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Hansa Biopharma

Building A Foundation For Growth

Sponsored Research

Price: SEK55
Target Price: SEK220

Analysts

Naresh Chouhan
naresh@intronhealthresearch.com
+44 20 8156 7791

Dominic Rose
dominic@intronhealthresearch.com

With the European post-approval study (PAS) underway, Hansa is building a solid base of experienced prescribers whom we expect to be converted into commercial users in 2025, after the study ends. We anticipate sales to be lumpy but steady over 2023-24, with an inflection in 2025 driven by the US launch and greater momentum in Europe. We have increased our estimate of Idefirix's net price in Europe by 20% as more data has emerged, leading to a sales upgrade in outer years. Outside of kidney, Idefirix has shown efficacy in AMR and we expect P2 data in GBS later this year. We reiterate our SEK220 PT, with higher EU sales mostly offset by FX.

EU Sales U/G As We Increase Idefirix's Net Price By 20% to €267k

With more sales data and published list prices in European markets, we have the confidence to increase our estimate of the average net realised price for Idefirix in Europe by ~20%, upgrading sales in further out years despite slower volume growth in the near-term due to PAS pt enrolment.

Idefirix is Building a Solid Foundation For An Inflection in 2025

Idefirix sales were stable at ~$2m/quarter in 2022, but we expect them to show lumpy growth (approx. double) every year to 2024, after which we anticipate an acceleration as the PAS ends and it launches in the US.

More Positive P&R Negotiations Remove Access Hurdles

Positive P&R decisions from Italy & the Czech Republic makes a total of 11 markets with secured access in Europe, including 4/5 major markets.

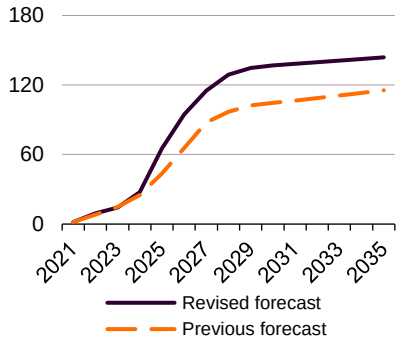
Important Catalysts Over Next 12 Months

In H2 2023, the P2 GBS data is expected to read out, along with 5-year data in kidney transplant, full data from P2 in AMR and initiation in DMD.

Cash Runway Now into 2025

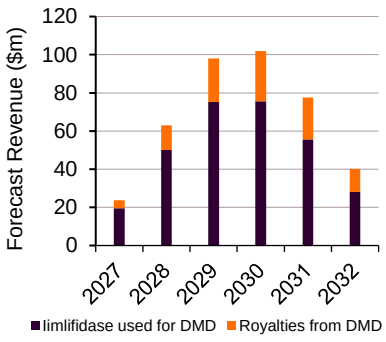
Following the two raises in 2022 ($110m total), Hansa now has runway into 2025, which should cover taking imlifidase to approval in the US and bringing NiceR into clinical development.

EU Idefirix rev forecast changes ($m)



Source: Intron Health estimates

Expected global revenue* in DMD



*Source: Intron Health estimates * Not risk-adjusted*

Summary Financials

	23E	24E	25E	26E
Sales $m	18.3	29.6	88.7	175.3
EPS (SEK)	-12.7	-12.5	-5.5	6.1
Net cash* ($m)	7.9	-50.7	-97.0	-96.3
2027 PE	2.1x			
Mcap ($m)	280			

Source: Intron Health estimates
** Excluding NovaQuest debt (2x borrowed)*

Contents

European PAS Slows Launch to 2025

The European post-approval study (PAS) is now well underway, but with 50 patients being recruited and only around 30 commercial patients treated in 2022, we expect it to be a drag to product sales growth over 2023-24. Regardless of that, we still forecast almost a doubling of product sales in both 2023 and 2024 and an acceleration thereafter as the PAS ends and the commercial rollout in the US begins.

Positive P&R Decisions Received in Italy & Czech

Idefirix received positive national reimbursement decisions in Italy and the Czech Republic in December 2022 and January 2023, respectively. To date, Hansa has secured P&R agreements in 11 European countries including most of the major European markets, removing market access hurdles which have previously delayed product uptake. Negotiation is ongoing in 9 countries, for which we expect decisions to be announced in 2023-2024.

