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Ascelia Pharma

Medvind i seglen

Positiva topline-data

Ascelia presenterade under föregående vecka topline-data från fas III-studien SPARKLE (n=85). Denna registreringsgrundande studie utvärderade effekten av Orviglance i en patientpopulation med kraftigt nedsatt njurfunktion som genomgick MR-scanning för att identifiera fokala leverskador. Studien mötte sitt primära effektmått, visualisering av fokala leverskador, med en god statistisk signifikans ($p < 0,001$) för samtliga tre oberoende radiologer som bedömde bilderna.

Möjligt att nå marknad under 2026

Vi anser att resultaten är lovande och bör ha god potential att utgöra grunden för ett marknadsgodkännande i USA och Europa. Ascelia guidar för att de kommer att skicka in en ansökan för marknadsgodkännande till amerikanska FDA under mitten av 2025. I ett scenario där Ascelia skickar in ansökan under mitten av 2025 bedömer vi att ett marknadsgodkännande i USA kan erhållas under 2026.

Höjer sannolikhet för godkännande

Ascelia hade under tisdagen en livesändning där de fördjupade sig ytterligare i Orviglance och de resultat som presenterats. Bolaget är fortfarande flexibla i sin kommersiella strategi i USA och lämnar dörren öppen för lansering i egen regi alternativt ett potentiellt partneravtal. De meddelar även att de kommer att återuppta den kliniska utvecklingen av Oncoral när bolaget är tillräckligt kapitaliserat. Med nuvarande kassa bedömer vi att pengarna kommer att räcka fram till Q2 2025.

Mot bakgrund av de lovande topline-data som presenterats i SPARKLE-studien höjer vi vår LoA för Orviglance till 85% (50%). Vårt nya motiverade värde uppgår till 15-18 kronor (7-8) per aktie. Aktien har presterat mycket starkt i år och stigit nära 200%, vilket kan vara en förklaring till att aktien hållits tillbaka av kortsiktig vinsthemtagning efter att data presenterats.

Change in estimates				Forecasts (SEKm)				Value and risk	
	24e	25e	26e	2023	2024e	2025e	2026e	Fair value	SEK 15.0 - 18.0
Total Revenues	0.0%	0.0%	76.0%	0	0	0	55	Share price	SEK 10.0
EBITDA, adj.	0.0%	0.0%	-55.7%	-	-	0%	N.m.	Risk level	High
EPS, adj.	0.0%	0.0%	-55.7%	-111	-35	-100	-203	Price Performance 12 months	
				-111	-35	-100	-203		
Upcoming events				EBIT, adj.	-111	-35	-100		
Q1 - report		16 May 2024		EPS, adj.	-3.2	-1.1	-2.9		
Company facts (SEKm)				EPS growth, adj.	N.m.	N.m.	N.m.		
Number of shares		35m		BV/share	2.1	1.1	3.9		
Market capitalisation		345		EBIT margin	Neg.	Neg.	Neg.		
Net debt		13		ROE, adj.	Neg.	Neg.	Neg.		
EV		358		ROCE, adj.	Neg.	Neg.	Neg.		
Free float		68%		EV/Sales	Neg.	35830.8	35830.8		
Daily trading volume, average		491k				X	X		
Bloomberg Ticker		ACE SS EQUITY		EV/EBITDA	Neg.	Neg.	Neg.		
Analyst				EV/EBIT	Neg.	Neg.	Neg.		
Ludvig Svensson				P/E, adj.	Neg.	Neg.	Neg.		
ludvig.svensson@carnegie.se				P/BV	1.6x	9.2x	2.6x		
				FCF yield	Neg.	Neg.	Neg.		
				Net debt / EBITDA	N.m.	N.m.	N.m.		
								Conflicts of interest	
								Yes	No
Liquidity provider									✓
Certified adviser									✓
Transactions 12m									✓

Investment case

I Ascelia ser vi ett biotechbolag med ett starkt kommersiellt fokus inom onkologi. Bolagets filosofi är att utveckla sÄrläkemedel med en relativt hög sannolikhet att nå marknad (kontrastmedel, omformulering av kända substanser, mm).

Den ledande kandidaten Orviglance är ett leverspecifikt kontrastmedel som adresserar patienter med svag njurfunktion – en patientpopulation där inga alternativ idag finns att tillgÅ. Vid MR-undersökning riskerar dÄrmed läkare att missa levermetastaser som behöver opereras bort. Vi bedömer sannolikheten att Orviglance nå marknad till 85%.

