BIOPHARMADIVE

Intercept, after biotech rollercoaster ride, agrees to buyout by Alfasigma

The deal values Intercept at about $800 million, a fraction of what it was once worth in the middle of the last decade.

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Liver drug developer Intercept Pharmaceuticals has agreed to be acquired by Italian company Alfasigma for about $800 million, the companies announced Tuesday, ending one of biotechnology's most noteworthy stories of investor exuberance and clinical disappointment in the last decade.

Alfasigma will pay Intercept investors $19 per share in cash, an 82% premium from Intercept's closing price on Monday. Alfasigma will fund the transaction with cash on hand and corporate credit facilities, and expects to close the deal by the end of 2023.

With the acquisition, Alfasigma will gain Ocaliva, a drug that treats the rare autoimmune disorder primary biliary cholangitis, or PBC, which had sales of $152 million in the first six months of the year. The company recorded losses of $38 million over the same period.

Alfasigma executives said the transaction will help it develop its U.S. presence. "Intercept represents a compelling fit with

Alfasigma's core business areas of gastroenterology and hepatology, and we believe that the transaction represents a transformational opportunity for both companies," said Alfasigma CEO Francesco Balestrieri in a statement.

A closely held company controlled by the family of its founder, Alfasigma markets drugs like Zelnorm and rifaximin for irritable bowel syndrome and sulodexide for post-thrombotic syndrome. It also provides contract manufacturing services, as well as nutritional supplements. Its factory in Shreveport, Louisiana, manufactures nutritional supplements for the U.S. market.

While Ocaliva first gained approval for PBC, the drug's potential in the liver disease NASH drove investor enthusiasm in Intercept. NASH, or non-alcoholic steatohepatitis, is a disease connected with obesity, and its believed to be growing widely in prevalence.

In 2014, a National Institutes of Health Phase 2 study of Ocaliva in people with NASH was stopped early because it had met its primary goal — improvement in disease activity score — at an interim analysis. Shares in the company nearly quadrupled in value and took the company's valuation to more than $7 billion, sparking an investor rush to find other companies working on NASH drugs.

The path to regulators was not straightforward, however. Intercept reported positive Phase 3 data in 2019, but the FDA asked for longer-term data, rejecting Intercept's first NASH application.

The FDA turned back a second application earlier this year, as Ocaliva's only modest benefit was balanced against signs of liver damage experienced by some trial participants given the drug. Following that rejection, Intercept canceled all work in NASH,

claiming it wasn't economically feasible to collect the data asked for by the FDA, and laid off staff.

Meanwhile, competition in Intercept's established market of PBC may be emerging, as CymaBay's seladelpar and Genfit's elafibranor near key milestones.

Raymond James analyst Steven Seedhouse described the transaction as a "great return" for Intercept investors.

"Given our bullish view of seladelpar and its ability to take market share in PBC beginning as early as late 2024, it isn't clear to us if [Ocaliva] will even generate that much net profit in the next ~10 years," Seedhouse wrote in a note to clients.