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Scilex Holding Company (SCLX) Rating: Buy Company Update Healthcare

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Portfolio Progress; ZTlido Sales Growth; 3Q23 Financials; Reiterate Buy

Stock Data			12/01/2023				
Price			\$1.35				
Exchange		NASDAC					
Price Target	\$12.0						
52-Week High		\$16.90					
52-Week Low		\$0.90					
Enterprise Valu		\$246					
Market Cap (M		\$211 155.9					
Shares Outstar 3 Month Avg V		1,009,569					
Short Interest (1,009,569					
Balance Shee			0.00				
Cash (M)			\$2.0				
Total Debt (M)			\$37.7				
Total Cash/Sha	are		\$0.01				
Book Value/Sh	are		\$(1.73)				
EPS (\$) Diluted		÷					
Full Year - Dec	2022A	2023E	2024E				
1Q		(0.22)A	(0.17)				
2Q		(0.19)A	(0.14)				
3Q		(0.63)A	(0.11)				
4Q FY	(0.17)	(0.22)	(0.08)				
Revenue (\$M)	(0.17)	(0.88)	(0.48)				
Full Year - Dec	2022A	2023E	2024E				
1Q		10.6A	15.5				
2Q		12.6A	22.5				
3Q		10.1A	28.5				
4Q		11.3	36.7				
FY	38.0	44.6	103.1				
15 <u>Vol. (mil)</u>			Price 20				
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DEC-22	APR-23 A	AUG-23	NOV-23				

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Commercial portfolio demonstrates progress. Last month, Scilex reported advancements with both its lead anti-migraine asset Elyxyb® (celecoxib oral solution) and its lead product for prophylaxis of painful gout flares, Gloperba® (oral colchicine solution) in the U.S. market. Scilex has entered into an agreement with a leading pharmacy chain in the U.S. to stock Elyxyb in over 500 stores where the product is currently not available. Scilex is also in the process of negotiating similar potential stocking arrangements with other major pharmacy chains in the U.S. Clinicians in a recent market research study expressed their desire for fast and safe alternatives for two large pools of acute migraine patients -those who have an insufficient response to triptan therapy, and those who have contraindications to triptan use. The Elyxyb product profile mapped with a high degree of certainty to these stated unmet needs. In clinical studies, patients treated with Elyxyb experienced pain relief in as little as 15 minutes, while significant pain relief vs. placebo was achieved within 45 minutes in approximately 50% of patients. In the case of Gloperba, we note that Scilex has completed commercial manufacturing of the product in the U.S. and is expecting to formally launch Gloperba in the U.S. in 1Q24. In our view, Gloperba could achieve peak U.S. sales totaling \$830M by 2035E, with nearly \$750M in net revenue to Scilex at peak. We reiterate our Buy rating and 12-month price target of \$12 per share.

ZTlido continues to demonstrate commercial traction. Scilex has also reported gross and net revenues for the month of November 2023. ZTlido® gross sales for November 2023 were in the range of \$14-15M with record full-year 2023 gross sales expected to be in the range of \$140-150M vs. \$96 million for 2022, representing growth in the range of 48-60%. ZTlido net sales for November 2023 were in the \$3.9-4.5M range with full-year 2023 net sales slated to be in the range of \$44-50M vs. \$38M for 2022, representing growth in the range of 16-32%. ZTlido full-year 2022 net sales totaled \$38M. We currently expect total 4Q23 net sales of \$11.3M and full-year 2023 net sales of \$44.6M. We now expect 2024 full-year net sales to rise to \$103.1M. Late last month, Scilex also announced the successful completion of a current Good Manufacturing Practices (cGMP) FDA inspection of the enhanced manufacturing facility of Oishi Koseido Co., Ltd. (Oishi) for ZTlido located in Tosu, Saga, Japan. This successful audit allows Scilex to continue selling ZTlido product manufactured at 250kg scale at Oishi's facility. This facility is also the manufacturing site for SP-103 (lidocaine topical system, a triple-strength formulation of ZTlido) that recently completed trials in acute back pain and neck pain.

For definitions and the distribution of analyst ratings, analyst certifications, and other disclosures, please refer to pages 4 - 5 of this report.

Financial results reported—by the numbers. Earlier in November 2023, Scilex reported its 3Q23 financial results. The company ended the period with roughly \$2M in cash and recorded a net loss of \$0.63 per share vs. our forecast for a net loss of only \$0.16 per share; this was primarily due to higher than expected operating expenses, particularly on the SG&A front. These expenses totaled \$40.4M in the quarter vs. our forecast for SG&A spending of only \$29M; R&D spending in 3Q23 was roughly in line with our estimate at \$4M vs. \$3.5M. We currently project a full-year 2023 net loss of \$0.88 per share, narrowing to a net loss of \$0.48 per share in 2024. Previously, we were estimating a full-year 2023 net loss of only \$0.72 per share and a full-year 2024 net loss of \$0.35 per share.

