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Scilex Holding Company (SCLX – $1.56*)
Buy; $4.00 PT; $326.9M Market Cap
Company Update
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ZTilido, Elyxyb Expected to be Key '24 Growth Drivers; Balance Sheet Fix Also a Top Priority; Reiterate Buy, $4 PT

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Summary and Recommendation

We return to pain therapeutics' specialist Buy-rated Scilex (SCLX; $4 PT), noting preliminary 4Q23 ZTlido sales growth, i.e., $12.7M to $18.7M to be nicely sustained into 2024; and potentially driving FY24 gross sales est. to exceed $200M. SCLX continues to drive expansion of its revenue stream for Elyxyb in acute migraine (in-licensed U.S./Canadian rights in 1Q23 and U.S. launch in 2Q23), alongside Gloperba commercial launch in 1Q24. We anticipate Elyxyb to follow the ZTlido playbook in terms of securing payer coverage, and anticipated to bring in meaningful revenues beginning 2H24. Recall that Elyxyb (celecoxib) is a liquid formulation of the cyclooxygenase-2-selective NSAID currently indicated for the acute treatment of migraines with or without aura. When compared in a post hoc analysis to PFE's Nurtec (Rimegepant) and ABBV's UBRELVY (Ubrogepant), both calcitonin gene-related peptide (CGRP) receptor antagonists, patients treated with Elyxyb were more likely to report pain freedom through 4 hours post-dose and were more likely to be pain-free 1hr after treatment through 3 hours post treatment than patients receiving either 100 mg UBRELVY or 75 mg Nurtec. Compared to Nurtec and UBRELVY tmax of 1-2 hrs (both oral tablet formulations), Elyxyb's liquid formulation leads to a shorter tmax of 42 mins, suggesting a differentiated approach and providing a quicker onset of action, which may lead to greater benefits. Importantly, clinicians need drug options for migraine patients who either do not respond well or have contraindications to triptans stemming from contraindications in patients with history of coronary artery disease, stroke, transient ischemic attack, or hemiplegic/basilar migraine or in patients with peripheral vascular disease; and we view Elyxyb as filling this niche. SCLX also has plans to run a pediatric study in migraine, in order to build on the well-characterized safety package. Additional head-to-head data for Elyxyb vs. anti-CGRPs is expected at the American Academy of Neurology (AAN' 24, 4/13-18) medical meeting.

Key Points

- **Preliminary 4Q23E/FY24E print and balance sheet fix progressing ahead of plan.** Management released preliminary financial results, highlighted by estimated 4Q23 total net revenue of $13.1M-$19.2M beating our/Street estimates of $10.7M, supporting a return to growth in 4Q for ZTlido net revenues, especially as (1) downward gross-to-net price pressure eases, and (2) unit volume-driven growth re-accelerates as a result of 2Q re-launch focused on gabapentin combination setting. The preliminary estimates indicate a 19% improvement over our/Street estimates, also coming ahead of management's prior conservative projections. In fact, released preliminary results suggest 4Q23 net revenues beat the worst-case scenario, indicating a minimum 30%+ q/q growth, i.e., $13.1M recorded in 4Q. FY23 ZTlido's gross/net sales are expected to be between $145M-$150M and $46M-$52M, respectively, with the total product gross and net revenue anticipated to range from $150M-$155M and $46.5M-$52.5M, beating our/Street FY23 net revenue estimates of $44M/$44.1M, representing ~22%/~38% y/y growth. Balance sheet clean-up remains a top priority, i.e., (1) expedited repayment of Oramed's 18-month senior secured promissory note (~$102M), possibly by 3/19/24 initial penny warrants' vesting date, and (2) anticipated sale of recently purchased SCLX's shares from Sorrento. Additional aid could also come from

ZTlido (possibly Elyxyb, Globerpa, and/or SP-102) ex-US market entry via partnerships, on top of debt restructuring and strategic partnership interest.

- **Preferred agent status & manufacturing expansion expect to aid ZTlido rev growth; late-stage pipeline progress also to gain increasing visibility.** New revenue estimates follow the announced inclusion of ZTlido as a preferred agent in the State of Tennessee's Medicaid Preferred Drug List (PDL), effective October 1, 2023, providing improved access to approximately 1.5M eligible adults. Future continued growth could be aptly derived from (1) successful completion of FDA Good Manufacturing Practices (GMP) inspection of Oishi Koseido's (Oishi) enhanced manufacturing facility in Tosu, Saga, Japan, permitting the facility to continue manufacturing at 250kg scale, and (2) the addition of two states adding ZTlido as a preferred agent to their Medicaid PDLs, effective January 1, 2024, and providing access to 5M covered Medicaid participants. Additionally, given that 72% of gout patients also have chronic kidney disease (CKD), SCLX is also expected to seek FDA approval for Gloperba label modification to include patients with renal impairment. Lastly, SCLX is expected to initiate an open-label trial for SP-102 in 1H24 to fulfill FDA guidance/expectations of adequate safety dataset prior to NDA filing, in addition to a Ph. III study for SP-103 in chronic neck pain, which is also expected to initiate in 2024.

Valuation

We base our Buy rating and 12-month price target of $4 per share on a discounted cash flow (DCF) analysis of revenue and cash flow projected through 2030. Our DCF analysis applies a WACC-calculated 12% discount rate and a 2% terminal growth rate, in line with other clinical-stage biotech companies. For 2030, the final projected year of our model, we forecast $470M in total risk-adjusted revenue.

Risks

History of operating losses. The company has a history of operating losses. Although SCLX has achieved profitability (adjusted EBITDA) in recent quarters, there are no assurances that the company will meet its goals or be able to sustain profitability in future periods.

Financial results. The company has raised money via public offerings several times in the past and may need to do so again if it cannot sustain positive cash flow.

Adoption of assets. If the adoption of SCLX's various assets fails to materialize, or does so at a slower rate than we estimate, our valuation could be materially affected.

Unfavorable clinical trial data. If the products developed by company's spinouts are unable to produce favorable clinical data or are unable to receive regulatory approval, the opportunity for the products could diminish, and our valuation could be adversely affected.

Regulatory risks. The company's compounding facilities are regulated on both the state and federal levels and have seen significant regulatory changes in recent years. If new, unfavorable regulations are instituted, this could have a negative effect on SCLX's operations.

Limited capital. SCLX is a small company with limited resources, which may force it to scale back on aggressive sales and marketing efforts. SCLX may also need to raise capital to sustain operations, which could further dilute existing shareholders.

Intense competition. Many larger companies also focus on SCLX's markets. These companies could develop new, more effective technologies that could decrease SCLX's ability to obtain market share. They could force SCLX and its various spinouts into litigation, which could meaningfully impact FCF and potentially limit commercial opportunities.

Intellectual property. The strength, maintenance, and defense of SCLX's patents, trademarks, and other intellectual property are critical in protecting the company from patent infringement. Should certain key patents be found invalid or expire, this could prevent SCLX's products from reaching their peak commercial potential.

Loss of management and other key employees. The loss of certain employees and executives could disrupt operations and severely impact the company.

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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HOLD [Neutral]	23.94%	31.25%
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