Hansa Biopharma

Sector: Biotech

Development progress combined with modest sales

Redeye updates its outlook on Hansa Biopharma anticipating gradual launch support during 2023 and supporting pipeline progress over the next 12 months. We make a negative revision after the recent Q1 2023 result mainly because Hansa is experiencing a period of slower patient enrolment despite the expanding market access,. Our Base Case is SEK166 (175) with a Bull Case of SEK390 (400) and a Bear Case of SEK45 (45).

Slow patient uptake

The patient uptake is slow despite market access in 12 European countries. This could be a result of both a gradual acceptance of Imlifidase as a new treatment and the fact that Hansa has initiated a confirmatory study in Europe that cannibalise on a proportion of the patient flow. At his stage we make a modest negative sales revision of 2-3% and we look forward to further feedback from Hansa regarding the European roll-out. Late in 2023e and in 2024e we can expect more clinics progressing towards treating a multiple of patients with the support from market access, increased real life experience and revised guidelines.

Valuation

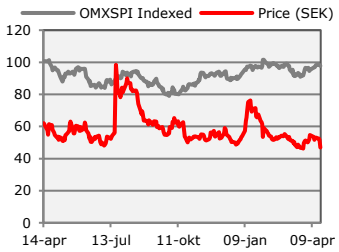
We point to a 200+% upside to our SEK 165 Base Case. Apart from gradually improving launch support there is also an opportunity to secure new collaborations and/or significant milestone payments reducing the future equity dilution risk. The main risk is an extended slow launch in Europe and the US market. Soft sales contribution could put pressure on Hansa to protect the equity base result in a larger and more dilutive equity funding.

Key Financials (SEKm)	2021	2022	2023E	2024E	2025E	2026E
Net sales	34	155	203	372	779	1362
Revenue growth	456%	356%	31%	84%	109%	75%
EBITDA	-538	-571	-621	-518	-169	346
EBIT	-547	-587	-643	-538	-199	302
EBIT Margin (%)	-1614%	-380%	-317%	-145%	-26%	22%
Net Income	-548	-611	-649	-533	-199	303
EV/Revenue	90,3	9,6	11,7	9,5	4,7	2,4
EV/EBITDA	neg	neg	neg	neg	neg	9,4
EV/EBIT	neg	neg	neg	neg	neg	10,8

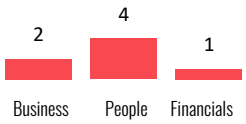
FAIR VALUE RANGE

BEAR	BASE	BULL
45	165	390

HNSA.SA VERSUS OMXSPI



REDEYE RATING



KEY STATS

Ticker	HNSA.SA
Market	Mid Cap
Share Price (SEK)	47
Market Cap (SEKm)	2 581
Net Debt (SEKm)	1 287
Free Float (%)	74%
Avg. daily volume ('000)	357

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Financials Q1 outcome

Hansa's soft Q1 (product) sales contribution suggests that specialist centres are adopting the treatment workflow to use Idefirix to increase the number of feasible Kidney transplants. It is still unclear if the main challenge is adapting to new work procedures or securing access to kidneys and donors that would typically not have been considered before Idefirix was approved. Hansa may also need to step up the supporting activities to gain momentum for the European launch. The table below illustrates Hansa's Q1 results:

Hansa Biopharma: Q4 Outcome

Hansa Outcome vs Redeye vs Consensus					Q1 2023
(SEKm)	Actual	Redeye	%	Cons.*	%
Revenues	24	23	5%	27	-10%
Product Sales	14	16	-11%	17	-16%
Number of patients	5	5	0%	6	-17%
EBIT	-182	-151	21%	-161	13%
Operational Cashflow	-207	-101	-105%	-101	-105%
Cash & Equivalents	1287	1339	-4%	1341	-4%
Shareholder's Equity	415,0	453	-8%		

** Factset complemented by Hansa's survey*

Source: Hansa Biopharma (historical), Redeye Research (forecasts)

