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Hansa Biopharma AB

Strong Fourth Quarter for Idefirix; Randomization in ConfIdeS on Track for Mid-2024 and NiceR Update Key Catalyst This Year

Stock Rating: **Outperform**

Symbol:	HNSA (OMX)
Price:	35kr (52-Wk.: 20kr-60kr)
Market Value (M):	172kr
Dividend/Yield:	0kr/0.00%
Fiscal Year End:	December

		2023A	2024E	2025E
Estimates				
EPS	Q1	(3.92)kr	(3.43)kr	(2.67)kr
	Q2	(4.79)kr	(3.18)kr	(2.78)kr
	Q3	(4.78)kr	(2.48)kr	(2.60)kr
	Q4	(2.36)kr	(2.33)kr	(2.48)kr
	FY	(15.84)kr	(11.27)kr	(10.48)kr
Sales (M)	Q1	24kr	54kr	66kr
	Q2	37kr	51kr	70kr
	Q3	23kr	56kr	80kr
	Q4	50kr	54kr	80kr
	FY	134kr	216kr	295kr
Valuation				
FY P/E		NM	NM	NM
EV/Sales		13.3x	8.3x	6.1x

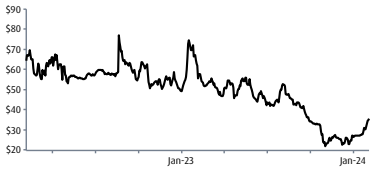
Trading Data (FactSet)

Shares Outstanding (M):	52.7
Float (M):	46.6
Avg. Daily Volume (90-day):	17

Financial Data (FactSet)

Book Value Per Share (MRQ):	(1)kr
Return on Equity (TTM):	(604.6)%
Enterprise Value (M):	1,789kr

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

Idefirix Sales and Pipeline Updates

- Idefirix sales were SEK 43 million, in line with the company's preannouncement earlier in January (see our note: Record Idefirix Fourth-Quarter Sales Beat Estimates; Two-Thirds of Target Randomized in ConfIdeS Trial) and beating our estimate of SEK 32 million prior to the company's preannouncement (see exhibit 1) and company distributed consensus of SEK 34 million for the quarter. Following underwhelming third-quarter sales of SEK 16.5 million, we are encouraged to see a strong rebound with sales up 163% sequentially, largely driven by uptake growth in new markets including the U.K., Germany, and Spain. Management expects continued commercial traction in these major markets to drive sales growth in 2024.
- Hansa provided an incremental update on enrollment and randomization in the U.S. ConfIdeS study evaluating Idefirix in kidney transplantation, with 104 patients now enrolled (versus 101 in its prior business update), and close to two-thirds of (40 of 64) targeted patients randomized. Based on the current rate of enrollment, we have graphed a timeline of potential enrollment progress in exhibit 4. Overall, progress appears to be pacing along and management maintained its guidance of completing randomization by mid-2024, noting randomization progress will continue more intermittently rather than linearly given variability in organ allocation for patients currently awaiting transplant. Hansa also noted plans to expand enrollment from 17 to 25 sites, which is anticipated to accelerate randomization. Given the study's 12-month endpoint, we expect results roughly one year after randomization, around mid-2025, which we believe will provide ample time for BLA submission in 2025, which management has also guided toward.
- The Eurotransplant Desensitization Program is progressing, with the first patient already treated and increasing identification of eligible patients in first and second wave patient assessments. Each wave of the program consists of 5 patients, with an initially planned four saves. As has been seen with commercial launch to date and the ConfIdeS trial randomization, identification of patients is a first step, but organ allocation can still take several months. Management also noted in follow-up that some patients in the Desensitization Program could end up being enrolled in the post-approval efficacy study in Europe.

Hansa Biopharma is focused on the development of the IgG-cleaving enzyme imlifidase for serious diseases driven by IgG antibodies. Marketed as Idefirix in Europe, the therapy has received conditional approval for desensitization of patients prior to kidney transplantation, with ongoing trials in kidney transplant and other indications.