Table 1: Status of Pricing & Reimbursement negotiations in European countries

Factor	Country
Secured Pricing & Reimbursement agreements	UK, Germany, France (Early Access Program), Italy, Sweden, Finland, Poland, Netherlands, Czech Republic, Greece, Finland
HTA dossiers submitted / Negotiation ongoing	Spain, Portugal, Belgium, Norway, Switzerland, Denmark, etc.

Source: Company reports

Post-Approval Study Temporarily Reduces Growth

Enrolment for the open-label Phase 3 post-approval study (PAS) continues in Europe. We expect the majority of the required 50 patients to enrol in 2023-2024, which inevitably reduces commercial product revenue (by c. $14m) as some eligible patients are diverted to the PAS. Although near-term product growth is impacted, we expect the PAS will help more centres gain experience of Idefirix and lead to repeat sales in future years.

Table 2: Patients treated with Idefirix in Europe – commercial and PAS

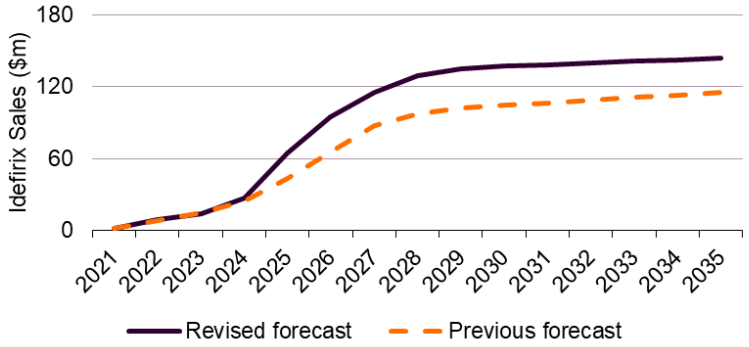
	2020	2021	2022	2023	2024	2025	2026
Total EU patients treated	2	6	30	77	123	242	355
of which are PAS			3	25	22		
Commercial patients (EU)	**2**	**6**	**27**	**52**	**101**	**242**	**355**
Growth		*157%*	*382%*	*93%*	*94%*	*139%*	*47%*
US patients treated						61	166
Total kidney patients	**2**	**6**	**30**	**77**	**123**	**303**	**521**

Source: Company reports; Intron Health estimates

Update to Idefirix Forecasts in Europe

Following the FY22 results, we revised our model to capture the updated price mix, uptake volume, and FX rate, which resulted in an upgrade in Idefirix sales in Europe beyond 2025.

Chart 1: New EU7 forecasts for Idefirix in kidney transplant*



*Source: Intron Health estimates *EU4/UK/Sweden/Norway*

Our model was updated according to recent developments and company guidance:

- We reduced the expected treatment volume in 2023-2024 to account for a slower uptake and the ongoing PAS programme as shown in Table 2
- We revised Idefirix's net realised price to €267k (up from €202k) following the publication of list prices in more countries and the reporting of more sales data
- The US dollar has weakened from the historical high in Oct '22, down by ~8% against the Euro, which increases revenue reported in dollars

Kidney Transplant Sales to Accelerate From 2025

In our view, Idefirix growth will accelerate from 2025 for the following reasons:

- Repeat sales from European specialist centres after gaining first use experiences in the first 4 years after launch
- P&R agreements are expected to be secured in all major European markets at the national and regional level
- The PAS study is expected to complete enrolment by 2024, which removes competition for product uptake in Europe
- Material sales are expected to begin in 2025 in the US, where concentrated product uptake is expected to flow through large transplant centres, resulting in a faster ramp up compared to Europe
- Potential for material royalty payments received from partners in RoW

Multiple Catalysts Expected in '23-'24

Hansa continues to advance Idefirix in all of its programmes, with a positive topline readout reported from the Phase 2 trial in AMR. In addition, a candidate from the NiceR program is expected to enter the clinic in H123, which will allow for repeat dosing.

