

Operationally Executing Towards Removal of Key Overhangs on Pain Portfolio and Balance Sheet. Reit. Buy; \$4 PT.

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STOCK DATA			
Market Cap (mil)			\$157.5
52-Week Range			\$0.90–\$16.90
3-Month ADTV			934,474
Shares Outstanding (mil)			155.9
Float (%)			57.5
Short Interest			4,875,102
Fiscal Year-End			December
FINANCIAL DATA			
FY	2022A	2023E	2024E
EPS	\$(0.17)	\$(0.85)	\$(0.61)
BALANCE SHEET DATA			
			3Q23
Cash & Equivalents			\$2.0
Current Assets			\$25.5
Total Assets			\$80.5
Total Liabilities			\$243.2
Total Debt			\$122.2
Shareholders' Equity			\$(162.7)
<i>\$ in millions.</i>			

Summary and Recommendation

Pain therapeutics' specialist SCLX (Buy – \$4 PT) recently released 3Q23 results, via 11/14 10-Q filing, noting return of growth in 4Q for ZTlido net revenues as (1) downward gross-to-net price pressure ease, which originally drove 3Q sales decline (20% q/q), and (2) unit volume driven growth re-accelerates as a result of 2Q re-launch focused on gabapentin combination setting (10/13 initiation); this is also notably visible in Bloomberg Symphony Health monthly retail prescription volume growth data (Exhibit 1). Additional pipeline/operational highlights included: (1) SP-102 positive FDA type C meeting de-risking of 505(b)(2) NDA filing for sciatica indication in follow-up to SCLX conducting an additional Ph. III open-label safety study (not efficacy), which remains on track for 1H24 initiation; (2) SP-103 (triple strength formulation of ZTlido) Ph. II randomized, double-blind, placebo-controlled trial in moderate-to-severe acute lower back pain (n=75) demonstrating favorable safety and tolerability alongside achieving pain reduction in those with higher severity of muscle spasms over the first week, with SCLX formalizing plans for late-stage development in chronic neck pain; (3) Elyxyb acute migraine launch execution progressing well (ahead of plan) alongside SCLX also preparing for upcoming Gloperba gout pain (slightly delayed) launch in 2024. Elyxyb's fast-onset of action and lack of cardiovascular-related contraindications on label enables robust positioning as an alternative to triptan therapy, as also supported by recent SCLX-sponsored market research study focused on neurologists, headache specialist and PCPs (n=150). Lastly, balance sheet overhang removal also remains a key priority via (1) anticipated sale of recently purchased SCLX's shares from Sorrento, and (2) expedited repayment of Oramed's senior secured promissory note (~\$102M), possibly by 3/19/24 initial penny warrants' vesting date. We believe the current EV of <3x projected 2025E revenues aptly bakes in any inherent balance sheet risks.

Key Points

- ZTlido sustainable growth dynamics encouraging.** Recently reported preliminary unaudited revenues for October indicate gross/net sales of \$14.5M-\$15.5M/\$4M-\$5M, implying YTD net sales of \$35M-\$40M, representing 15-32% growth y/y compared to the \$30.4M net sales for 2022 YTD through October'22. These growth trends are also reflected in Bloomberg Symphony Health prescription data, with 3Q volume indicating 11.0% growth q/q, and 47.2% growth y/y. ZTlido has gained meaningful market share in a steadily growing lidocaine patch market over the past four years, primarily driven by strong payer coverage. The recently launched sales campaign focuses on using ZTlido as an add-on to gabapentinoid, which is backed by clinical data demonstrating stronger analgesia; enabling SCLX to tap a larger TAM (~50M unit volume/year) where an improved customer mix, i.e., Medicare focused, allows for improved gross-to-net dynamics. Recently, on 11/15 and 11/17, SCLX announced two new patents for ZTlido 1.8% had been issued by the U.S. Patent and Trademark Office, further strengthening the proprietary lidocaine topical system's IP protection.
- De-risked late-stage development for SP-102 in sciatica treatment.** On the heels of the recent positive Type C meeting with FDA for SP-102, SCLX is on track for its NDA filing and a potential first epidural steroid injection (ESI) approval for sciatica in the U.S. SCLX previously generated positive primary and secondary efficacy data from the pivotal Ph. III C.L.E.A.R. randomized placebo-controlled study of SP-102. The study demonstrated statistically significant reductions in the change in average daily pain in the affected leg over 4 weeks i.e., LS mean of -0.52 vs placebo (p<0.002), with additional statistically significant results in the change in average daily pain in the affected leg over 4 weeks i.e., LS *(continued on page 2)*

