Hansa Biopharma AB (HNSA.ST)
Rating: Buy

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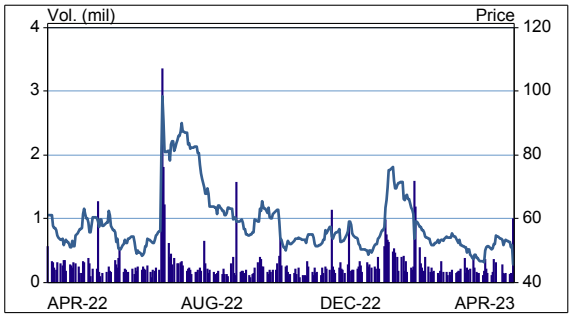
Imlifidase Market Grows in Europe and HNSA-5487's Clinical Development Begins; Reiterate Buy; PT Lowered to SEK224

Stock Data	04/20/2023
Price	SEK45.66
Exchange	OMX
Price Target	SEK224.00
52-Week High	SEK105.80
52-Week Low	SEK45.42
Enterprise Value (M)	SEK1,870
Market Cap (M)	SEK2,395
Shares Outstanding (M)	52.4
3 Month Avg Volume	259,479
Balance Sheet Metrics	
Cash (M)	SEK1,286.8
Total Debt (M)	SEK762.6
Total Cash/Share	SEK24.54

EPS (SEK) Diluted			
Full Year - Dec	2021A	2022A	2023E
1Q	(2.34)	(3.11)	(3.92)A
2Q	(2.98)	(3.82)	(3.38)
3Q	(3.34)	(3.45)	(3.25)
4Q	(3.67)	(3.19)	(3.16)
FY	(12.33)	(13.57)	(13.70)

Revenue (SEK)			
Full Year - Dec	2021A	2022A	2023E
1Q	8,998.0	30,280.0	24,194.0A
2Q	4,535.0	26,396.0	34,333.0
3Q	4,947.0	67,083.0	43,261.0
4Q	15,398.0	30,766.0	50,636.0
FY	33,878.0	154,525.0	152,424.0

'000 SEK



Lower than expected 1Q sales, but European market expansion should drive revenue growth. Hansa's 1Q results were a bit disappointing, with Idefirix sales of SEK14.3M below our estimate of SEK23.0M and consensus at SEK17.0M. Still, we remind investors that quarter-to-quarter volatility is expected due to the nature of the indication and even just a few patients can materially affect numbers. Moreover, we believe revenue will grow this year as the European market expansion continues. During the quarter, Hansa received a positive reimbursement decision in Spain, which has the highest rate or organ donation from deceased people in Europe, with 35.3 donations per million people. Additionally, the company expanded its commercialization partnership with Medison Pharma for Idefirix to cover the Baltics. Recall, it was through this partnership that market access was secured in Israel, Poland and Czech Republic. Procedures to receive access are ongoing in eight additional countries including Portugal, Belgium, and Switzerland. During the earnings call, management indicated that the company has secured repeated sales at the clinic level and additional repeat orders are anticipated. This should give physicians more experience using Idefirix for kidney transplantation, which should translate in increased adoption. Lastly, our confidence in further supported by the ongoing revisions to the euro transplant allocation system that should result in wider usage of Idefirix. These revisions have the goal of optimizing the working flow, increasing the number of patients that receive an organ transplant. Protocols are already in place in the UK, with protocols in Germany going into effect in June. In the US, Hansa continues to make progress towards approval for imlifidase, with 62/64 patients enrolled into the pivotal, randomized, controlled trial, ConfIdeS. The company will add additional centers, up to a total of 20, to accelerate randomization, which we see as a proactive move to ensure randomization is completed by 2H23, as previously guided. Based on Idefirix sales for 1Q, we adjust our product sales estimate for FY23 to SEK127.5M, resulting in a price target change to SEK224 from SEK241. We maintain our Buy rating.

HNSA-5487, the company's second-generation enzyme, enters the clinic. Hansa is currently conducting a Phase 1 clinical study for HNSA-5487 in healthy volunteers. We see this achievement as a milestone for the company, as the development of a new immunoglobulin-cleaving enzyme that allows for repeat dosing, expands the potential application of Hansa's platform. HNSA-5487 is expected to enable a more durable impact on pathogenic IgG. Management indicated that while results from the Phase 1 trial will inform the indication selection strategy, We see clear utility in autoimmune conditions with severe flares but, in our view, HNSA-5487 could have potential in areas like oncology, stem cell transplantation and gene therapy. Of note, imlifidase has enabled efficient transduction of transgenes by removing adeno-associated virus (AAV) antibodies in preclinical studies, and Sarepta (SRPT; not rated) has announced plans to advance imlifidase into the clinic this year as a potential pretreatment to their gene therapy (SRP-9001) in Duchenne muscular dystrophy (DMD) patients with pre-existing IgG antibodies. We currently do not include HNSA-5487 in our valuation model thus, it represents further potential upside.

