



Press  
Release

# Vifor Pharma reports strong H1 2021 growth, on track to meet full year guidance<sup>1</sup>

- Net sales up 5.0% and EBITDA up 5.3% at constant exchange rates (CER), as patient access recovered in line with easing COVID-19 restrictions in key markets
- Ferinject® / Injectafer® sales up 22.8% at CER – strong recovery in Q2 in line with lockdown easing and better patient access to i.v. iron treatment
- Nephrology – major pipeline progress including regulatory submissions of avacopan and difelikefalin in Europe, as well as vadadustat by Akebia in the US
- ESA portfolio performance impacted by COVID-19 and phasing
- Veltassa® – revised DIAMOND study and sustained commitment to evidence-based care in chronic kidney disease (CKD) and heart failure through multiple studies
- Full year guidance confirmed – at CER, net sales expected to grow at low-to-mid single-digit and EBITDA to grow at high single-digit rate.<sup>1</sup>

**St. Gallen, Switzerland, 5 August 2021** – Vifor Pharma Group reported profitable revenue growth in H1 supported by a strong recovery in Ferinject®/Injectafer® with sales up 22.8% at CER as a result of improved patient access as COVID-19 restrictions eased in key markets. Based on the solid results in H1 2021, the Group is confident of achieving its full year guidance.

## FINANCIAL PERFORMANCE<sup>2</sup>: CONTINUED OVERALL GROWTH

- Reported net sales of CHF 859.3 million, up 1.5% (up 5.0% at CER)
- EBITDA of CHF 281.0 million, up 0.2% (up 5.3% at CER). Excluding other income, EBITDA increased 9.4% (up 15.0% at CER)
- Other income of CHF 20.4 million, down 51.7% due to lower income from partnering and other activities
- Gross profit margin of 62.5%, up 1.4 percentage points driven by higher share of sales from the iron portfolio
- Net profit attributable to shareholders of Vifor Pharma Ltd. of CHF 124.4 million, driven by lower depreciation, amortization and impairment, as well as the strong net financial result in H1 2021
- Strong balance sheet with a net cash position of CHF 86.6 million and an equity ratio of 76.5%

## Commenting on the first half-year results, Stefan Schulze, Chief Executive Officer of Vifor Pharma, said:

“Vifor Pharma saw continued growth in reported revenues and profitability in the first half of 2021. This encouraging performance was boosted by a significant rebound in sales of our i.v. iron therapy Ferinject®/Injectafer®, as patient access improved in many markets in line with the easing of COVID-19 restrictions. Despite ongoing challenging conditions in certain regions, we continued to increase our leadership in iron deficiency and made further substantial progress in strengthening our leadership position in the treatment of kidney diseases. We anticipate several approvals and launches in our innovative nephrology pipeline over the next 18 months, keeping our promise to patients to support them leading better, healthier lives. Based on a solid first half and continued positive momentum, we are confident of delivering our guidance for the full year.”

## FERINJECT®/INJECTAFER® REBOUNDS IN LINE WITH LOCKDOWN EASING IN Q2

- Ferinject®/Injectafer® net sales increased 22.4% (up 22.8% at CER) to CHF 320.5 million in H1 2021 from CHF 261.9 million a year earlier. Our US partner American Regent recorded net sales of USD 239.2 million in H1 2021. As a result, Vifor Pharma posted net sales of CHF 73.7 million, up 1.4% or 8.5% at CER.

- Net sales recovered strongly in line with easing of COVID-19 restrictions and improved patient access to infusions since March. Overall utilization of i.v. iron highly correlated with intensity of lockdown measures.
- Investment in clinical data continued, with results from a sub-analysis of the AFFIRM-AHF study on quality of life published by the European Heart Journal in June, highlighting the need for frequent iron deficiency screening and treatment for chronic heart failure patients.
- Blood donations fell during the pandemic, raising awareness of the importance of Patient Blood Management (PBM). An update to the international Clinical Practice Guidelines for Blood Conservation was published in June, changing the approach from blood conservation to PBM, and emphasizing the importance of identifying and treating iron-deficiency anemia in cardiac surgery patients with i.v. iron.
- Preliminary results from a real-world study on PBM of around 31,000 patients are expected at the end of 2021 with the manuscript to be published in 2022.

