

Hansa Biopharma AB (HNSA.ST)
Rating: Buy

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4Q Strength Provides a Needed Boost to Confidence; Target to SEK174

Stock Data		02/02/2024	
Price		SEK31.32	
Exchange		OMX	
Price Target		SEK174.00	
52-Week High		SEK61.85	
52-Week Low		SEK20.14	
Enterprise Value (M)		SEK1,504	
Market Cap (M)		SEK1,650	
Shares Outstanding (M)		52.7	
3 Month Avg Volume		215,695	
Balance Sheet Metrics			
Cash (M)		SEK908.0	
Total Debt (M)		SEK762.6	
Total Cash/Share		SEK17.24	
EPS (SEK) Diluted			
Full Year - Dec	2022A	2023A	2024E
1Q	(3.11)	(3.92)	(3.02)
2Q	(3.82)	(4.79)	(3.24)
3Q	(3.45)	(4.78)	(3.15)
4Q	(3.19)	(2.36)	(3.19)
FY	(13.57)	(15.83)	(12.60)
Revenue (SEK)			
Full Year - Dec	2022A	2023A	2024E
1Q	30,280.0	24,194.0	47,522.0
2Q	26,396.0	36,652.0	49,294.0
3Q	67,083.0	22,837.0	45,751.0
4Q	30,766.0	50,411.0	53,609.0
FY	154,525.0	134,094.0	196,176.0

'000 SEK



Strong revenue driven by Idefirix in new markets and progress in clinical development offer momentum into 2024. After an up and down year for Idefirix, Hansa finished the year strongly with Idefirix sales up ~63% QoQ in 4Q23, mainly driven by the growth in the U.K., Germany, and Spain. With the addition of Germany and Italy, seven countries now include Idefirix in their medication guidelines and recommendations. Over time, we expect more countries will recognize the value of Idefirix to transplant patients, which should drive the long-term uptake of patients. In addition, Hansa announced the first patient treated in the new Eurotransplant desensitization program. Management emphasized that the program aims to initiate the uptake of Idefirix for commercial patients in eight member countries like Germany, Benelux, and some Eastern European countries, which is beneficial to increase patient accessibility. Hansa secured pricing and reimbursement of Idefirix in 5 additional markets, including Slovenia, Spain, Italy, Belgium, and the Czech Republic, taking the full market access countries to 14. The company plans to launch Idefirix in more EU countries, such as Portugal and Switzerland, in 2024. With the stronger 4Q, our estimates for 2024 go up modestly, resulting in a modest bump to our price target to SEK174 from SEK173.

Progress for other programs is on track. The progress of the pivotal US ConfideS trial in kidney transplantation remains on track. The program enrolled 104 patients and randomized 40 of the 64 targeted patients. While the number of randomized patients hasn't moved meaningfully so far this year, we'd note that it tends to come in bunches as organs aren't allocated at a set schedule. Management is optimistic about the timeline as they mentioned there are 17 activated centers, and more centers would be activated in the coming weeks, as well as 'high-double-digit' numbers of patients on the waiting list. We continue to expect Hansa to submit BLA in 2025. For the other pipeline opportunities, the pretreatment program (SRP-9001-104 Phase 1b) with Sarepta (SRPT, not rated) for the gene therapy to treat Duchenne muscular dystrophy (DMD) is expected to dose the first patient in early 2024 and to report the first high-level data read-out in 2024. Of greater focus for us, the NiceR program of NHSA-5487, the next-generation enzymes with lower immunogenicity that would allow for repeat dosing in a range of indications, is expected to complete a full analysis of the NICE-01 Phase 1 study and select the first indication in 2024. Management confirmed that the upcoming Phase 2 study would be in patients of the selected indication—the potential indications including IgG-driven autoimmune diseases, gene therapy, and oncology. We believe NiceR program has the potential to significantly expand the opportunity of the Hansa platform. We expect additional data from the Guillain Barre Syndrome study this year. The company has enrolled 18 patients in the anti-GBM study and we're hopeful the company can complete enrollment in 3Q25.