Positive Topline Readout in P2 AMR

On November 28th, 2022, Hansa reported positive topline data from its Phase II trial in antibody-meditated rejection (AMR) after kidney transplantation. The study showed that Idefirix was effective in reducing donor-specific antibodies and is significantly superior compared to standard of care (plasma exchange). A total of 30 patients were enrolled in this trial, randomised 2:1 to receive Idefirix or plasma exchange. The full dataset will be released in H223. We currently forecast just $55m risk-adjusted peak sales for this potentially large indication.

Pipeline Programs Continue to Advance

Table 3: Anticipated key catalysts for pipeline programmes

Programmes	Geography	Launch year	Risk adjusted peak sales ($m)	Next catalysts
Kidney transplant	EU4/UK/Sweden/Norway	2020	138	H2 2023 - Data from 5-year follow up study; 2023/2024 - Securing access in additional markets (Spain, Belgium, etc.)
Kidney transplant	US	2025	216	2023/2024 – ConfideS topline data readout and BLA submission
Anti-GBM	EU4/UK/Sweden/Norway and US	2025	37	2024 - Topline readout from Phase 3 trial
GBS	EU4/UK and US	2026	56	H2 2023 - Topline readout from Phase 2 trial
AMR - kidney	EU4/UK and US	2026	55	H2 2023 - Full data release from Phase 2 trial
DMD and LGMD (Sarepta Deal)	Global	2027	37	2023 - Initiation of Phase 1 trial
NiceR candidate	Global	2028+	-	H1 2023 - Initiate of Phase 1 trial

Source: Company reports; Intron Health estimates EU7: EU4+UK+Sweden+Norway

- **Kidney transplant (US)**: Enrolment for the ConfideS study continues (51/64 already enrolled) and is expected to complete in H123. Trial randomisation is expected to complete in H223 due to uncertainty with kidney transplant availability. We forecast a potential BLA submission in 2024 and launch in 2025.
- **AMR:** Full data from the positive Phase 2 will be released in H223 while Hansa determines the path forward, which may require a registrational Phase 3 study
- **Anti-GBM**: Initiated first site in the Phase 3 study in Dec ’22, which is expected to enrol 50 patients across the US, UK and EU. This is in line with our previous expectation for a potential approval and launch in 2025.
- **GBS:** Following Hansa’s efforts in accelerating enrolment that was delayed by COVID, 5 more patients have been enrolled in Q4 (25/30 enrolled to-date) with the remaining expected in H123.
- **NiceR:** Received approval to initiate a Phase 1 study in H123 with asset HNSA-5487, targeting therapeutic areas which require repeat dosing such as chronic autoimmune disorders, oncology and transplantation

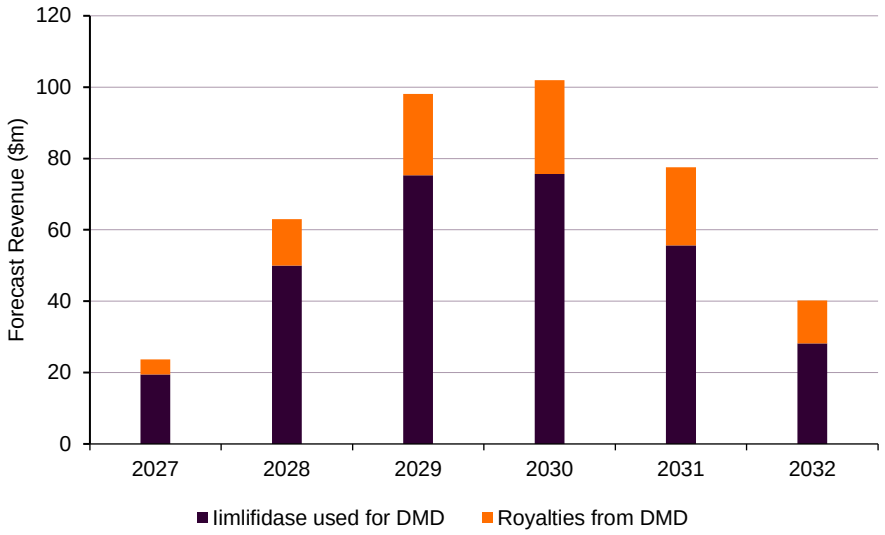
- **DMD:** Sarepta is on track to initiate a Phase 1 trial in 2023 with imlifidase as a pre-treatment with SRP-9001 gene therapy in DMD patients with high levels of neutralizing antibodies.

