First Take

Hansa Biopharma AB (HNSA.ST)

February 28, 2022

Price: SEK57.06; Market Cap (M): SEK2,538; *2/25/2022 Close*

Rating: Buy; Price Target: SEK217.00

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Imlifidase Gains Early Reimbursement Access Authorization in France; Reiterate Buy

Temporary reimbursement authorization grants Hansa access to key French market until national level reimbursement is expected to be secured next year. Hansa enjoyed a big win as Imlifidase was granted early access post-marketing authorization in France—greatly expanding patient access through the addition of one of the biggest European markets—and in our view, helping overcome a major obstacle to uptake for an innovative but expensive (>$300K) therapy. Recall, that though Imlifidase is the first and only practical desensitization strategy for highly sensitized kidney transplant patients, EU uptake has thus far been lackluster, as only four countries have provided full or partial national level reimbursements. Hansa has been working hard to secure these, but the process is slow and must be done on a country-by-country basis, with COVID-19 only adding delays, so we see this as an important milestone that we believe could accelerate the launch. The French regulator (Haute Autorité de Santé) awarded early access post-marketing authorization (Autorisation d'accès précoce) for "desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor," the same patient population as the EU authorization. As such, for one year from authorization, imlifidase therapy will be covered at 100% in France. This grants access to an almost $100M market given the 3,600 annual transplants, 80% of whom are from deceased donors, and 11.1% of whom are considered highly sensitized. We see imlifidase as a superior alternative for patients than languishing on dialysis waiting for a difficult-to-find match, offering better outcomes and quality of life, as well as one that's significantly cheaper over time for the healthcare system. Pricing and reimbursement negotiations are currently ongoing in 14 countries including all five major European markets, where we expect decisions to be made later this year or in early 2023. The company is also investing heavily in provider education and has reported positive initial provider experiences and is making progress on adding Imlifidase to treatment guidelines with a European Society for Organ Transplantation (ESOT) work stream underway. In our view, all these efforts should begin translating to meaningful launch traction over the next year and we see peak EU sales at almost $450M. However, if the drug gains approval in the U.S., possibly in 2025, we expect the learnings from the EU launch to translate into much faster uptake and we model peak U.S. sales of $356M in 2035.

Valuation and risks. Our Buy rating and price target of SEK217 for Hansa 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, Gullian-Barré syndrome, and as a pretreatment for Sarepta's (SRPT; not rated) gene therapies in Limb-Girdle and Duchene muscular dystrophy. Our DCF model utilizes a terminal decline rate of 5% and a discount rate of 9.5%, based on the company's WACC (Beta of 1.0, equity risk premium of 6.0%). 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, Gullian-Barré syndrome and Ab mediated kidney rejection at 35% as Phase 2 studies are progressing in both indications and the mechanism of action appears well- suited for both, Goodpasture syndrome at 50% based on the promising data from the investigator- initiated Phase 2 and the expectation of a near-term Phase 3, and pretreatment for gene therapies at 25% 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 only just begun to currently generate revenue last quarter and 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; (v) partnership, as the Sarepta agreement, a major component of our valuation, depends heavily on Sarepta's ability to execute, which may not pan out as expected; and (vi) COVID-19 disrupting clinical trials.

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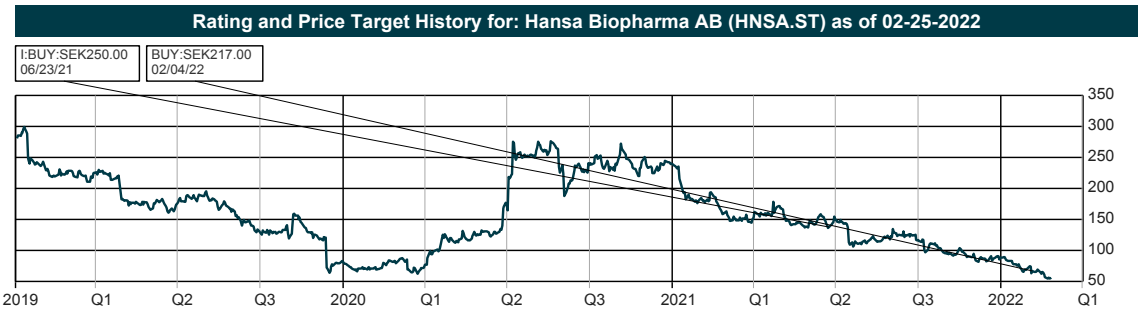

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			IB Service/Past 12 Months	
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Neutral	42	6.57%	12	28.57%
Sell	1	0.16%	0	0.00%
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