- Enrollment progress continues across the Phase III anti-GBM study (GOOD-IDES-02) with 18/50 patients enrolled versus 16 patients as of its last business update and is expected to complete in 2025. However, if the pace of enrollment in the GOOD-IDES-02 accelerates, there is potential for this enrollment to complete in 2024, and given the six-month primary endpoint, could result in anti-GBM being the first indication to be filed for approval in the United States. We have also graphed a potential enrollment timeline based on the current enrollment rate seen in exhibit 5. Enrollment in the investigator-sponsored ANCA-associated vasculitis trial appears to have leveled off, with 3 of the targeted 10 patients enrolled to date as of its third-quarter earnings release and no new patients since then. Given that the investigator-sponsored study is being conducted at only one center, we expect enrollment will take time.
- Efforts to expand Idefirix into broader markets continue, including in the Middle East and North Africa (MENA), where the company has partnered with NewBridge Pharmaceuticals to enable supply. In collaboration with Medison Pharma, Hansa has also obtained a positive reimbursement decision in Slovenia, now marking 14 European countries with commercial access to Idefirix.

What's Next

- Initial high-level results from the Phase Ib study with Sarepta's (SRPT $121.53; Outperform, covered by Tim Lugo) SRP-9001 gene therapy in DMD (Duchenne muscular dystrophy) are expected this year, with dosing of the first three patients expected in the near term. The Phase Ib study has the ability to expand to five or six patients, and following initial results a decision will be made whether to expand to a potentially pivotal Phase IIb study, which would trigger a milestone payment to Hansa.
- For HNSA-5487, analysis of exploratory endpoints related to IgG recovery and immunogenicity continues and is anticipated to complete in 2024, which will help inform selection of a lead indication for the asset. Notably, the analysis may include details pertaining to whether autoantibodies generated in response to HNSA-5487 are neutralizing.
- Also expected this year are results from a comparative efficacy analysis of patients receiving imlifidase versus standard-of-care treatment in GBS (data from the International GBS Outcome Study database [IGOS], announced as positive in December), as well as initiation of a partnered clinical study with Genethon (private) evaluating imlifidase as treatment prior to Genethon's GNT-0003 gene therapy in Crigler-Najjar syndrome.

Exhibit 1
Hansa Biopharma
Fourth Quarter 2023 Variance Analysis
(SEK in millions except EPS)

	HNSA Q4 2023A	WB Q4 2023E	Variance
Idefirix Sales	43.3	43.0	0.8%
Total Revenue	50.4	50.0	0.8%
COGS	18.1	8.6	110.8%
R&D	108.3	97.5	11.1%
SG&A	106.0	112.9	(6.1%)
Net Loss	(124.5)	(193.0)	(35.5%)
EPS	(2.36)	(3.66)	(35.5%)

Sources: Hansa Biopharma reports and William Blair Equity Research

Exhibit 2
Hansa Biopharma
Financial Estimates
(currency in SEK in millions except EPS)

	WB Previous 2024E	WB Revised 2024E	WB Previous 2025E	WB Revised 2025E	WB Previous 2026E	WB Revised 2026E	WB Previous 2027E	WB Revised 2027E
Idefirix Sales	174	184	268	257	428	411	641	613
Total Revenues	206	216	305	295	459	442	675	646
COGS	26	55	40	64	71	89	128	123
SG&A	429	403	572	537	678	637	750	705
R&D	369	410	398	442	439	488	482	536
Net Loss	(750)	(649)	(856)	(735)	(902)	(756)	833	(708)
EPS	(13.01)	(11.27)	(12.19)	(10.48)	(11.23)	(9.43)	(9.96)	(8.47)