We expect a slight negative consensus revision due to Hansa's Q1 result, significantly as it increases the risk of a soft 2023 with moderate annual growth. Later in 2023, we expect additional support from countries like Italy, Spain, Poland, Scotland and the Czech Republic (recent reimbursements). Hansa continues to make clinical study progress, and this includes:

- Confirmatory European study (PAES) on track for completion in 2025
- The pivotal US study ConfIdeS is near fully enrolled (62 out of 64 patients), and the study is on track for BLA submission in 2024, according to Hansa.
- NiceR, or now with the clinical reference HNSA-5487, is moving into the clinical stage, and this is a significant opportunity potentially opening up for repeat dosing of Imflifidase.
- The pivotal phase 3 study for Anti-GBM commenced, and this study will enrol 50 patients.
- AMR and GBS are now fully enrolled in phase 2, with data read-out to follow during H2 2023

The moderate launch support continues to pressure the net operational cash burn (SEK 207m) even if the liquid position is a robust SEK1,287m. The pivotal US study is about to complete the enrolment very soon, and Hansa has also recently recruited Matthew Shaulis as CCO and US President (of the US affiliate, Hansa Biopharma Inc) to establish Hansa's US organisation ahead of the Imlifidase US launch and advance Hansa's global commercial priorities.

Our estimate revision to 2025E

We make a modest negative revision, as illustrated in the table below. Our revised product sales base case for 2023 mainly reflects a slightly slower transition to centers advancing into treating the second and the third patient. So far, most or nearly all active centers have treated the first patient. The ongoing supporting study in Europe is also absorbing (or cannibalising) some of the patients flow at this launch stage when specialists will likely treat the most sensitised patients during 2023. See the table below:

Hansa Biopharma: Our estimate changes to 2025E

Hansa: Redye's Post Quarter revision compared with consensus												
(SEKm)	2023E	Cons.*	Diff.	RR**	2024E	Cons.*	Diff %	RR**	2025E	Cons.*	Diff %	RR**
Net sales	203	190	7%	-1%	372	371	0%	-2%	779	875	-11%	-3%
Patients	50	51	-1%	-3%	99	100	-1%	-4%	219	203	8%	-3%
EBIT	-643	-627	3%	10%	-538	-513	5%	9%	-199	-195	2%	2%
Cash & Equivalents	1 488	1004	48%	-3%	1 310	880	49%	-6%	1 157	1332	-13%	-8%
Shareholder's Equity	512	128	300%	-12%	256	-36		-31%	53	153	-65%	-70%

** Consensus based on Factset complemented by Hansa's survey*
*** Redeye post quarter revision*
Source: Redeye Research and Factset

Source: Redeye Research (forecasts)

Note that the consensus revision is still mainly unchanged, and we are expecting a slight negative revision for the consensus over the following weeks. Our EBIT and Operating cash flow change for 2025 seems dramatic, but it reflects % changes near nil. The positive cash balance revision results from the fact that our base case now includes a SEK 600-900m equity funding over the next 24 months protecting Hansa's equity balance. The recent directed share issue suggests that this could be executed on a favourable rebate protected by the ongoing pipeline progress and the cash position.

Our P&L base case to 2026E

2023e and 2024e reflect that Imflidase/Idefirix treatment is a new method and, in many ways, a new SOC for these highly s sensitised patients. Many centres are waiting for more experience, including real-life results from the initial patient and result from other centres. Some centres will likely wait for the ongoing post (conditional) approval study results. Most centres will face a delay between national access and the local ability to handle patients. This includes taking the local decision and establishing local protocols and procedures. During 2023 we can expect a more significant proportion of local recentres to have reached a more dynamic stage when patients can be transplanted based on Idefirix among the top five European countries, including UK, Spain and Italy. The transparency is probably limited ahead of Q2, which could be relatively soft, and we expect Hansa to be able to deliver a considerable improvement during H2 2023. The changes in the donor allocation system are also a process that needs to improve following recent changes in guidelines.

Our margins also reflect a higher OPEX level during 2023 as Hansa is advancing several pipeline projects, increasing the support of the ongoing launch and preparing for the US launch in 2025. This includes progressing the pivotal study in late 2023 and 2024 and establishing the commercial launch organisation ahead of the launch.