Financial update for 4Q. Hansa Biopharma recorded a total revenue of SEK 50.4M (SEK 43M in product sales and SEK 7M under agreement with Sarepta) in 4Q23, much higher than our estimate of SEK 41.3M and representing a ~63% increase compared to SEK30.8M in 4Q22. The total revenue of Idefirix sales reached SEK 103.7M vs SEK 86.7M. The total revenue in 2023 was SEK 134.1M, lower than SEK 154.5M in 2022, due to the decrease in contract revenue of SEK 30.4M compared to SEK 67.8M in 2022. The company posted a loss per share of SEK 2.40 in 4Q23 and SEK 15.86 in 2023, both lower than our estimate of loss per share. In 4Q22 and 2022, the EPS losses were SEK 3.22 and SEK 13.6, respectively. SG&A expenses rose to SEK 106M in 4Q23 (v.s. SEK 83.7M in 4Q22), and the expenses for 2023 rose to SEK 450.5M (v.s. SEK 337.9M), lower than our estimate of SEK 127M and SEK 471M, respectively. The increase in SG&A expenses was mainly driven by expanded commercial activities and organizational expansion related to the launch of Idefirix in Europe. R&D grew to SEK 108.3M in 4Q23 (v.s. SEK 92.3M in 4Q22) and SEK 411.3M in 2023 (SEK 337.9M in 2022), in line with our estimate of SEK 106M and SEK 409M, respectively. The expenses were driven by conducting the U.S. ConfideS study, EMA post-approval commitments, anti-GBM phase 3 study, and HNSA-5487 program development. At the end of 2023, the company's cash, cash equivalents, and investments stood at SEK 732.1M.

Valuation and Risks. Our Buy rating and price target for Hansa of SEK174 are based on our sum-of-the-parts NPV valuation for each of the company's indications for imlifidase: highly sensitized kidney transplants, Goodpasture syndrome, Ab mediated kidney rejection, Guillain-Barré syndrome, and as a pretreatment for Sarepta's (SRPT; not rated) gene therapies in LimbGirdle and Duchene muscular dystrophy. Our DCF model utilizes a terminal decline rate of 5% and a discount rate of 10.4%, based on the company's WACC (Beta of 1.1, risk-free rate of return of 3.5% and market premium of 6.3%). We adjust each pipeline asset for the probability of success (PoS) with highly sensitized kidney transplants at 75% as a Phase 3 asset already approved in the EU, Goodpasture syndrome at 60% as a Phase 3 study was initiated last year, Ab mediated kidney rejection at 35% as the asset has generated positive data in Phase 2 studies, GuillainBarré syndrome at 60% as Phase 2 studies are progressing and the mechanism of action appears well suited for this indication, and pretreatment for gene therapies at 45% because while we believe imlifidase is going to be highly efficacious at removing anti-vector Abs, we have some reservations about Sarepta's gene therapy program. For the time being, we do not include other early-stage programs or collaborations but look to do so in the future. Risks include (i) financial, because the company has capital needs that exceed current cash balance; (ii) dilutive, as Hansa is likely going to need to raise additional capital; (iii) reimbursement, because the high cost of imlifidase may cause payors to resist coverage; (iv) regulatory, because imlifidase only has conditional approval in the EU and no US approval; and (v) partnership, as the Sarepta agreement, a major component of our valuation, depends heavily on Sarepta's ability to execute.

