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## Vifor Pharma bets on portfolio before potential split



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Vifor Fresenius Medical Care Renal Pharma's decision to pay \$50m up front to license Rayaldee, a project that last year got an FDA complete response letter, could be seen as a bit of a gamble. Despite the setback, the vitamin D prohormone treatment is hoping to get past the regulator at the second time of asking by the new October 22 PDUFA date – helping Vifor Pharma with its plans to spin out of its parent, Galenica.

However, Rayaldee, developed by Opko Health, is a less risky bet than it looks. It was slapped with the complete response letter in March, but the problem appears to have concerned deficiencies at Opko's third-party contract manufacturer. With no safety, efficacy or labelling issues and no requests for additional trials Rayaldee should theoretically sail through approval.

### Conscious uncoupling

The addition of an asset that fits squarely into Vifor Pharma's already strong nephrology medicines and dialysis portfolio might indicate that the split from Galenica is drawing nearer. In September the Swiss company said it was looking to spin out the increasingly profitable Vifor business in one to three years.

Beefing up the division now will give an independent Vifor the best start in life, but earlier comments from the company could mean that the deal with Opko will be one of many.

Speaking to *EP Vantage* at the time of the spinout, Søren Tulstrup, chief executive of Vifor Pharma, said: "If you want to finance the future growth of Vifor Pharma you need over time a different set of investors that are more risk-willing and willing to put in money for the long term."

Mr Tulstrup also said Vifor had "firepower north of SFr1bn (\$1.1bn)", and would also be looking at cardiology, infectious diseases and gastro-intestinal products to boost its portfolio.

Vifor has already struck deals with Roche for Mircera, to treat anaemia associated with chronic kidney disease, and with Relypsa for a potassium binder that can also be used in cardiology. In March its Galenica parent cut 2016 earnings guidance to take account of future M&A and licensing deals, again indicating that the split could be close.

### Useful revenue

Today's deal between VFMCRP, a common company of Galenica and Fresenius Medical Care, will give it the right to develop and sell Rayaldee in large parts of the world including Europe and Canada. Alongside the \$50m up-front payment, Opko is entitled to additional sales and development milestones of up to \$232m and double-digit royalties. The group also has an option over US rights.

Rayaldee is used to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease. SHPT is caused by low vitamin D hormone, causing excessive calcium and phosphorus to be released from bone, leading to softening of the bones and calcification of vascular and renal tissues.

VFMCRP estimates that SHPT affects 40-60% of patients with moderate chronic kidney disease, and approximately 90% of patients with the advanced condition. According to *EvaluatePharma* sales of Rayaldee are forecast to reach \$560m by 2022 – a share of which will come in handy for an independent Vifor.

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