Valuation and risks. We assess Scilex using a discounted cash flow (DCF)-based valuation methodology. This applies an 85% probability of approval to SEMDEXA (SP-102), while we assume 100% probability of approval for ZTlido, Elyxyb, Gloperba and SP-103. In our view, the SP-103 candidate should readily achieve market entry because it is simply a triple-strength version of the existing ZTlido product. We utilize a 10% discount rate and 1.5% terminal growth rate. In our view, these assumptions are reasonable given the well-established, mature and broad nature of Scilex's target markets and the risk-mitigated, well-characterized nature of its portfolio of marketed products and development-stage candidates. Our assumptions correspond to a total firm value of \$3.8B, which yields a price objective of \$12 per share assuming 313.7M fully diluted shares outstanding as of end-3Q24. Risks include, but are not limited to: (1) inability to achieve meaningful market traction with ZTlido, Elyxyb or Gloperba due to greater than anticipated competitive pressures or setbacks in obtaining reimbursement and formulary access; (2) failure to obtain regulatory approval in the U.S. for SEMDEXA or SP-103; (3) financial market risks; (4) broader macroeconomic risks related to U.S. government funding negotiations and ongoing geopolitical fallout related to the Ukraine and Middle Eastern conflicts; and (5) near to medium-term dilution risk.

Table 1: Scilex Holding Company (SCLX)—Historical Income Statements, Financial Projections

FY end December 31

\$ in thousands, except per share data

		2023E			2024E						
	2022A	1QA	2QA	3QA	4QE	2023E	1QE	2QE	3QE	4QE	2024E
Revenue Product revenue	38'034	10'582	12'582	10'117	11'335	44'616	15'507	22'457	28'476	36'706	103'146
Research and other	- 30 034	10 562	12 302	-	-	44 0 10	15 507	- 22 457	20470	- 30700	103 140
Total revenue	38'034	10'582	12'582	10'117	11'335	44'616	15'507	22'457	28'476	36'706	103'146
Expenses											
Cost of product and service revenue	10'797	3'591	4'177	3'392	3'741	14'901	4'962	6'962	8'258	10'278	30'460
Research & development	9'054	2'736	3'204	4'072	4'100	14'112	4'200	4'400	4'500	4'900	18'000
Selling, general and administrative	64'895	28'701	26'989	40'431	38'000	134'121	40'000	40'000	40'000	40'000	160'000
Intangible amortization	3'922	1'027	1'026	1'027	1'000	4'080	1'000	1'000	1'000	1'000	4'000
Total expenses	88'668	36'055	35'396	48'922	46'841	167'214	50'162	52'362	53'758	56'178	212'460
Gain (loss) from operations	(50'634)	(25'473)	(22'814)	(38'805)	(35'506)	(122'598)	(34'655)	(29'905)	(25'282)	(19'472)	(109'314)
Other income/expense											
Interest income/expense	(9'604)	1	(5)	(513)	(1'900)	(2'417)	(1'800)	(1'390)	(950)	(430)	(4'570)
Gain (loss) on derivative liability	8'310	(5'253)	(82)	4'245	-	(1'090)	-	-	-	-	-
Gain (loss) on debt extinguishment	28'634	-	-	(449)	-	(449)	-	-	-	-	-
Scilex Notes principal / debenture fair value change	-	-	(3'748)	-	-	(3'748)	-	-	-	-	-
Loss (gain) on foreign currency exchange	(66)	(20)	(3)	(7)	-	(30)	-	-	-	-	-
Total investment income and other	27'274	(5'272)	(3'838)	3'276	(1'900)	(7'734)	(1'800)	(1'390)	(950)	(430)	(4'570)
Loss before provision for income taxes	(23'360)	(30'745)	(26'652)	(35'529)	(37'406)	(130'332)	(36'455)	(31'295)	(26'232)	(19'902)	(113'884)
Deferred income tax benefit	(4)	(8)	-	-	-	(8)	-	-	-	-	-
Net loss/income	(23'364)	(30'753)	(26'652)	(35'529)	(37'406)	(130'340)	(36'455)	(31'295)	(26'232)	(19'902)	(113'884)
Net loss per share (basic)	(0.17)	(0.22)	(0.19)	(0.63)	(0.22)	(0.88)	(0.17)	(0.14)	(0.11)	(0.08)	(0.48)
Net loss per share (diluted)	(0.17)	(0.22)	(0.19)	(0.63)	(0.22)	(0.88)	(0.17)	(0.14)	(0.11)	(0.08)	(0.48)
Weighted average number of shares outstanding (basic)	134'226	141'660	142'626	139'808	168'775	148'217	208'850	228'950	244'050	259'150	235'250
Weighted average number of shares outstanding (diluted)	134'226	141'660	142'626	139'808	168'775	148'217	208'850	228'950	244'050	259'150	235'250

Source: Company reports and H.C. Wainwright & Co. estimates.

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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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Distribution of Ratings Table as of December 1, 2023						
			IB Se	IB Service/Past 12 Months		
Ratings	Count	Percent	Count	Percent		
Buy	553	88.76%	137	24.77%		
Neutral	56	8.99%	7	12.50%		
Sell	0	0.00%	0	0.00%		
Under Review	14	2.25%	6	42.86%		

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