HNSA

FY December 31

In SEK ('000) except per share data

	FY 2020A	FY 2021A	FY 2022A	FY 2023A	1Q24E	2Q24E	3Q24E	4Q24E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E	FY 2031E	FY 2032E	FY 2033E
Product sales	-	15,017	86,735	103,712	42,522	44,294	40,751	49,609	177,176	254,662	300,081	778,532	1,956,012	3,933,853	6,193,745	8,595,726	10,253,406	10,877,168
YoY growth (%)	0%	NA	478%	20%	197%	50%	147%	14%	71%	44%	18%	159%	151%	101%	57%	39%	19%	6%
Royalty and license revenue	1,746	-	-	-	-	-	-	-	-	-	-	368,899	399,869	464,010	537,826	556,854	558,897	547,719
Milestone revenue	-	18,861	67,790	30,382	5,000	5,000	5,000	4,000	19,000	24,000	32,000	40,000	-	300,000	100,000	400,000	400,000	400,000
Patent reimbursement	524	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Contract revenue	3,828	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	6,098	33,878	154,525	134,094	47,522	49,294	45,751	53,609	196,176	278,662	332,081	1,187,431	2,355,881	4,697,863	6,831,571	9,552,580	11,212,303	11,824,888
Cost of product sales	997	15,425	38,477	63,143	8,504	8,859	8,150	9,922	35,435	50,932	60,016	155,706	391,202	786,771	1,238,749	1,719,145	2,050,681	2,175,434
As a % of product sales	NA	103%	44%	61%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Gross Profit (Loss)	5,101	18,453	116,048	70,951	39,018	40,435	37,600	43,687	160,741	227,730	272,064	1,031,725	1,964,679	3,911,093	5,592,822	7,833,434	9,161,622	9,649,454
Research and development	227,191	230,764	346,244	411,332	104,854	111,294	104,387	111,200	431,734	464,111	501,240	541,340	584,647	631,419	681,932	736,487	795,406	859,038
YoY growth (%)	18%	2%	50%	19%	13%	-3%	9%	3%	5%	7%	8%	8%	8%	8%	8%	8%	8%	8%
As a % of product sales	NA	1537%	399%	397%	247%	251%	256%	224%	244%	182%	167%	70%	30%	16%	11%	9%	8%	8%
Selling, general and administrative	202,987	327,262	337,861	450,492	105,358	112,639	111,738	113,411	443,146	460,872	542,089	612,561	653,191	718,510	790,361	869,397	956,337	1,023,280
YoY growth (%)	21%	61%	3%	33%	2%	-13%	0%	7%	-2%	4%	18%	13%	7%	10%	10%	10%	10%	7%
As a % of product sales	NA	2179%	390%	434%	248%	254%	274%	229%	250%	181%	181%	79%	33%	18%	13%	10%	9%	9%
Other operating expenses	(2,270)	7,398	20,532	(2,377)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income (Loss)	(422,807)	(546,971)	(588,588)	(788,496)	(171,194)	(183,498)	(178,524)	(180,924)	(714,139)	(697,254)	(771,265)	(122,176)	726,841	2,561,164	4,120,529	6,227,551	7,409,880	7,767,136
Financial income/(expense), net	1,914	(1,151)	(21,391)	(42,316)	-	-	-	-	-	(5,093)	(6,002)	(12,580)	(22,796)	(39,302)	(61,308)	(81,129)	(96,850)	(102,118)
Income (Loss) before income tax provision	(420,893)	(548,122)	(609,979)	(830,812)	(171,194)	(183,498)	(178,524)	(180,924)	(714,139)	(702,347)	(777,267)	(134,756)	704,045	2,521,863	4,059,221	6,146,422	7,313,030	7,665,018
Income tax expenses (benefit)	(40)	158	1,155	908	-	-	-	-	-	-	-	-	30,978	110,962	438,903	1,352,213	1,608,867	1,686,304
Tax rate (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	4%	4%	22%	22%	22%	22%
Net Income (Loss)	(420,853)	(548,280)	(611,134)	(831,720)	(171,194)	(183,498)	(178,524)	(180,924)	(714,139)	(702,347)	(777,267)	(134,756)	673,067	2,410,901	3,620,319	4,794,209	5,704,163	5,978,714
Earnings (loss) per share																		
Basic EPS	(9.98)	(12.33)	(13.60)	(15.83)	(3.02)	(3.24)	(3.15)	(3.19)	(12.60)	(10.69)	(10.27)	(1.78)	8.89	31.86	47.84	63.36	75.38	79.01
Diluted EPS	(9.98)	(12.33)	(13.60)	(15.83)	(3.02)	(3.24)	(3.15)	(3.19)	(12.60)	(10.69)	(10.27)	(1.78)	8.18	29.19	43.71	57.76	68.64	71.86
Basic Shares Outstanding ('000)	42,177	44,473	44,924	52,540	56,672	56,672	56,672	56,672	56,672	65,672	75,672	75,672	75,672	75,672	75,672	75,672	75,672	75,672
Shares Considered for Diluted EPS Calculation ('000)	42,177	44,473	44,924	52,540	56,672	56,672	56,672	56,672	56,672	65,672	75,672	75,672	82,324	82,592	82,834	83,002	83,101	83,203
Actual Diluted Shares Outstanding ('000)	44,822	48,449	51,306	57,678	61,723	61,820	61,921	62,025	61,872	71,310	81,705	81,982	82,324	82,592	82,834	83,002	83,101	83,203

Source: Company reports, H.C. Wainwright estimates.

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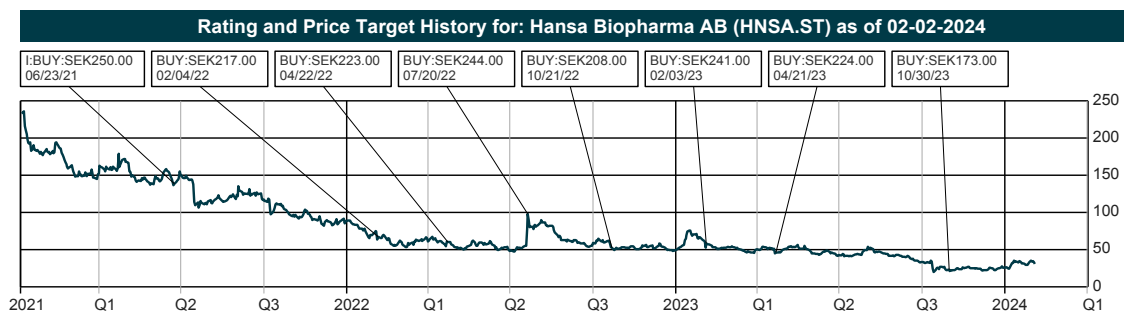
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			Count	Percent
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