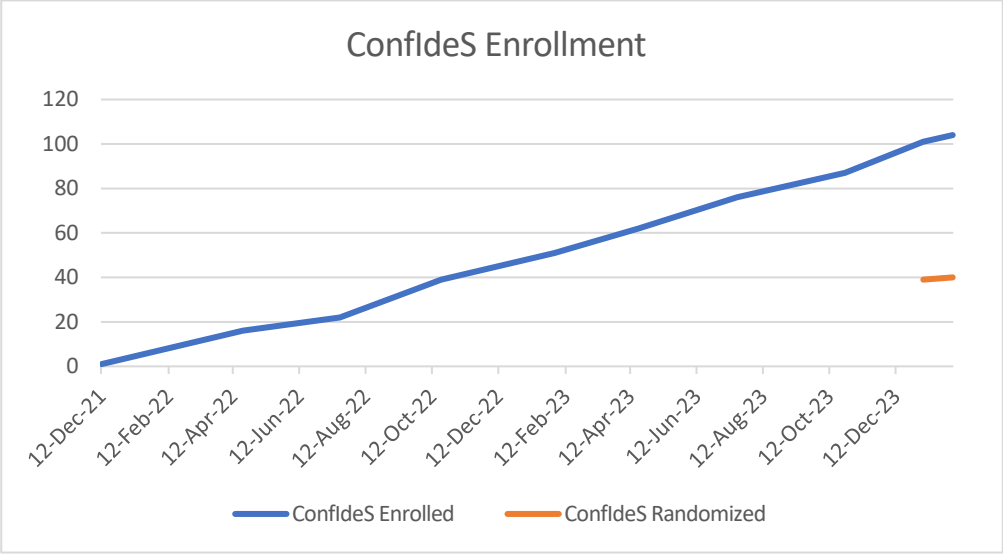
Sources: Hansa Biopharma reports and William Blair Equity Research

Exhibit 3
Hansa Biopharma AB
Timeline

	Date	Product	Event
2024	Mid-Year	Imlifidase	Full results from Phase II Study in GBS
		Imlifidase	Initial results from Phase Ib study in DMD with Sarepta
		Imlifidase	Comparative analysis of GBS Phase II to IGOS data
		Imlifidase	Completion of randomization in Phase III ConfIdeS Phase III U.S. study in kidney transplantation
		Imlifidase	Initiation of clinical study with imlifidase prior to GNT-0003 in Crigler-Najjar
		HNSA-5487	Potential immunogenicity updates form healthy volunteers and initiation of disease specific trials with NiceR program
2025		**Imlifidase**	**U.S. kidney transplantation BLA submission**
		Imlifidase	Completion of enrollment in Phase III anti-GBM study

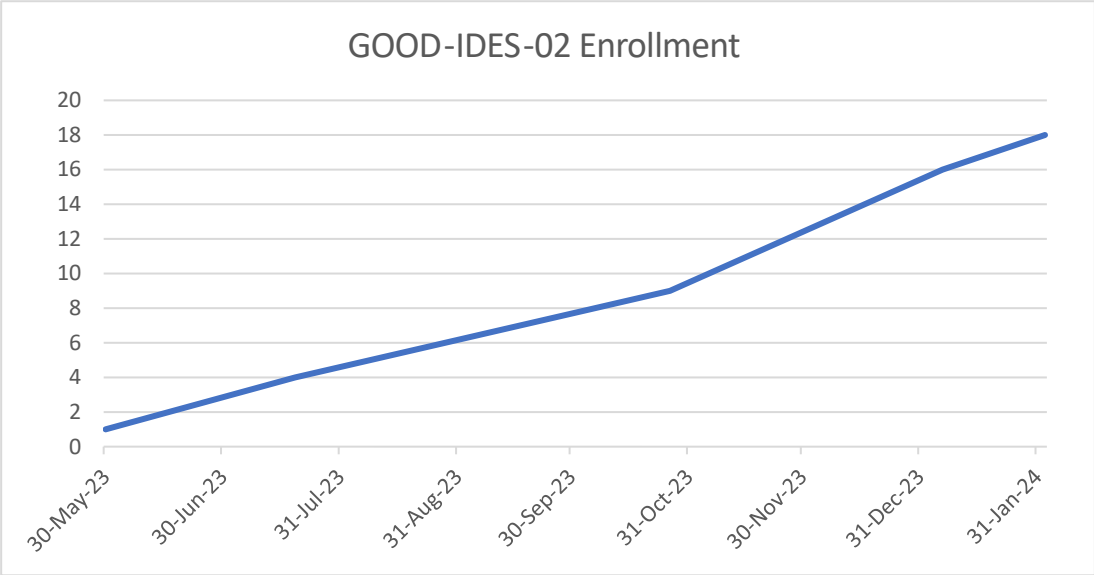
Source: Company Reports

Exhibit 4
Hansa Biopharma AB
ConfideS Enrollment Timeline



Source: William Blair Equity Research

Exhibit 5
Hansa Biopharma AB
GOOD-IDES-02 Enrollment Timeline



Source: William Blair Equity Research

Cash and Cash Runway

- Hansa finished the quarter with SEK 732 million, which management expects will provide runway into 2025. This provides capital through randomization of the ConfIdeS trial and additional data from the GBS trial and NiceR program, but additional capital will be needed to reach the results of the ConfIdeS trial in mid-2025.