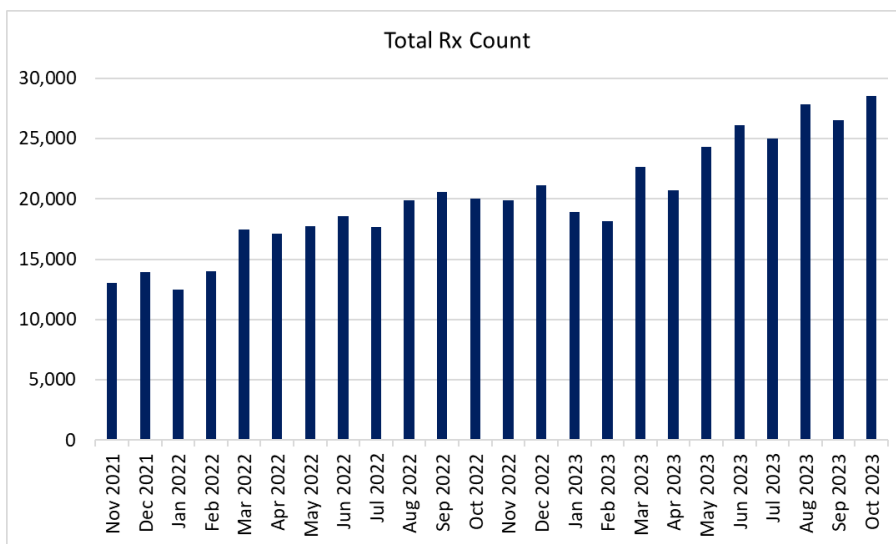
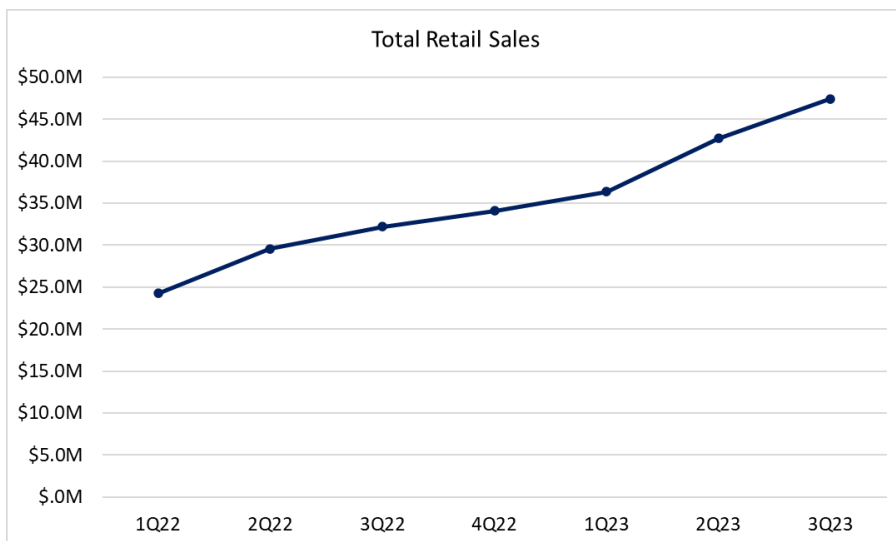
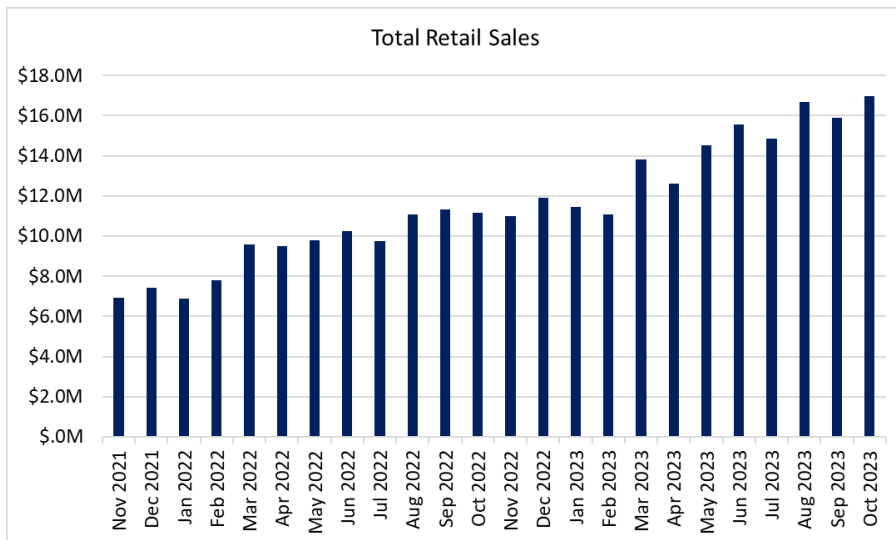
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mean of -0.52 vs placebo ($p=0.002$), with additional statistically significant results in Disability Index, global change, worst pain in affected leg, average daily lower back pain, and brief pain inventory for pain severity. Importantly, time to repeat injections of 84 vs. 58 days (SP-102 vs placebo; $p=0.001$), implies reduced physician and patient burden, translating to healthcare cost savings. Overall, we view SP-102 as de-risked with a potential market of 12M+ ESI unit volume, the majority of which is for lumbar radiculopathy/sciatica management by interventional pain physicians as a non-surgical, non-opioid alternative. SCLX plans to initiate an open-label safety and efficacy trial ($n \sim 700$) in 1H24 for SP-102 to fulfill FDA guidance/expectations of adequate safety dataset prior to NDA filing and for product registration. Enrollment is expected to complete in 2025.