Under 2026 kan Orviglance bli det första kontrastmedlet på marknaden för dessa patienter – en marknad värd upp till USD 600m årligen i USA, Europa och Japan – där vi estimerar en global toppförsäljning om USD +200m. I USA planerar Ascelia att sälja Orviglance genom en egen säljstyrka för att fånga det fulla värdet av produkten, och vi ser framför oss lukrativa rörelsemarginaler om +50% för denna affär.

Utöver Orviglance utvecklar Ascelia Oncoral – en oral formulering av den välkända cancerdödande substansen irinotecan. Genom en oral formulering är ambitionen att få en 1) bättre effekt, 2) bättre biverkansprofil, 3) bekvämare administrering för patienter. Trots sitt relativt tidiga stadie har Ascelia slutit ett spännande samarbetsavtal med Taiho Pharma, en internationell spelare inom onkologifältet, där Oncoral ska utvärderas tillsammans med Taihos Lonsurf i en fas II-studie inom magsäckscancer. Vi bedömer att samarbetet har hög sannolikhet att utvecklas till ett formellt licensavtal vid positiva data.

Bolagsprofil

Ascelia är ett bioteknikbolag som för närvarande har två produktkandidater under klinisk utveckling: Orviglance (ett leverspecifikt kontrastmedel baserat på mangan) och Oncoral (en oral formulering av irinotecan för behandling av magsäckscancer).

Värdering

Vi tillämpar en DCF-värdering av Ascelia. Vårt motiverade värde är 15-18 kr per aktie.

Värdering

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	550	Risk free nominal rate	2.5%	WACC	18%	19%	20%	21%	22%
PV of terminal value (perpetuity formula)	0	Market risk premium	5.5%	NPV	656	594	537	486	439
Enterprise value	550	Small cap premium	4%	NPV/share	19	17	16	14	13
Latest net debt	13	Extra risk premium	8%						
Minority interests & other	0	WACC	20.0%						
Equity value	537								
No. of shares outstanding (millions)	34.6								
Equity value per share (SEK)	16								
Implicit multipl. 2023e		Terminal value assumptions							
EV/Sales	nm.	Long term growth rate	nm.						
EV/EBITDA	nm.	Long term EBIT margin	nm.						
EV/EBIT	nm.	Depreciation (% of sales)	nm.						
EV/NOPLAT	nm.	Capex (% of sales)	nm.						
P/E	nm.	Working cap. (% of sales)	nm.						
ROIC/WACC	nm.	Tax rate	nm.						
Current Share price	11.8								

Källa: Bolaget, Penser Access by Carnegie

Income statement							
	2020	2021	2022	2023	2024e	2025e	2026e
Net sales	0	0	0	0	0	0	55
Cost of goods sold	0	0	0	0	0	0	-5
Gross profit	0	0	0	0	0	0	49
R & D Expenses	-65	-108	-118	-81	-25	-45	-61
Other Operating Expenses	-29	-30	-29	-30	-10	-55	-192
EBITDA	-93	-138	-147	-111	-35	-100	-203
EBITDA, adjusted	-93	-138	-147	-111	-35	-100	-203
EBITA, adjusted	-93	-138	-147	-111	-35	-100	-203
EBIT	-93	-138	-147	-111	-35	-100	-203
EBIT, adjusted	-93	-138	-147	-111	-35	-100	-203
Net Financial Items	-6	8	14	1	-2	-2	0
Profit before tax	-100	-130	-133	-110	-37	-102	-203
Profit before tax, adjusted	-100	-130	-133	-110	-37	-102	-203
Taxes	1	4	2	0	0	0	0
Net income	-99	-126	-131	-109	-37	-102	-203
Net income, adjusted	-99	-126	-131	-109	-37	-102	-203
<i>Sales Growth</i>	<i>Neg.</i>	<i>Neg.</i>	<i>0%</i>	<i>Neg.</i>	<i>Neg.</i>	<i>0%</i>	<i>N.m.</i>
<i>Gross Margin</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>90.0%</i>
<i>EBIT Margin, Adjusted</i>	<i>Neg.</i>	<i>Neg.</i>	<i>Neg.</i>	<i>Neg.</i>	<i>Neg.</i>	<i>Neg.</i>	<i>Neg.</i>
<i>EPS, Adjusted</i>	<i>-3.44</i>	<i>-3.64</i>	<i>-3.79</i>	<i>-3.16</i>	<i>-1.07</i>	<i>-2.95</i>	<i>-5.88</i>
<i>EPS Growth, Adjusted</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>	<i>N.m.</i>

