
| Dec 2023 | 3.51 | 139.36% | 3.87 | 2.66 | 4.94 | 3 |
| Dec 2024 | 5.00 | 42.49% | 2.72 | 4.34 | 6.00 | 3 |
| Dec 2025 | 5.75 | 15.14% | 2.36 | 4.69 | 7.44 | 3 |
| Dec 2026 | 6.87 | 19.35% | 1.98 | 5.76 | 8.95 | 3 |
| Dec 2027 | 7.73 | 12.57% | 1.76 | 6.59 | 9.34 | 3 |
| Dec 2028 | 7.67 | -0.71% | 1.77 | 6.85 | 8.50 | 2 |

*Figure 9: FLXN EPS Estimates (Source: Seeking Alpha)*

Not only is the current share price at a discount compared to the projected growth, but it is extremely discounted considering the company could be recording a positive EPS in 2-3 years.

Another important factor in deciding to add to my position is FLXN's charts. The stock attempted to break through the $15.50 resistance line on the daily chart (Figure 10) but was abruptly rejected. Now, the stock is selling off under low volume during this recent biotech pullback and is approaching the oversold area on the RSI.


*Figure 10: FLXN Daily (Source: Trendspider)*

Although I would have liked to see the share price burst through that resistance area, the stock was trading at a normal volume and the RSI was in the overbought area. Therefore, I wasn't surprised to see the share price get denied and sell-off. The stock has pulled back on low volume, which could be a great opportunity to add to my position in anticipation that the stock will catch a bid as we move closer to the PDUFA date. If Flexion receives an FDA approval, we should see a positive reaction in the share price that breaks through the $15.50 resistance and continues into the Q3 earnings

## Conclusion

ZILRETTA's PDUFA date is rapidly approaching which should provide an opportunity to add to my speculative position. ZILRETTA's data looks promising, so I am expecting the FDA to give Flexion the thumbs up, which will allow Flexion's sales force to promote that new attribute to both new and existing accounts. Admittedly, I don't expect sales to double overnight; however, having the repeat administration label for the knee will bolster my confidence that the same will happen for the shoulder and hip indications. Therefore, I believe this sNDA decision is providing a great opportunity to buy at a discount valuation, with a daily chart with bullish technicals.

*What's My Plan?* I am going to see if the stock can bounce off the bottom of the Bollinger band before the PDUFA date before clicking the buy. If the stock continues to fall leading into the PDUFA date, I will wait for the FDA's decision before committing to another buy. If the company hits above $19M on its Q3 revenue, I will start adding on any technical pullback. I still plan to hold FLXN for a few years in anticipation that ZILRETTA leads the company to profitability or is potentially acquired by a larger biotech company.

**Disclosure:** I am/we are long FLXN. I wrote this article myself, and it expresses my own opinions. I am not receiving compensation for it (other than from Seeking Alpha). I have no business relationship with any company whose stock is mentioned in this article.