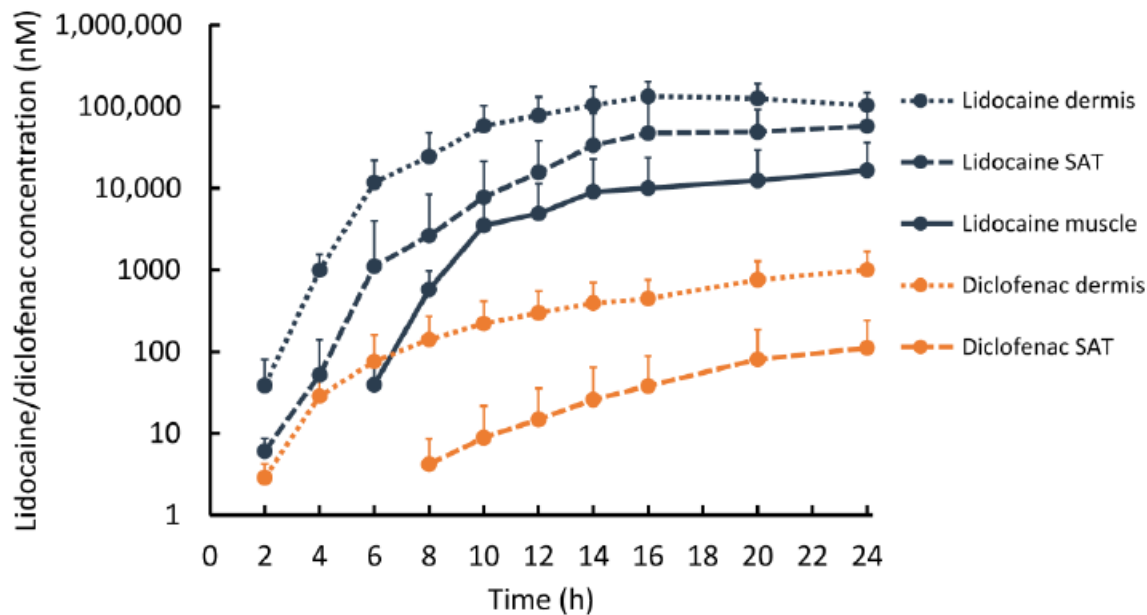
- SP-103 aimed at maximizing value of lidocaine topical system in highly prevalent forms of musculoskeletal (nociceptive) pain, with focused initial late-stage development in chronic neck pain.** SCLX published new SP-103 data, a 5.4% lidocaine topical system (3x the strength of ZTlido, with the same adhesive formulation) demonstrating that SP-103 improved skin penetration, delivering drug into muscle tissue more effectively than ZTlido (Birngruber et al, *Pharmaceutics*, 2023). The research examined drug penetration in the dermis, subcutaneous adipose tissue, and muscle comparing SP-103 to control, a topical pain relief gel Pennsaid (2% diclofenac) *ex-vivo* in explanted porcine tissue, and also *in-vivo* in anesthetized domestic pigs adding the Ztilido 1.8% as well. *Ex vivo* data demonstrated that diclofenac was below the lower limit of quantification (LLOQ) in the muscle whereas SP-103 achieved levels of 39.3 ± 29.1 nM 6h post treatment suggesting greater diffusive transport of SP-103 even without systemic blood circulation (Exhibit 2). In the *in vivo* experiments, while Pennsaid concentrations in the muscle (8.6 ± 1.7 mm) remained around the LLOQ levels throughout the 24-hour study course, SP-103 was able to reach a concentration almost 5-fold higher than that by ZTlido at 24 hours, i.e., SP-103: 23.4 ± 34.7 nM vs ZTlido: 4.9 ± 1.4 nM (Exhibit 3). 24-hour AUC of lidocaine concentrations in the muscle showed that SP-103 was significantly higher than that of ZTlido ($p=0.008$), although no statistical significance was observed when compared to control (Pennsaid, no lidocaine), possibly due to small sample size. These data support the preliminary analysis of the Ph. II SP-103 randomized, placebo-controlled study reported in September, performed in 75 subjects with moderate to severe acute lower back pain (SP-103 $n=38$, placebo $n=37$) that (1) SP-103 was safe and well tolerated; (2) 3x the strength in lidocaine did not lead to systemic toxicity or increased reactions at the application site; and (3) a reduction in pain by the Sum of Pain Intensity Differences (SPID-7) analysis over the first week (-1.5 point [95% CI: $-0.2, 3.2$]) in a subpopulation of patients with more severe muscle spasms. A separate investigator-initiated study of ZTlido in chronic non-radicular neck pain showed preliminary promising results of reduction in average daily pain over one-month treatment period of ZTlido. Based on these preclinical and clinical datasets, SCLX plans to develop SP-103 in chronic neck pain, with an expected EOP2 meeting with FDA after the completion of data analysis of the above mentioned two clinical studies. A Ph. III study for SP-103 is expected to initiate in 2024.