Our annual base case to 2026E is illustrated in the table below. In 2025 we expect more substantial growth in Europe, and in 2026, we expect some early contribution from the US

launch. In the US, we expect a faster take-up rate as a result of the support from the larger US study, including at least 15 leading centres and the European clinical experience, which will be substantial at this stage, including expertise from the actual treatment of patients as well as the more extensive post-approval study with results in H2 2023.

Hansa Biopharma: Yearly estimates to 2026E

Hansa Biopharma: Estimate (SEKm)									
(SEKm)	2022	2023Q1	2023Q2	2023Q3	2023Q4	2023	2024	2025	2026
Net sales	155	24	39	59	81	203	372	779	1362
Gross Profit	116	15	31	46	64	155	294	631	1110
EBITDA	-538	-177	-164	-136	-141	-621	-518	-169	346
EBIT	-587,0	-182,3	-164,1	-154,7	-141,8	-642,9	-538,4	-199,5	302,4
Adjusted Diluted EPS	-12,3	-3,5	-3,2	-3,0	-1,8	-8,4	-6,9	-2,6	3,9
Cash & Equivalents	1496	1287	1143	1012	1487	1488	1310	1157	1589
Shareholder's Equity	606	415	249	93	512	512	256	53	352
Patients (European and US)		4	9	15	21	50,3	99	219	332
(%)									
Revenue Growth	356%	-20%	46%	-12%	163%	31%	84%	109%	75%
Gross margin	75%	60%	79%	79%	79%	77%	79%	81%	82%
EBITDA margin	-348%	-731%	-424%	-231%	-174%	-307%	-139%	-22%	25%
EBIT margin	-380%	-753%	-425%	-263%	-175%	-317%	-145%	-26%	22%
Net Income Margin (%)	-395%	-761%	-429%	-266%	-177%	-321%	-143%	-26%	22%

Source: Redeye Research

Source: XVIVO (historical, white), Redeye Research (forecasts, grey)

Some events could trigger a positive revision, including more substantial milestones, signing contributions (from Hansa's opportunities in genetics and oncology), and a potential partner for the approaching phase III study in AMR. Additional milestone contributions reduce the need for additional equity funding protecting the equity base at the risk of further dilution (increasing the number of shares) at a stage where Hansa's potential is far from fully reflected in the valuation.

Valuation

We base our valuation on discounted cash flow (DCF) analysis. Our fair Base case does not include the likely support from future M&A. We use an 11% weighted-average cost of capital (WACC) (based on Redeye's Quality Rating System) to discount Hansa's projected future cash flows. We use a case-based approach, with what we judge as a fair Base Case, an optimistic Bull Case, and a pessimistic Bear Case. Our Base Case, fair value estimate, amounts to SEK 165 (175) per share, while our valuation range equals SEK 45-390 per share. We believe the Company's share could reach our Base Case (SEK 165) within the coming 12-24 months when Hansa has elevated its European sales and when Hansa is approaching the US launch. Hansa is also in an excellent position to advance the pipeline during the same period.

Base Case: SEK 165 (175) per share

Our Base Case implies that Hansa is supported by structural growth from the Imlifidase (Idefirix) segment and additional support from GBS and Anti-GBS (see below in the sum—of—the—parts valuation) and collaborations in Genetics. We do not include support from NiceR nor the opportunity to advance Oncology collaborations based on NiceR (a different version of Imlifidase). Our base case features;

- Pro-forma sales growth at a CAGR of some 72% for 2022-2026E
- EBIT margin reaches some 22% in 2026E
- Sales growth at a CAGR of some 46% for 2026E-2031E
- EBIT margin rises to some 62% in 2031E
- EBIT margin settles at some 22% in 2037E, with terminal growth of some 1%
- A SEK450m-650m equity fundraising to protect the equity base before mid-2024

Bull Case: SEK 390 (400) per share

Our Bull case is based on a faster uptake with Imlifidase securing support from a larger patient pool beyond the most sensitised patients. Hansa also successfully established NiceR as a technology platform, improving the outlook for protecting an extended period of growth. We have also included a higher LOA/POS for the Genetics collaborations.