## **NEPHROLOGY: SOLID PERFORMANCE OF PORTFOLIO AND SUBSTANTIAL PIPELINE PROGRESS**

- Velphoro<sup>®</sup> net sales increased 8.1% (up 13.6% at CER) to CHF 79.9 million from CHF 73.9 million a year earlier, mainly driven by US and Japan.
- Venofer<sup>®</sup> net sales decreased -1.5% (up 2.7% at CER) to CHF 67.3 million in H1 2021. Growth in local currency was mainly driven by continued stronger demand in hospitals in the US.
- Erythropoiesis-Stimulating Agent (ESA) portfolio decreased by -15.8% to CHF 246.4 million (down -9.7% at CER) compared to the prior year period. Mircera<sup>®</sup> net sales were CHF 218.9 million, down -18.5% compared to the prior year period (down -12.6% at CER). In addition to negative foreign exchange effects, Mircera<sup>®</sup> performance was mainly driven by phasing impacts and lower volumes resulting from an excess mortality rate in the dialysis segment due to COVID-19. Retacrit<sup>®</sup> net sales totalled CHF 27.5 million, up 14.1%, driven by increased adoption in existing markets, new customer accounts and higher demand following the multi-dose vial launch.
- Vifor Pharma continued to make substantial progress in its growing nephrology pipeline in H1 2021, including:
  - Avacopan – positive topline data from the pivotal phase-III ADVOCATE trial were published in the New England Journal of Medicine in February. Further to the acceptance to review the Marketing Authorization Application (MAA) for treatment of ANCA-associated vasculitis by the European Medicines Agency (EMA) in November 2020, the MAA was submitted to Swissmedic and Health Canada in April. Vifor Fresenius Medical Care Renal Pharma (VFMCRP) signed an agreement in May with Otsuka Canada Pharmaceutical (OCPI) to promote and distribute avacopan in Canada.
  - Difelikefalin – US FDA acceptance and priority review of Cara Therapeutics' New Drug Application (NDA) for treatment of moderate-to-severe CKD-associated pruritus was announced in March, with a Prescription Drug User Fee Act (PDUFA) target date of 23 August 2021, and the EMA accepted the MAA for difelikefalin injection for review. VFMCRP signed an out-licensing agreement with OCPI in May to commercialize difelikefalin in Canada.
  - Vadadustat – in June, Akebia Therapeutics announced the FDA had accepted for filing the NDA for treatment of anemia due to CKD, with a target PDUFA date of 29 March 2022. At the time of filing, the FDA also indicated that they were not currently planning to hold an Advisory Committee meeting to discuss the application for vadadustat.
  - ANG-3777 – Vifor Pharma and Angion Biomedica announced completion of enrolment for the phase-II trial in patients at risk of cardiac-surgery associated acute kidney injury (CSA-AKI).

## **VELTASSA<sup>®</sup>: SUSTAINED COMMITMENT TO DRIVE EVIDENCE-BASED CARE**

- Veltassa<sup>®</sup> net sales were CHF 54.8 million in H1 2021, down -8.1% from CHF 59.6 million (down -3.1% at CER). Net sales in the US amounted to CHF 46.8 million. Performance was primarily impacted by market access and reimbursement hurdles and lower than anticipated overall market growth in the chronic setting.
- Work to further differentiate Veltassa<sup>®</sup> continued, with the first patient enrolled in the CARE-HK global study platform in April. This registry aims to improve understanding of treatment decisions with RAASi (renin-angiotensin aldosterone system inhibitor) in clinical practice, barriers to optimal guideline-directed care in heart

failure patients with or at high risk of hyperkalemia, and to assess potential use of Veltassa® in the management of this patient population.

- In June, the phase-IIIb DIAMOND study was amended with new and clinically relevant endpoints, including a new primary endpoint of efficacy in potassium management in high-risk heart failure patients treated with guideline-recommended doses of RAASi. This decision was made on the recommendation of the study's independent Executive Committee and following the significant impact of COVID-19 on recruitment. Readout is expected in H2 2021.

## OTHER IRON THERAPIES

- Vamifeport (VIT-2763) was granted orphan drug designation by the FDA and EMA for sickle cell disease (SCD) in Q1 2021. A phase-IIa trial in SCD has been initiated.

## CORPORATE DEVELOPMENTS

- Dr. Alexandre LeBeaut and Åsa Riisberg were elected to the Board of Directors at the Annual General Meeting in May. Dr. Gianni Zampieri and Gilbert Achermann did not stand for re-election.
- Abbas Hussain was appointed Chief Executive Officer of Vifor Pharma, succeeding Stefan Schulze, who has decided to step down for personal reasons. Abbas Hussain will join the company on 16 August 2021.