- Additional revenue streams emerging from Elyxyb and Gloperba.** Following the in-licensing of the U.S./Canadian rights to Elyxyb (celecoxib, oral solution) in 1Q23 and the U.S. launch in 2Q23, SCLX recently announced the increase of Elyxyb manufacturing to meet the rising demand and has produced the first commercial batch of SCLX labeled Elyxyb. Elyxyb oral solution is a prescription NSAID for acute migraine treatment with or without aura. Recently, SCLX conducted a market research study ($n=150$) of neurologist, headache specialists, and primary care physicians that highlighted 93% of clinicians treating migraine reported having moderate to extremely high unmet needs for alternative options to triptan therapy (5-HT_{1B/1D} receptor agonist). In particular, clinicians need drug options for migraine patients who either do not respond well or have contraindications to triptan. Elyxyb has the potential to address these, given that (1) it achieved significant pain relief within 45 minutes in $\sim 50\%$ patients (47.7% at 45 minutes post-dose vs. 37.1% by placebo, $p=0.021$) (Lipton et al, *J Pain Res*, 2021); (2) 46.2% of Elyxyb-treated patients achieved pain free at 2 hours vs. 31.1% in placebo group ($p<0.001$); (3) a post-hoc analysis indicated its superiority in pain freedom rates (60 min through 3 hr post dosing) to oral CGRP antagonists, ubrogepant 100mg and rimegepant 75mg (Exhibit 4); and (4) triptan drugs are contraindicated in patients with history of coronary artery disease, stroke, transient ischemic attack, or hemiplegic/basilar migraine, or in patients with peripheral vascular disease, whereas Elyxyb does not have these limitations (although it is contraindicated in CABG setting). Separately, SCLX expects to commercialize Gloperba in 1Q24, which is anticipated to bring meaningful revenues entering into 2025. Gloperba is FDA-approved colchicine USP oral solution for prophylaxis of gout flares. The unmet need in the gout therapeutic area lies in the GI side effects and patient compliance. Gloperba oral solution enables easier dosing adjustment and reduction, which may be able to reduce side effects and could improve disease management.
- 3Q23 EPS of $\$(\$0.63)$ came in below our/Street estimates of $\$(\$0.19)/\$(\$0.17)$.** This was primarily due to the premium on redemption of preferred stock ($\$52.6$ M) representing a dividend to the preferred stockholder. R&D expenses of $\$4.1$ M (+229% y/y) were higher than our/Street estimates of $\$3.5$ M/ $\$3.3$ M, driven by planning of Ph. II SP-104 trial and Ph. III SP-102 trial. SG&A expenses of $\$40.4$ M (+151% y/y) were higher than our/Street estimates of $\$25.6$ M/ $\$27.3$ M, primarily driven by a $\$12.3$ M increase in advisory expenses (including an aggregate of $\$9.4$ M fees to the Hudson Bay Parties) and a $\$6.8$ M increase in personnel expense resulting from headcount increase. SCLX ended the quarter with cash and cash equivalents of $\sim \$2$ M and net accounts receivable/inventory of $\sim \$20$ M. SCLX entered into Securities Purchase Agreement with Oramed on 9/21 and issued to Oramed an 18-month senior secured promissory note with principal amount of $\$101.875$ M. Mgmt. reaffirmed its commitment to repay the outstanding principal in full by Mar'24, as it evaluates a number of strategic financing options including sale of securities that SCLX repurchased from Sorrento.