Source: Ascelia Pharma, Penser by Carnegie

Cash flow statement							
	2020	2021	2022	2023	2024e	2025e	2026e
EBIT	-93	-138	-147	-111	-35	-100	-203
Other Cash flow Items	9	8	6	5	0	0	1
Changes in working capital	-1	13	15	-22	4	-3	-10
Cash flow from operating activities	-85	-116	-126	-128	-31	-103	-212
Investments in intangible fixed assets	76	0	0	0	0	0	0
Cash flow from Investments	76	0	0	0	0	0	0
Free cash flow	-9	-117	-126	-128	-32	-103	-213
New share issue / repurchase	93	185	0	0	0	200	200
Change in liabilities	0	0	-1	-1	33	-33	0
Cash flow from financing	93	185	-1	-1	33	167	200
Cash flow	83	68	-127	-129	1	64	-13
Net debt	-185	-262	-150	-22	-21	-83	-70

Source: Ascelia Pharma, Penser by Carnegie

Balance sheet							
	2020	2021	2022	2023	2024e	2025e	2026e
ASSETS							
Other intangible assets	57	57	57	57	57	58	57
Tangible fixed assets	2	2	0	0	0	0	0
Other fixed assets	-	-	0	1	1	1	1
Total fixed assets	59	59	58	58	59	59	58
Inventories	0	0	0	0	0	0	3
Accounts receivable	0	0	0	0	0	0	5
Other current assets	12	13	11	7	10	12	8
Cash and cash equivalents	185	262	150	22	21	83	70
Total current assets	196	275	161	29	31	95	86
TOTAL ASSETS	255	333	219	87	90	154	145
EQUITY AND LIABILITIES							
Equity	236	308	181	74	37	135	132
Total equity	236	308	181	74	37	135	132
Other long-term liabilities	1	1	0	0	33	0	0
Total long-term liabilities	1	1	0	0	33	0	0
Accounts payable	4	6	16	2	4	3	5
Other current liabilities	14	19	22	11	15	15	7
Total current liabilities	18	25	38	13	19	18	13
TOTAL EQUITY AND LIABILITIES	255	333	219	87	90	154	145

Source: Ascelia Pharma, Penser by Carnegie

Growth and margins							
	2020	2021	2022	2023	2024e	2025e	2026e
Revenue growth	Neg.	Neg.	0%	Neg.	Neg.	0%	N.m.
EBITDA growth, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT growth, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EPS growth, adjusted	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.
Gross margin	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.	90.0%
EBITDA margin	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBITDA margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
Profit margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Source: Ascelia Pharma, Penser by Carnegie

Return							
	2020	2021	2022	2023	2024e	2025e	2026e
ROE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
ROCE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
ROIC, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Source: Ascelia Pharma, Penser by Carnegie

Capital efficiency

	2020	2021	2022	2023	2024e	2025e	2026e
Inventory / total revenue	-	-	-	-	5%	5%	5%
Accounts receivable / total revenue	-	-	-	-	20%	10%	10%
Accounts payable / COGS	-	-	-	-	-	-	>100%
Total short-term liabilities / total cost	20%	18%	26%	11%	54%	18%	5%
Working capital / total revenue	-	-120940%	-262020%	-	-89975%	-59985%	7%

Source: Ascelia Pharma, Penser by Carnegie

Financial position

	2020	2021	2022	2023	2024e	2025e	2026e
Net debt	-185	-262	-150	-22	-21	-83	-70
Equity ratio	92%	92%	83%	85%	42%	88%	91%
Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.

Source: Ascelia Pharma, Penser by Carnegie

Per share data

	2020	2021	2022	2023	2024e	2025e	2026e
EPS	-3.44	-3.64	-3.79	-3.16	-1.07	-2.95	-5.88
EPS, adjusted	-3.44	-3.64	-3.79	-3.16	-1.07	-2.95	-5.88
FCF per share	-0.33	-3.37	-3.64	-3.70	-0.92	-2.99	-6.14
Book value per share	8.22	8.90	5.23	2.15	1.08	3.91	3.81
Number of shares, m	28.7	34.6	34.6	34.6	34.6	34.6	34.6
Number of shares after dilution, average	28.7	34.6	34.6	34.6	34.6	34.6	34.6