- Pro-forma sales growth at a CAGR of some 75% for 2022-2026E
- EBIT margin reaches some 27% in 2026E
- Sales growth at a CAGR of some 56% for 2026E-2031E
- EBIT margin rises to some 69% in 2031E
- EBIT margin settles at some 30% in 2037E, with terminal growth of some 2%
- A SEK450m-650m equity fundraising to protect the equity base before mid-2024 could be reduced with additional support from Hansa's genetic collaborations and potential future Oncology collaborations.

Bear Case: SEK 45 (45) per share

Our Bear case implies that Hansa's period of moderate, gradual Idefirix launch support is extended. We still include US support after 2026, with a potential delay into 2027. Even if Hansa has the advantage of additional study support and clinical experience from the European market, we include a modest US take-up rate. Our Bear case does not include support beyond the core Imlifidase indication.

- Pro-forma sales growth at a CAGR of some 59% for 2022-2026E
- EBIT margin reaches some 7% in 2026E
- Sales growth at a CAGR of some 25% for 2026E-2031E
- EBIT margin rises to some 40% in 2031E
- EBIT margin settles at some 15% in 2037E, with terminal growth of some -2%
- A SEK450m-650m equity fundraising to protect the equity base before mid-2024, which could come with an elevated rebate reflecting a higher dilution risk

Base Case: Sum of the part

A sum-of-the-parts valuation also supports our Base case. See the table below. This is also based on the same WACC (11%) and that Hansa will protect the equity base with fundraising by mid-2024.

Hansa Biopharma: Our sum-of-the-parts valuation

Project	Indication	Stage	Launch	Peak sales**	LOA(%)	Value (SEKm)	Per share(SEKm)
Imlifidase	Kidney Tx	Conditional Approval*	2021	5758	100%	9 590	124
Imlifidase	Anti-GBM	Phase III	2024	536	55%	486	6
Imlifidase	GBS	Phase II	2025	1376	30%	617	8
Imlifidase	AMR	Phase II	2025	695	17%	1096	14
Imlifidase	Gene Therapy	Near Phase I	2026	241	30%	604	8
			Net cash, end Q1			489	6
			Shared costs			-200	-3
** Conditional approvad in Europé and in Phase 3 in US*			**Equity Value**			**12 683**	
*** SEK'm risk weighted*			Shares outstanding***			77,4	
**** Including our future equity based fundraising in our base case*			**Base case**				**165**

Source: Redeye Research

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors rated on a scale of 0 to 1. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 2

We rate Hansa high in terms of transparency and business control.

Business: 4

Hansa confirms a high rating based on the Idefirix approval and a novel approach. Hansa is also expanding its product pipeline, and if successful, Hansa can secure a more extended period of profitable global growth.

Financials: 1

Hansa is well financed to 2025 ahead of the US launch based on the USD 70m credit facility (NovaQuest) and a recent directed share issue of USD 40m. We expect Hansa to undertake a second directed share issue within 9-18m to protect the equity balance during this extended period of the initial Idefirix launch and the investments in the extended pipeline.

The R&D risk is moderate to significant. We expect a positive cash flow when the European launch progresses into a larger market after 2024, especially with support from the US market after 2025. With improved cash generation and margins, we can expect a positive review of our financial rating, possibly already in 2024. Note that a significant part of Hansa's OPEX is directed at supporting future launches and the development of new solutions.