Exhibit 1. Bloomberg Symphony Health Retail Data Indicate Resumption of Durable Growth of ZTlido Sales



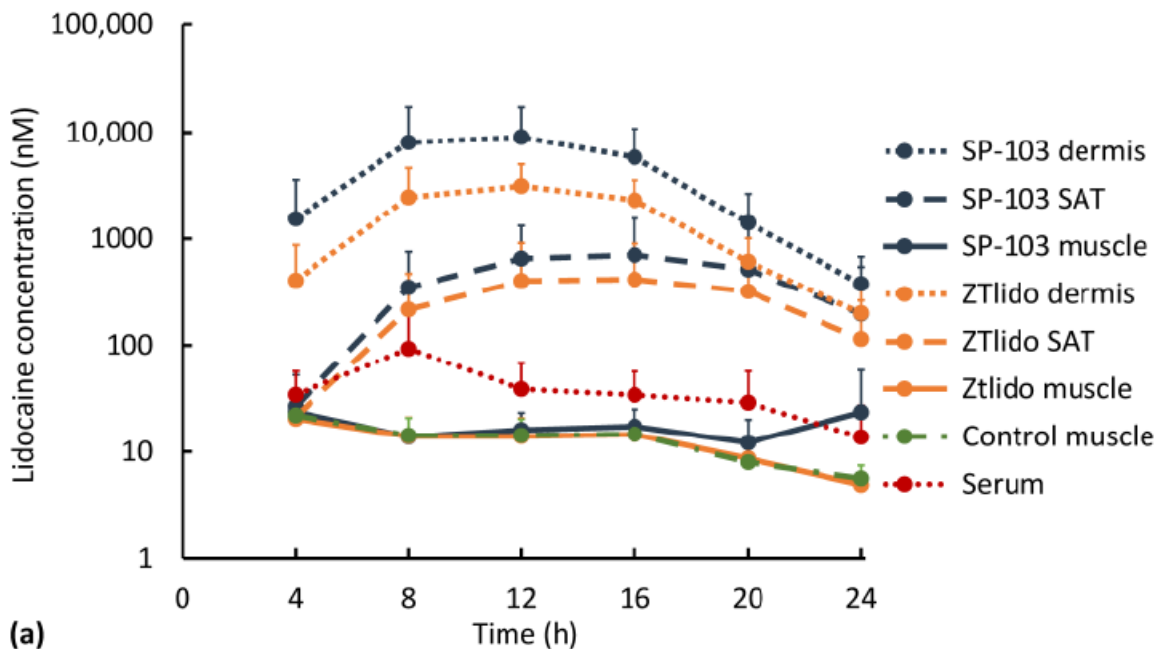
Source: Bloomberg/Symphony Health; B. Riley Securities Research