Phase I Pre-Treatment for DMD Therapy to Initiate

Neutralizing antibodies may exist in patients from prior exposure which binds to and deactivates virus capsids and render these patients unable to benefit from gene therapies.

In 2023, the Phase 1 study evaluating imlifidase as a pre-treatment for SRP-9001 is expected to initiate. Imlifidase is expected to eliminate neutralizing antibodies for AAV-rh74, the vector for SRP-9001, which prevents up to 20% of patients from benefiting from the therapy. By effectively cleaving IgG, imlifidase can enable an additional ~120 patients at peak years for SRP-9001, according to our model. Besides the $10m upfront Hansa has already received, it is eligible to receive up to $397.5 million in milestone payments and up to mid-teens in royalty revenues on SRP-9001 for DMD and Limb girdle muscular dystrophies (LGMD), in additional to all imlifidase sales. Our model values the opportunity as being worth an NPV of ~$100m.

Chart 2: Anticipated global revenue* & royalties* from imlifidase in DMD (Sarepta)



*Source: Intron Health estimates * Non-risk adjusted*

Potential for expanding into additional systemic gene therapies

In our view, imlifidase has the potential to be used as a pre-treatment for removing neutralizing antibodies in most systemic gene therapies. Besides DMD, Hansa is in partnership development in LGMD with Sarepta and in Pompe Diseases with AskBio. Following proof-of-concept in DMD, we believe additional partnerships are likely.

Cash Runway Through 2025

Following the direct share issue in December 2022, Hansa raised ~$40m to support the ongoing Idefirix launch in Europe, planning for launch in the US as well as advancing the NiceR programme into clinical development.

Table 4: Hansa cash position (excludes NovaQuest debt)

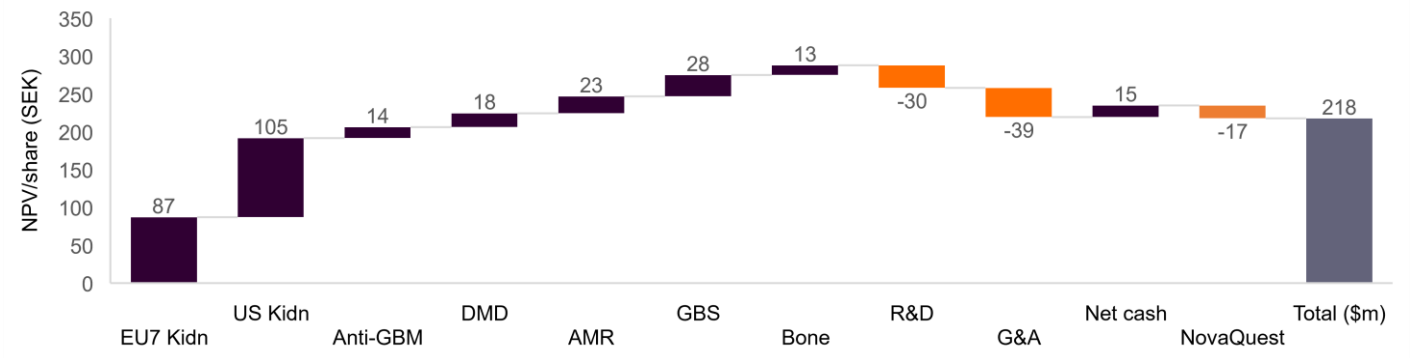
SEKm	2022A	2023	2024	2025	2026
Cash and cash equivalents	1,496	879	263	83	123
Total debt*	0	0	0	600	1,000
Net cash (debt)	**1,496**	**879**	**263**	**-517**	**-877**

Source: Company reports; Intron Health estimates

SEK220/Share Valuation – 4x Upside

Our updated model supports a PT of SEK220/share, reflecting changes to Idefirix's projection and higher net realised prices in Europe. We also account for the equity raise dilution and FX changes, as well as minor P&L updates following the quarter.