Source: Ascelia Pharma, Penser by Carnegie

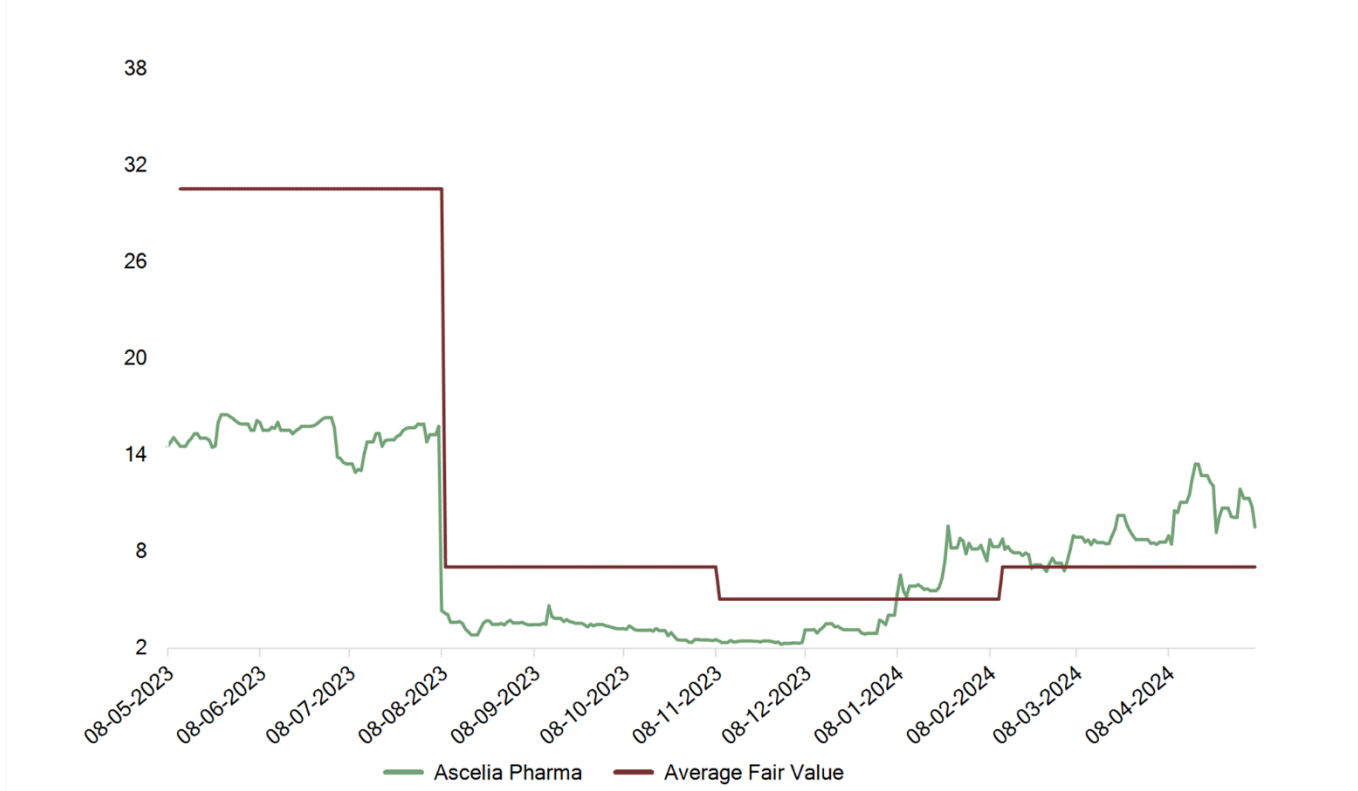
Valuation

	2020	2021	2022	2023	2024e	2025e	2026e
P/E, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
P/BV	6.9x	3.4x	2.9x	1.6x	9.2x	2.6x	2.6x
P/FCF	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
FCF-yield	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
Dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Payout ratio, adjusted	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales	Neg.	100x	100x	Neg.	100x	100x	6.6x
EV/EBITDA, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EV/EBIT, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EV	1,434	771	367	95	358	358	358
Share price, year end	56.4	29.9	14.9	3.4	10.0	10.0	10.0

Source: Ascelia Pharma, Penser by Carnegie

Share Price and Average Fair Value Chart

Ascelia Pharma (ACE SS EQUITY)



Source: Penser by Carnegie, IDC

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SE-103 38 Stockholm
Tel: +46 8 676 88 00 Fax +46 8 676 88 95