Stock Thoughts and Model Updates

Overall, we view the quarter positively given the sustained momentum of Idefirix sales in the fourth quarter, with expectations for further growth in new markets and regions in the coming year, although we acknowledge organ availability will continue to create volatility. Following the company's planned restructuring to prioritize key clinical and commercial goals, we have reduced our expense estimates, beginning in the second quarter of this year. While there have been some concerns regarding the pace of randomization in the ConfIdeS trial given volatility in organ availability, we believe (as does management) that reaching targeted randomization completion in mid-2024 and a BLA filing in 2025 is viable given the expansion of enrollment sites as well as the current status with roughly two-thirds of targeted patients randomized. Beyond ConfIdeS, the year is positioned for multiple readouts, and we continue to believe immunogenicity results from HNSA-5487 are a key catalyst for the stock given the significant number of indications that would be amenable to re-dosing of an IgG degrading enzyme, and positive results would drive upside to the stock. Our updated fair value for Hansa is roughly SEK 48 per share, with potential sales of Idefirix in patients prior to kidney transplantation being the primary value driver, and we therefore reiterate our Outperform rating.

Valuation. Hansa shares are currently trading at SEK 31.32 with a market cap of SEK 1.65 billion. The company is in the early stages of the commercial launch of Idefirix in Europe for desensitization of highly sensitized patients prior to kidney transplant, with recent transplantation guidelines and reimbursement agreements suggesting increased uptake in the coming quarters. In addition, a pivotal trial of imlifidase in the United States in kidney transplant patients and ongoing trials in additional indications including anti-GBM and GBS offer compelling opportunities to expand the overall market opportunity for the drug. We estimate peak sales of Idefirix in kidney transplant desensitization of SEK 4.4 billion in 2035, and a fair value across indications of SEK 48 per share, and therefore we rate shares Outperform.

Risks. Given the novelty of Idefirix as the first therapy approved for desensitization of highly sensitized patients prior to kidney transplant, the commercial launch requires meaningful education of physicians, reimbursement agreements with payers, and navigation of kidney allocation systems across geographies, creating risk of commercial adoption. In addition, Hansa continues to explore the efficacy of imlifidase across numerous indications and geographies, including the pivotal ConfIdeS trial to support approval in kidney transplant patients in the United States.

Hansa Biopharma
Company Rating: Outperform
2/2/2024

Income Statement

(currency in SEK in thousands except EPS and shares in thousands)