Exhibit 2. Ex Vivo Results Confirm SP-103's Potent Muscle Tissue Penetration



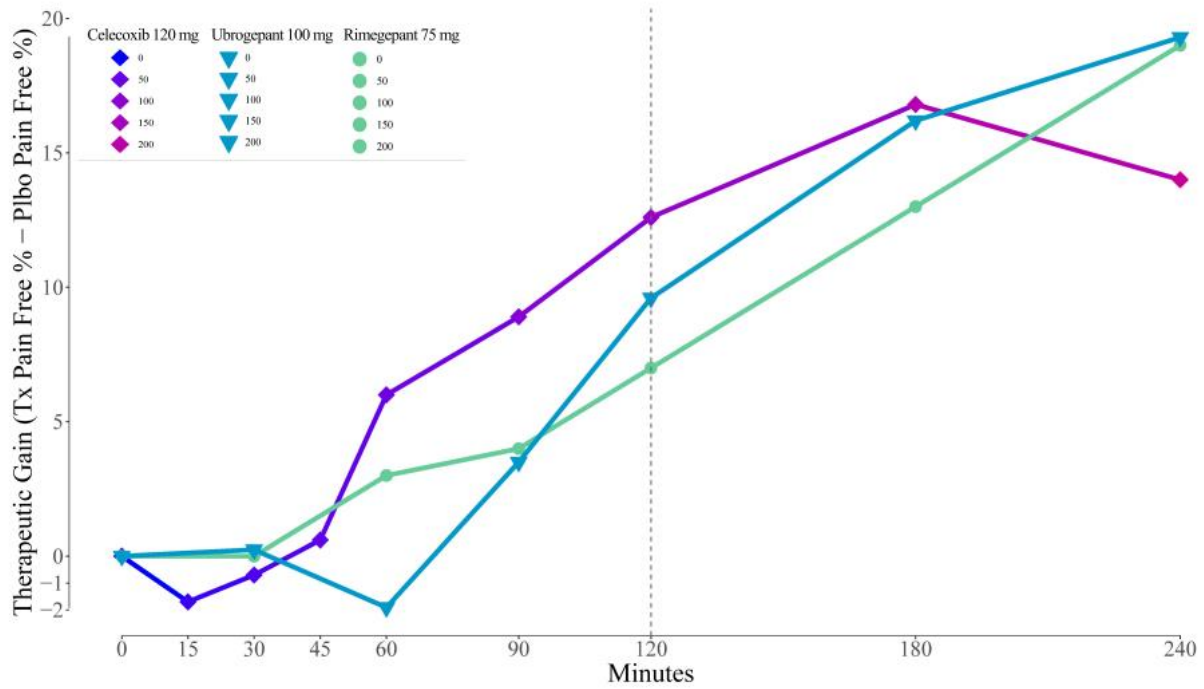
Source: Birngruber et al, *Pharmaceutics*, 2023

Exhibit 3. In Vivo Experiments Demonstrate SP-103 Led to Almost 5-Fold Higher Lidocaine Concentration in the Muscle at 24 Hours than ZTlido



Source: Birngruber et al, *Pharmaceutics*, 2023

Exhibit 4. Elyxyb More Likely Led to Pain Free from 60 Minutes through 3 Hours Post-Dose, Compared to CGRP Receptor Antagonists



Source: *Tepper et al, poster presented at BRAINWeek 2023*

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.