Further progress with data readouts coming later this year. During 1Q23, enrollment in the Phase 2 study of imlifidase in Guillain-Barre Syndrome (GBS) was completed. Topline data on safety, tolerability and potentially the early effect in imlifidase-treated patients, is expected during 2H23. Also in 2H23, we expect Hansa to report the full dataset from the Phase 2 study evaluating safety, tolerability, and efficacy of imlifidase in the treatment of active and chronic active antibody mediated rejection (AMR) following kidney transplantation. Topline data from this study showed a significantly superior capacity for imlifidase to reduce donor-specific antibodies (DSAs) five days after treatment, compared to plasma exchange. However, the full data set will help shape expectations for this program as efficacy and safety are monitored during a six-month follow-up period. Lastly, Hansa is also announcing in 2H23 the five-year data from the long-term follow-up study in kidney transplantation from the four Phase 2 studies that led to conditional approval in Europe, which should also help drive adoption, in our view.

Financial update for 1Q23. Hansa Biopharma recorded total revenue of SEK24.2M in 1Q23, compared to SEK30.3M in the same period last year, driven by SEK9.9M in upfront payments the company received under the Sarepta agreement, and SEK14.3M from Idefirix product sales in Europe. Net loss stood at SEK205.4M (a loss per share of SEK3.92), above our estimate of SEK151.2M, or SEK3.53 loss per share. 1Q22 net loss was SEK138.4M, or SEK3.11 loss per share. R&D expenses rose to SEK92.8M from SEK70.9M in 1Q22 and were roughly in line with our estimate of SEK92.2M. The YoY increase was primarily driven by the ongoing U.S. ConfIdeS study, the EU post approval study, the anti-GBM Phase 3 study, and development costs for HNSA-5487. SG&A expenses amounted to SEK103.3M from SEK80.4M in 1Q22 and were above our estimate of SEK88.4M. The increase in SG&A expenses was mainly driven by Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix in Europe. By the end of 1Q23, cash and cash equivalents, including short-term investments, amounted to SEK1,286.8M, compared to SEK753.7M for the same period last year. The company's cash runway is expected to fund operations into 2025.

Valuation and Risks. Our Buy rating and our new price target for Hansa of SEK224, down from SEK241, 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 gene therapies in LimbGirdle and Duchene muscular dystrophy. Our DCF model utilizes a terminal decline rate of 5% and a discount rate of 10.1%, based on the company's WACC (Beta of 1.0, 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 40% 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, Guillain-Barré syndrome at 30% as Phase 2 studies are progressing and the mechanism of action appears well suited for this indication, and pretreatment for gene therapies at 20% 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