Chart 3: Hansa value per share (SEK) split into individual components – waterfall chart



Source: Intron Health estimates

Financial Statements

Group P&L

Table 5: Hansa Group P&L (SEK000s)

SEK (000s)	2022	2023	2024	2025	2026	2027
Revenue	**154,525**	**191,979**	**311,465**	**931,688**	**1,841,923**	**3,137,965**
growth	**356.1%**	**24.2%**	**62.2%**	**199.1%**	**97.7%**	**70.4%**
Cost of revenue	-38,477	-44,155	-65,408	-177,021	-331,546	-517,764
growth	149%	15%	48%	171%	87%	56%
as % of sales	-24.9%	-23.0%	-21.0%	-19.0%	-18.0%	-16.5%
Gross profit	**116,048**	**147,824**	**246,057**	**754,667**	**1,510,377**	**2,620,201**
Gross margin	**75%**	**77%**	**79%**	**81%**	**82%**	**84%**
SG&A	-336,242	-369,866	-499,319	-599,183	-689,061	-757,967
growth	2.7%	10.0%	35.0%	20.0%	15.0%	10.0%
as % of sales	-218%	-193%	-160%	-64%	-37%	-24%
R&D	-346,060	-449,878	-404,890	-425,135	-446,391	-468,711
growth	50.0%	30.0%	-10.0%	5.0%	5.0%	5.0%
as % of sales	-298%	-304%	-165%	-56%	-30%	-18%
Other operating income	3,229	0	0	0	0	63,961
Other operating expenses	-24,023	0	0	0	0	0
EBIT	**-587,048**	**-671,920**	**-658,153**	**-269,651**	**374,924**	**1,457,484**
EBIT margin	**-380%**	**-350%**	**-211%**	**-29%**	**20%**	**46%**
Net financial expense	-21,365	-992	-1,411	-19,693	-49,693	-52,693
Profit before tax	-608,413	-672,912	-659,563	-289,344	325,232	1,404,791
Tax	0	0	0	0	0	0
Effective tax rate	0.0%	-20.0%	-20.0%	-20.0%	-20.0%	-20.0%
Net income	**-608,413**	**-672,912**	**-659,563**	**-289,344**	**325,232**	**1,404,791**
growth	11.0%	10.6%	-2.0%	-56.1%	-212.4%	331.9%
Earnings per share (diluted)	**-13.54**	**-12.71**	**-12.46**	**-5.47**	**6.15**	**26.54**
growth	**9.9%**	**-6.1%**	**-2.0%**	**-56.1%**	**-212.4%**	**331.9%**
Number of shares (000s, diluted)	44,924	52,924	52,924	52,924	52,924	52,924

Source: Intron Health estimates

Group Balance Sheet

Table 6: Hansa Group balance sheet

SEK (000s)	2022	2023	2024	2025	2026	2027
Intangible assets	46,866	27,341	26,657	25,991	25,341	24,707
PP&E	8,113	12,471	16,483	20,880	25,739	30,971
Leased assets	27,723	27,723	27,723	27,723	27,723	27,723
Financial assets	0	0	0	0	0	0
Non-current assets	**82,702**	**67,535**	**70,863**	**74,594**	**78,803**	**83,402**
Accounts receivable	42,959	63,116	102,399	306,308	605,564	1,031,660
Inventory	973	15,779	34,133	127,628	252,318	429,858
Prepaid expenses & accrued income	64,593	64,593	64,593	64,593	64,593	64,593
Other receivables	0	0	0	0	0	0
Short term investments	0	0	0	0	0	0
Cash and cash equivalents	1,496,179	879,470	262,885	82,701	123,046	291,593
Current assets	**1,604,704**	**1,022,959**	**464,011**	**581,231**	**1,045,521**	**1,817,704**
Total assets	**1,687,406**	**1,090,494**	**534,874**	**655,825**	**1,124,324**	**1,901,106**
Share capital	55,034	55,034	55,034	55,034	55,034	55,034
Share premium	3,739,386	3,721,421	3,721,421	3,721,421	3,721,421	3,721,421
Treasury shares	-1,862	-1,862	-1,862	-1,862	-1,862	-1,862
Reserves	127	127	127	127	127	127
Retained earnings	-3,186,777	-3,859,689	-4,519,253	-4,808,596	-4,483,365	-3,078,574
Total shareholders' equity	**605,909**	**-84,969**	**-744,533**	**-1,033,876**	**-708,645**	**696,146**
Deferred tax liabilities	405	405	405	405	405	405
Provisions	767,793	767,793	767,793	473,648	105,967	-335,251
Debt	0	0	0	600,000	1,000,000	700,000
Lease liabilities	21,326	21,326	21,326	21,326	21,326	21,326
Contingent consideration	757	757	757	757	757	757
Deferred revenues	29,500	29,500	29,500	29,500	29,500	29,500
Non-current liabilities	**819,781**	**819,781**	**819,781**	**1,125,636**	**1,157,955**	**416,737**
Lease liabilities	7,165	6,888	6,888	6,888	6,888	6,888
Accounts payable	107,767	142,011	185,954	230,394	281,342	334,551
Other liabilities	604	604	604	604	604	604
Accrued expenses and deferred income	105,750	165,750	225,750	285,750	345,750	405,750
Deferred revenues	40,430	40,430	40,430	40,430	40,430	40,430
Current liabilities	**261,716**	**355,683**	**459,626**	**564,066**	**675,014**	**788,223**
Total shareholders' equity and liabilities	**1,687,406**	**1,090,494**	**534,874**	**655,825**	**1,124,324**	**1,901,106**