Scilex Holdings, Inc. (SCLX)												Mayank Mamtani
DCF analysis												B. Riley Securities
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Fiscal year	2020A	2021A	2022A	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	Terminal value
Fiscal year end date	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24	12/31/25	12/31/26	12/31/27	12/31/28	12/31/29	12/31/30	
Revenues	\$ 23.6	\$ 31.3	\$ 38.0	\$ 44.0	\$ 57.43	\$ 79.12	\$ 121.29	\$ 165.30	\$ 220.07	\$ 297.14	\$ 406.66	
Cost of product sales	\$ (2.1)	\$ (3.6)	\$ (10.8)	\$ (14.8)	\$ (18.95)	\$ (19.78)	\$ (16.98)	\$ (23.14)	\$ (30.81)	\$ (41.60)	\$ (56.93)	
Gross Profit	\$ 21.4	\$ 27.7	\$ 27.2	\$ 29.2	38.5	59.3	104.3	142.2	189.3	255.5	349.7	
Intangible Amortization	\$ (3.7)	\$ (3.7)	\$ (3.9)	\$ (4.9)								
R&D expense	\$ (10.0)	\$ (9.2)	\$ (9.1)	\$ (14.9)	(33.9)	(23.8)	(7.1)	(5.0)	(5.2)	(5.5)	(5.8)	
SG&A expense	\$ (43.0)	\$ (50.6)	\$ (64.9)	\$ (123.4)	(112.9)	(124.2)	(136.6)	(143.5)	(150.6)	(153.6)	(156.7)	
Total operating expenses	\$ (56.7)	\$ (63.5)	\$ (77.9)	\$ (138.3)	(146.9)	(148.0)	(143.8)	(148.4)	(155.9)	(159.1)	(162.5)	
Operating income (EBIT)	\$ (35.3)	\$ (35.8)	\$ (50.6)	\$ (109.0)	(108.4)	(88.6)	(39.4)	(6.3)	33.4	96.4	187.2	
Taxes	0.1	(0.0)	-	-	-	-	(5.3)	(2.0)	2.0	8.3	36.5	
After tax operating income	(35.3)	(35.8)	(50.6)	(109.0)	(108.4)	(88.6)	(34.1)	(4.3)	31.4	88.1	150.8	
(+) depreciation and amortization	14.4	11.7	7.1	4.3	5.8	6.0	1.3	1.4	1.6	1.7	6.1	
(-) capital expenditures	0.3	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(-) change in working capital	(7.1)	(13.6)	(45.7)	(94.4)	(7.2)	(7.3)	(7.5)	(7.6)	(7.8)	(7.9)	(8.1)	
(+) deferred taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(+) other non-cash items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Unlevered free cash flow	(27.7)	(37.7)	(89.2)	(199.0)	(109.7)	(90.0)	(40.3)	(10.5)	25.2	81.9	148.7	
Time period (years)				0.17	1.17	2.17	3.17	4.17	5.17	6.17	7.17	
Discount factor				0.98	0.89	0.80	0.72	0.65	0.58	0.53	0.47	
PV				(48.9)	(97.2)	(71.8)	(29.0)	(6.8)	14.7	43.0	70.4	
EV	672.46											PV of Terminal Value
+ Cash and Cash equivalents	1.95											797.93
Company value	674.42											
- Long-term debt	122.2											
Equity value	\$552											
Fully diluted shares outstanding	155.9											
Price/share	\$ 4.00											
WACC	11.0%											
Terminal growth rate	2.0%											
Shares (10-Q, Nov. 14, 2023)												
Dilution												
1,130,907 shares, on exercise of convertible notes 1.131 shares \$8.00 WAEP 0.000												
30,665,000 shares, on exercise of stock options 30.665 shares \$4.63 WAEP 0.000												
10,467,692 shares, on exercise of warrants 10.468 shares \$1.49 WAEP 0.000												
0,000 shares, on exercise of unvested RSUs 0.000 shares \$0.00 WAEP 0.000												
Possible dilution (million shares) 0.000												
Assumptions			WACC Calculations				Balance Sheet					
Date	11/22/2023		Risk-free rate	2.0%		Total debt	122.15					
Fiscal year ending (1-12)	12		Adjusted beta	1.3		Cash and equivalents	1.95					
Fiscal year ending (month)	December		Rm-Rf	7.0%		Net debt	120.20					
Projections discounted to (1-12)	12.00		Re	11.0%		Debt, as a % of equity	77.55%					
Projections discounted to (month)	December		Rd	0.0%		Cash per share	0.01					
Shares outstanding	155.943		WACC, calculated	11.0%		Closing price, 11-22-23	\$ 1.01					
						Closing market cap, 11-22-23	\$ 157.50					

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

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Rating	B. Riley Securities, Inc. Research Distribution ¹	B. Riley Securities, Inc. Banking Services in the past 12 months ¹
BUY [Buy]	76.98%	41.86%
HOLD [Neutral]	23.02%	22.22%
SELL [Sell]	0.00%	0.00%

(1) As of midnight on the business day immediately prior to the date of this publication.

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