	2023A	Q1E	Q2E	Q3E	Q4E	2024E	2025E	2026E	2027E	2028E
Product Sales	103,712	45,543	43,870	48,160	46,448	184,021	257,190	411,388	613,230	1,054,341
Other Revenue	30,382	8,600	7,335	7,663	7,892	31,490	37,683	30,544	33,239	33,822
Total Revenue	134,094	54,143	51,204	55,823	54,340	215,511	294,873	441,932	646,469	1,088,163
COGS	63,143	13,663	13,161	14,448	13,934	55,206	64,298	88,712	122,646	210,868
SG&A	450,492	105,992	100,692	95,658	100,441	402,783	537,080	637,010	704,671	753,319
R&D	411,332	108,251	102,838	97,697	101,604	410,390	442,078	487,901	535,744	565,694
Other operating expenses (gain)	(2,377)					-	-	-	-	-
Operating expenses	922,590	227,906	216,692	207,802	215,979	868,379	1,043,455	1,213,623	1,363,061	1,529,881
Operating income (loss)	(788,496)	(173,763)	(165,488)	(151,979)	(161,639)	(652,868)	(748,582)	(771,691)	(716,592)	(441,718)
Interest income (expense)	(42,316)	(7,053)	(2,546)	1,190	12,827	4,418	13,891	15,875	9,466	324
Net income (loss before tax)	(830,812)	(180,816)	(168,033)	(150,789)	(148,812)	(648,450)	(734,691)	(755,816)	(707,126)	(441,395)
Income tax (benefit)	908	151	140	126	124	541	613	631	590	(24,861)
Net income (loss) after tax	(831,720)	(180,967)	(168,173)	(150,915)	(148,936)	(648,992)	(735,304)	(756,447)	(707,716)	(416,533)
Net loss atributable to common shareholders	(831,720)	(180,967)	(168,173)	(150,915)	(148,936)	(648,992)	(735,304)	(756,447)	(707,716)	(416,533)
Earnings per share, basic	**(15.84)**	**(3.43)**	**(3.18)**	**(2.48)**	**(2.33)**	**(11.27)**	**(10.48)**	**(9.43)**	**(8.47)**	**(4.89)**
Earnings per share, basic (USD)	**(1.51)**	**(0.33)**	**(0.30)**	**(0.24)**	**(0.22)**	**(1.07)**	**(1.00)**	**(0.90)**	**(0.81)**	**(0.47)**
Weighted average common shares, basic	52,501	52,706	52,935	60,876	63,919	57,609	70,139	80,222	83,524	85,205

Sources: Hansa Biopharma, Inc. reports and William Blair Equity Research

Please consult the following link for disclosures: https://williamblair.bluematrix.com/sellside/Disclosures.action?ajax&page=ajax/williamblairDisclosures.jsp&firmId=18877&companySymbol=HNSA

HNSA

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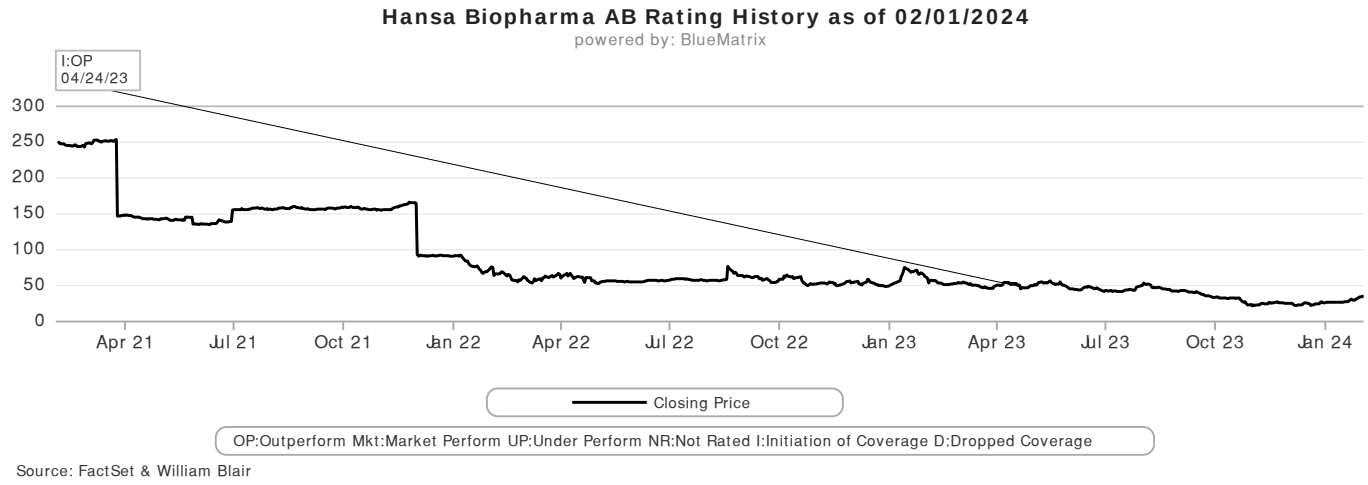
DOW JONES: 38519.80
S&P 500: 4906.19
NASDAQ: 15361.60



Additional information is available upon request.

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Outperform (Buy)	70	Outperform (Buy)	7
Market Perform (Hold)	29	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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