H.C.WAINWRIGHT&CO.

Company Update
Healthcare

November 7, 2023

Scilex Holding Company (SCLX)
Rating: Buy

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SP-102 Regulatory Feedback; Positive Revenue Trends; Reiterate Buy

Stock Data	11/06/2023
Price	$1.48
Exchange	NASDAQ
Price Target	$12.00
52-Week High	$16.90
52-Week Low	$1.21
Enterprise Value (M)	$231
Market Cap (M)	$227
Shares Outstanding (M)	153.5
3 Month Avg Volume	815,261
Short Interest (M)	4.73
Balance Sheet Metrics	
Cash (M)	$34.1
Total Debt (M)	$37.7
Total Cash/Share	$0.22
Book Value/Share	$0.07

EPS ($) Diluted			
Full Year - Dec	2022A	2023E	2024E
1Q	--	(0.22)A	(0.14)
2Q	--	(0.19)A	(0.11)
3Q	--	(0.16)	(0.07)
4Q	--	(0.16)	(0.04)
FY	(0.17)	(0.72)	(0.35)

Revenue ($M)			
Full Year - Dec	2022A	2023E	2024E
1Q	--	10.6A	18.8
2Q	--	12.6A	25.0
3Q	--	13.9	32.3
4Q	--	16.3	40.5
FY	38.0	53.4	116.6

Positive Type C meeting held regarding SP-102 registrational pathway. Last week, Scilex announced that it had held a Type C meeting with the FDA, in which the company reached agreement with the agency on the path forward to advance the clinical development of SP-102 (SEMDEXA™) and on the requirements to file a New Drug Application (NDA). During this meeting, Scilex received advice on expectations and requirements to file the NDA, including the scope of clinical and preclinical data needed to be submitted in support of the regulatory submission. Scilex intends to file the SP-102 NDA utilizing the 505(b)(2) regulatory pathway to reference the currently approved drug, dexamethasone sodium phosphate injection. The FDA provided guidance regarding expectations for the size of safety database needed prior to the NDA filing and circumstances under which one adequate and well-controlled trial would be sufficient for product registration. Based on the feedback received from the agency, Scilex is now planning to commence an open-label multi-center safety and efficacy trial in 1H24 in which it will seek to enroll approximately 700 patients with moderate-to-severe lumbosacral radicular pain (LRP) requiring an epidural steroid injection. SP-102 is slated to be administered in up to three injections during a six-month observation period. Completion of enrollment is slated to occur in 2025. In the wake of this development, which we believe mitigates the risk profile of the SP-102 program and provides a significantly clearer path to potential approval of the product, we reiterate our Buy rating with a 12-month price target of $12 per share. While we had originally speculated upon the potential approval of SP-102 next year, we currently assume approval and market entry in 2026. Our probability of approval has risen to 85% from the prior 80% based on the clarity received from the FDA. We believe that SP-102 could have blockbuster peak sales potential in the U.S. alone.

ZTlido continues to demonstrate commercial traction. Scilex has also reported gross and net revenues for the month of October 2023. Record ZTlido gross sales for October 2023 were achieved, in the range of $14.5-15.5M with record year-to-date gross sales through October 2023 in the range of $110-120M vs. $74.8 million for year-to-date through October 2022, representing growth in the range of 47-60%. Full-year gross sales for ZTlido in 2022 were $96M. ZTlido net sales for October 2023 were in the $4-5M range with year-to-date net sales through October 2023 in the range of $35-40M vs. $30.4M for year-to-date through October 2022, representing growth in the range of 15-32%. ZTlido full-year 2022 net sales totaled $38M. As a reminder, we currently expect total 3Q23 net sales of $13.9M and full-year 2023 net sales of $53.4M; we continue to believe Scilex can achieve these projections. We expect 2024 full-year net sales to rise to $116.6M. In our view, longer-term growth should come from continued expansion of the ZTlido revenue base as well as contributions from Gloperba (colchicine oral solution for treatment of gout) and—to a lesser extent—Elyxyb (celecoxib oral solution for treatment of migraines).

SP-103 skin penetration study results appear in peer-reviewed publication. Also last week, Scilex announced the publication of a peer-reviewed article that contains the results of previously-completed skin penetration studies conducted at the Institute for Biomedical Research and Technologies in Graz, Austria. A set of studies assessed drug delivery from SP-103, ZTlido and control (Pennsaid, 2% diclofenac) using open flow microperfusion. Interstitial fluid from the dermis, subcutaneous adipose tissue, and muscle was continuously sampled to assess drug penetration in all tissue layers. *Ex vivo* and *in vivo* experiments showed a higher diffusive transport of lidocaine vs. diclofenac. The data showed a clear contribution of diffusive transport to lidocaine concentration, with SP-103 resulting in a significantly higher lidocaine concentration in muscle tissue than commercially available ZTlido (p=0.008). Scilex believes that these results indicate that SP-103 is highly effective in delivering lidocaine into muscle tissue in areas of localized pain for the treatment of musculoskeletal pain disorders, which ought to hint at potent efficacy in these indications. Results of these studies were presented at the annual meeting of American Association of Pharmaceutical Scientists (AAPS 2023 PHARMSCI 360), in Orlando, Florida on October 23, 2023; and published in the peer-reviewed journal *Pharmaceutics* by Multidisciplinary Digital Publishing Institute (MDPI).