Income Statement

FY December 31

In SEK ('000) except per share data	FY 2020A	1Q21A	2Q21A	3Q21A	4Q21A	FY 2021A	1Q22A	2Q22A	3Q22A	4Q22A	FY 2022A	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E	FY 2031E	FY 2032E
Product sales	-	6,026	-	-	8,991	15,017	24,237	19,458	22,703	20,337	86,735	127,536	174,149	665,454	1,782,731	3,832,549	6,316,727	9,194,830	11,427,214	12,404,964	12,881,239
Royalty and license revenue	1,746	-	-	-	-	-	-	-	-	-	-	-	-	676,766	1,871,716	2,634,994	2,856,211	3,314,358	3,841,614	3,977,526	3,992,123
Milestone revenue	-	2,972	4,535	4,947	6,407	18,861	6,043	6,938	44,380	10,429	67,790	24,888	19,000	200,000	300,000	300,000	300,000	300,000	325,000	400,000	400,000
Patent reimbursement	524	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Contract revenue	3,828	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	**6,098**	**8,998**	**4,535**	**4,947**	**15,398**	**33,878**	**30,280**	**26,396**	**67,083**	**30,766**	**154,525**	**152,424**	**193,149**	**1,542,220**	**3,954,447**	**6,767,544**	**9,472,937**	**12,809,188**	**15,593,829**	**16,782,490**	**17,273,361**
Gross Profit (Loss)	**5,101**	**7,264**	**2,202**	**(2,788)**	**11,775**	**18,453**	**19,046**	**21,321**	**49,450**	**26,231**	**116,048**	**120,132**	**158,319**	**1,409,129**	**3,597,901**	**6,001,034**	**8,209,592**	**10,970,222**	**13,308,386**	**14,301,497**	**14,697,114**
Research and development	227,191	47,403	54,501	60,619	68,241	230,764	70,907	92,684	90,378	92,091	346,060	409,153	436,289	469,081	506,607	547,136	590,907	638,179	689,234	744,372	803,922
Selling, general and administrative	202,987	60,086	81,248	82,768	103,160	327,262	80,384	90,306	83,479	82,073	336,242	405,806	473,605	568,326	681,991	774,075	824,170	906,587	997,246	1,096,970	1,206,667
Other operating expenses	(2,270)	3,461	(1,191)	2,004	3,124	7,398	2,778	6,162	15,083	(3,229)	20,794	813	-	-	-	-	-	-	-	-	-
Operating Income (Loss)	**(422,807)**	**(103,686)**	**(132,356)**	**(148,179)**	**(162,750)**	**(546,971)**	**(135,023)**	**(167,831)**	**(139,490)**	**(144,704)**	**(587,048)**	**(695,641)**	**(751,575)**	**371,722**	**2,409,302**	**4,679,823**	**6,794,515**	**9,425,455**	**11,621,906**	**12,460,155**	**12,686,524**
Financial income/(expense), net	1,914	(251)	(248)	(201)	(451)	(1,151)	(3,357)	(2,154)	(13,966)	(1,888)	(21,365)	(22,717)	-	(7,745)	(16,245)	(31,892)	(50,455)	(72,714)	(91,241)	(100,242)	(106,232)
Income (Loss) before income tax provision	**(420,893)**	**(103,937)**	**(132,604)**	**(148,380)**	**(163,201)**	**(548,122)**	**(138,380)**	**(169,985)**	**(153,456)**	**(146,592)**	**(608,413)**	**(718,358)**	**(751,575)**	**363,977**	**2,393,057**	**4,647,931**	**6,744,060**	**9,352,741**	**11,530,666**	**12,359,912**	**12,580,292**
Income tax expenses (benefit)	(40)	(10)	(9)	(10)	187	158	57	87	495	516	1,155	356	-	17,879	105,294	856,043	1,483,693	2,057,603	2,536,746	2,719,181	2,767,664
Net Income (Loss)	**(420,853)**	**(103,927)**	**(132,595)**	**(148,370)**	**(163,388)**	**(548,280)**	**(138,437)**	**(170,072)**	**(153,951)**	**(147,108)**	**(609,568)**	**(718,714)**	**(751,575)**	**346,099**	**2,287,762**	**3,791,888**	**5,260,367**	**7,295,138**	**8,993,919**	**9,640,732**	**9,812,628**
Basic EPS	**(9.98)**	**(2.34)**	**(2.98)**	**(3.34)**	**(3.67)**	**(12.33)**	**(3.11)**	**(3.82)**	**(3.45)**	**(3.19)**	**(13.57)**	**(13.70)**	**(13.32)**	**5.82**	**38.49**	**63.79**	**88.49**	**122.72**	**151.30**	**162.18**	**165.07**
Diluted EPS	**(9.98)**	**(2.34)**	**(2.98)**	**(3.34)**	**(3.67)**	**(12.33)**	**(3.11)**	**(3.82)**	**(3.45)**	**(3.19)**	**(13.57)**	**(13.70)**	**(13.32)**	**5.36**	**34.34**	**56.62**	**78.04**	**107.70**	**132.18**	**141.26**	**143.51**
Basic Shares Outstanding ('000)	42,177	44,473	44,473	44,473	44,473	44,473	44,473	44,491	44,588	46,129	44,924	52,444	56,444	59,444	59,444	59,444	59,444	59,444	59,444	59,444	59,444
Shares Considered for Diluted EPS Calculation ('000)	42,177	44,473	44,473	44,473	44,473	44,473	44,473	44,491	44,588	46,129	44,924	52,444	56,444	64,515	66,627	66,974	67,403	67,738	68,041	68,250	68,375
Actual Diluted Shares Outstanding ('000)	44,822	47,476	48,361	49,232	48,726	48,449	48,702	48,398	50,147	57,977	51,306	58,108	62,586	66,134	66,627	66,974	67,403	67,738	68,041	68,250	68,375

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

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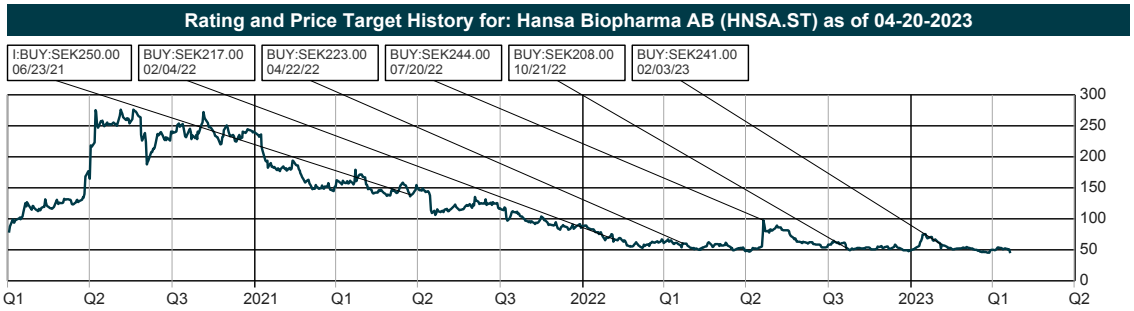

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			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	560	87.91%	130	23.21%
Neutral	63	9.89%	11	17.46%
Sell	0	0.00%	0	0.00%
Under Review	14	2.20%	3	21.43%

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