	2022	2023E	2024E	2025E
INCOME STATEMENT				
Net sales	155	203	372	779
Cost of Revenues	38	47	78	148
Gross Profit	116	155	294	631
Operating Expenses	688	777	812	800
EBITDA	-571	-621	-518	-169
Depreciation & Amortization	16	22	20	30
EBIT	-587	-643	-538	-199
Net Financial Items	-23	0	12	12
EBT	-610	-643	-526	-187
Income Tax Expenses	1	6	11	16
Non-Controlling Interest	0	0	0	0
Net Income	-611	-649	-533	-199
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	1 496	1 488	1 310	1 157
Inventories	1	6	19	47
Accounts Receivable	108	122	130	171
Other Current Assets	0	0	0	0
Total Current Assets	1 605	1 615	1 459	1 375
Non-current assets				
Property, Plant & Equipment, Net	8	7	7	2
Goodwill	0	0	0	0
Intangible Assets	47	48	52	68
Right-of-Use Assets	28	19	12	4
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	83	74	71	74
Total Assets	1 687	1 689	1 530	1 449
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	7	7	7	7
Accounts Payable	27	44	52	86
Other Current Liabilities	228	299	332	395
Total Current Liabilities	262	350	392	488
Non-current liabilities				
Long-Term Debt	763	783	783	783
Long-Term Lease Liabilities	31	20	20	23
Other Long-Term Liabilities	26	26	80	100
Total Non-current Liabilities	820	828	882	906
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	606	512	256	53
Total Liabilities & Equity	1 687	1 690	1 530	1 448
CASH FLOW				
NOPAT	-588	-649	-549	-216
Change in Working Capital	35	69	20	28
Operating Cash Flow	-499	-577	-442	-120
Capital Expenditures	-3	-3	-6	-9
Investment in Intangible Assets	0	-10	-11	-24
Investing Cash Flow	229	-13	-17	-33
Financing Cash Flow	1 119	562	281	0
Free Cash Flow	-502	-590	-459	-153

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2023–2026)	-686
Momentum Period (2027–2030)	5 624
Stable Period (2031–)	7 380
Firm Value	12 317
Net Debt (last quarter)	-11 031
Equity Value	23 348
Fair Value per Share	165

	2022	2023E	2024E	2025E
CAPITAL STRUCTURE				
Equity Ratio	0,4	0,3	0,2	0,0
Debt to equity	1,3	1,5	3,1	14,7
Net Debt	-734	-705	-527	-374
Capital Employed	1426	1339	1138	960
Working Capital Turnover	-1,0	-0,9	-1,5	-2,9
GROWTH				
Revenue Growth	356%	31%	84%	109%
Basic EPS Growth	-6%	-19%	-27%	-63%
Adjusted Basic EPS Growth	-6%	-19%	-26%	-62%
PROFITABILITY				
ROE	-90%	-116%	-139%	-129%
ROCE	-41%	-48%	-47%	-21%
ROIC	650%	489%	313%	113%
EBITDA Margin (%)	-370%	-307%	-139%	-22%
EBIT Margin (%)	-380%	-317%	-145%	-26%
Net Income Margin (%)	-395%	-321%	-143%	-26%
VALUATION				
Basic EPS	na	-9,4	-6,9	-2,6
Adjusted Basic EPS	na	-9,4	-6,9	-2,6
P/E	na	neg	neg	neg
EV/Revenue	na	9,7	7,6	4,2
EV/EBITDA	na	neg	neg	neg
EV/EBIT	na	neg	neg	neg
P/B	na	5,2	13,1	68,4

SHAREHOLDER STRUCTURE (%)	**CAPITAL**	**VOTES**
Redmile Group LLC	19,8%	20,7%
Hansa Biopharma AB	4,7%	0,5%
Nexttobe AB	4,6%	4,8%
Avanza Pension	4,0%	4,2%
Fjärde AP-fonden	4,0%	4,2%
Thomas Olausson	3,9%	4,1%

SHARE INFORMATION	
Reuters code	HNSA-SE
List	Mid Cap Stockholm
Share price	47,0
Total shares, million	56,6

MANAGEMENT & BOARD	
CEO	Søren Tulstrup
CFO	Donato Spota
Chairman	Peter Nicklin
IR	Klaus Sindahl

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Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the Company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Recommendation structure
Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each Company is sanalysed and evaluated. This analysis aims to provide an independent assessment of the Company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

Redeye Rating (2023-04-21)

Rating	People	Business	Financials
5p	32	15	4
3p - 4p	156	138	48
0p - 2p	5	40	141
Company N	193	193	193

Duplication and distribution

CONFLICT OF INTERESTS

Johan Unnérus owns shares in the Company: Yes
Richard Romanius owns shares in the Company: No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.