Source: Intron Health estimates

Group Cash Flow

Table 7: Hansa Group cash flow

SEK (000s)	2022	2023	2024	2025	2026	2027
EBIT	**-587,048**	**-671,920**	**-658,153**	**-269,651**	**374,924**	**1,457,484**
D&A	329	989	839	853	834	947
Incentive programme costs	60,391	60,000	60,000	60,000	60,000	60,000
Pension contributions	0	0	0	0	0	0
Unrealised FX differences	0	0	0	0	0	0
Interest paid	5,101	-992	-1,411	-19,693	-49,693	-52,693
Income taxes paid	-1,565	0	0	0	0	0
CFO before change in WC	**-522,792**	**-611,923**	**-598,724**	**-228,491**	**386,066**	**1,465,739**
Accounts receivable	-33,247	-20,157	-39,283	-203,909	-299,255	-426,096
Inventory	-731	-14,806	-18,354	-93,495	-124,690	-177,540
Operating receivables	-1,994	0	0	0	0	0
Accounts payable	54,407	34,244	43,943	44,440	50,948	53,208
Operating liabilities	0	0	0	0	0	0
Total change in WC	**18,435**	**-720**	**-13,694**	**-252,965**	**-372,997**	**-550,428**
Cash flow from operations	**-504,357**	**-612,643**	**-612,418**	**-481,456**	**13,069**	**915,311**
Acquisition of intangible assets	0	0	0	0	0	0
Acquisition of PP&E	-3,157	-3,788	-4,167	-4,584	-5,042	-5,547
Proceeds from equipment sales	0	0	0	0	0	0
Purchase of short term investments	0	0	0	0	0	0
Sale of short term investments	232,644	0	0	0	0	0
Proceeds from sales of shares in Genovis AB	0	0	0	0	0	0
Cash flow from investing	**229,487**	**-3,788**	**-4,167**	**-4,584**	**-5,042**	**-5,547**
Issue of shares	397,646	0	0	0	0	0
Cost of share issue	0	0	0	0	0	0
Sale of treasury shares	0	0	0	0	0	0
Net debt issued/repaid	0	0	0	600,000	400,000	-300,000
Issue of warrants	728,373	0	0	-294,145	-367,681	-441,218
Dividends	0	0	0	0	0	0
Repayment of lease liabilities	-6,888	-277	0	0	0	0
Cash flow from financing	**1,119,131**	**-277**	**0**	**305,855**	**32,319**	**-741,218**
Net change in cash & cash equivalents	**844,261**	**-616,709**	**-616,585**	**-180,185**	**40,345**	**168,547**
Cash & cash equivalents, beginning of year	**651,342**	**1,496,179**	**879,470**	**262,885**	**82,701**	**123,046**
Effects of FX on cash	576	0	0	0	0	0
Cash & cash equivalents, end of year	**1,496,179**	**879,470**	**262,885**	**82,701**	**123,046**	**291,593**

Source: Intron Health estimates

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Full 12-month historical recommendation changes are available on request

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