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 $3.4B, which yields a price objective of $12 per share assuming 274.4M 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 the U.S. government shutdown negotiations and ongoing geopolitical fallout related to the Ukraine war; and (5) possible 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	3QE	4QE	2023E	1QE	2QE	3QE	4QE	2024E
Revenue											
Product revenue	38'034	10'582	12'582	13'948	16'252	53'364	18'785	24'964	32'332	40'537	116'618
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	38'034	10'582	12'582	13'948	16'252	53'364	18'785	24'964	32'332	40'537	116'618
Expenses											
Cost of product and service revenue	10'797	3'591	4'177	4'882	5'851	18'501	6'011	7'739	9'376	10'945	34'071
Research & development	9'054	2'736	3'204	3'300	3'500	12'740	3'800	4'200	4'700	5'300	18'000
Selling, general and administrative	64'895	28'701	26'989	29'000	30'000	114'690	32'000	32'000	32'000	32'000	128'000
Intangible amortization	3'922	1'027	1'026	1'000	1'000	4'053	800	800	800	800	3'200
Total expenses	88'668	36'055	35'396	38'182	40'351	149'984	42'611	44'739	46'876	49'045	183'271
Gain (loss) from operations	(50'634)	(25'473)	(22'814)	(24'234)	(24'099)	(96'620)	(23'826)	(19'775)	(14'544)	(8'508)	(66'653)
Other income/expense											
Interest income/expense	(9'604)	1	(5)	(1'700)	(2'292)	(3'996)	(1'950)	(1'490)	(1'050)	(480)	(4'970)
Gain (loss) on derivative liability	8'310	(5'253)	(82)	-	-	(5'335)	-	-	-	-	-
Gain (loss) on debt extinguishment	28'634	-	-	-	-	-	-	-	-	-	-
Loss (gain) on foreign currency exchange	(66)	(20)	(3)	-	-	(23)	-	-	-	-	-
Total investment income and other	27'274	(5'272)	(3'838)	(1'700)	(2'292)	(13'102)	(1'950)	(1'490)	(1'050)	(480)	(4'970)
Loss before provision for income taxes	(23'360)	(30'745)	(26'652)	(25'934)	(26'391)	(109'722)	(25'776)	(21'265)	(15'594)	(8'988)	(71'623)
Deferred income tax benefit	(4)	(8)	-	-	-	(8)	-	-	-	-	-
Net loss/income	(23'364)	(30'753)	(26'652)	(25'934)	(26'391)	(109'730)	(25'776)	(21'265)	(15'594)	(8'988)	(71'623)
Net loss per share (basic)	(0.17)	(0.22)	(0.19)	(0.16)	(0.16)	(0.72)	(0.14)	(0.11)	(0.07)	(0.04)	(0.35)
Net loss per share (diluted)	(0.17)	(0.22)	(0.19)	(0.16)	(0.16)	(0.72)	(0.14)	(0.11)	(0.07)	(0.04)	(0.35)
Weighted average number of shares outstanding (basic)	134'226	141'660	142'626	158'725	168'775	152'946	183'850	198'950	209'050	219'150	202'750
Weighted average number of shares outstanding (diluted)	134'226	141'660	142'626	158'725	168'775	152'946	183'850	198'950	209'050	219'150	202'750

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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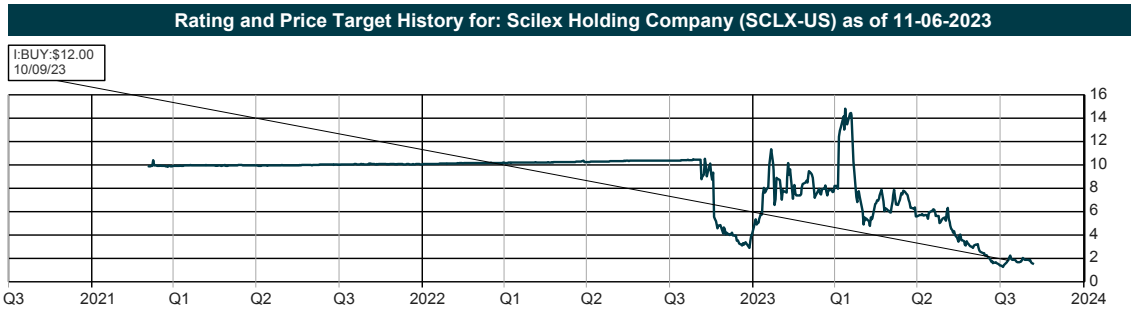

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Distribution of Ratings Table as of November 6, 2023

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	569	89.75%	140	24.60%
Neutral	56	8.83%	9	16.07%
Sell	0	0.00%	0	0.00%
Under Review	9	1.42%	3	33.33%

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