## 1. FINANCIAL PERFORMANCE<sup>2</sup>

<i>In million CHF</i>	<i>H1 2021</i>	<i>H1 2020</i>	<i>Change</i>
<b>Net sales</b>	859.3	846.2	1.5%
<b>EBITDA</b>	281.0	280.4	0.2%
<b>Net profit attributable to shareholders of Vifor Pharma Ltd.</b>	124.4	67.9	83.2%
<b>Core earnings per share from continuing operations (in CHF)</b>	2.92	2.38	22.7%

## KEY PROFIT AND LOSS FIGURES

Vifor Pharma Group **net sales** increased by 1.5% to CHF 859.3 million compared to H1 2020, or 5.0% at CER, as patient access recovered in line with easing COVID-19 restrictions in key markets. The growth was mainly driven by our iron portfolio with better patient access to i.v. iron treatment.

**EBITDA** increased to CHF 281.0 million compared to CHF 280.4 million in H1 2020, an increase of 0.2% or 5.3% at CER despite a significant decline in other income. Excluding other income, EBITDA increased by 9.4% compared to H1 2020, or 15.0% at CER. This is a result of profitable growth in net sales combined with diligent cost containment.

**Other income** was CHF 20.4 million compared with CHF 42.2 million in H1 2020. This was primarily due to lower income from partnering and other activities compared to H1 2020.

**Cost of sales** amounted to CHF 329.7 million compared to CHF 345.9 million in H1 2020, resulting in a gross profit margin of 62.5% compared to 61.1% in H1 2020. The gross profit margin increase is primarily due to the higher share of sales from injectable iron products.

**Marketing and distribution** expenses amounted to CHF 193.5 million, up 0.6% from H1 2020. The additional investments in pre-launch activities of our pipeline products were largely offset by cost containment.

**Investments in R&D** amounted to CHF 108.1 million compared to CHF 146.6 million in H1 2020. The decrease was mainly attributable to the impairment of the CCX140 intangible asset of CHF 56.2 million in H1 2020 partially offset by higher DIAMOND, CARE-HK and vamifeport (VIT-2763) study costs in H1 2021 compared to H1 2020.

**General and administration** expenses amounted to CHF 71.0 million compared to CHF 90.1 million in H1 2020. The decrease was mainly driven by a reduction of personnel related costs across support areas.

**Core earnings per share from continuing operations** amounted to CHF 2.92 in H1 2021, an increase of 22.7% compared to CHF 2.38 in H1 2020. The increase is due to revaluation gains on financial investments of CHF 22.4 million and unrealized foreign currency gains of CHF 13.3 million in the net financial result of H1 2021. Core earnings are defined as net profit attributable to shareholders of Vifor Pharma Ltd. adjusted for proportionate amortization and impairment of intangible assets of CHF 65.2 million in H1 2021 (H1 2020: CHF 104.6 million).

## CASH FLOWS

**Cash flow from operating activities** amounted to CHF +189.8 million compared to CHF +172.6 million in H1 2020. The increase is due to lower investments in net working capital in H1 2021 compared to H1 2020.

**Cash flow from investing activities** amounted to CHF -98.6 million. The key drivers are capital expenditures of CHF -26.0 million in production related assets, milestone payments for in-licensing agreements of CHF -27.5 million, investments in IT projects of CHF -15.0 million and the equity investment in Angion Biomedica Corp. of CHF -22.3 million concurrent with Angion's initial public offering in February 2021.

**Cash flow from financing activities** amounted to CHF -208.9 million and was mainly influenced by dividend distributions of CHF -189.8 million, whereof CHF -60.0 million was paid to Fresenius Medical Care and CHF -129.8 million was distributed to shareholders of Vifor Pharma.

## FINANCIAL POSITION

**Goodwill and intangible assets** amounted to CHF 2,447.5 million at the end of H1 2021 compared to CHF 2,454.5 million at the end of 2020, representing 49.8% of total assets (end of 2020: 47.1%).

**Financial assets** amounted to CHF 386.2 million at the end of H1 2021 compared to CHF 725.7 million at the end of 2020. The significant decrease is due to the fair value loss of CHF 386.5 million on our equity investment in ChemoCentryx, Inc. Revaluation adjustments on our equity investments are recorded in other comprehensive income.

Vifor Pharma Group achieved a net cash position of CHF 86.6 million at the end of H1 2021 compared to a **net cash position** of CHF 190.6 million at the end of 2020. The decrease in net cash is mainly due to the dividend payment of CHF 189.8 million and investments made in H1 2021 which exceed the cash generated from operating activities.

With CHF 3,763.0 million of **shareholders' equity** at the end of H1 2021, Vifor Pharma Group continues to have a strong equity ratio of 76.5%.

## 2. FINANCIAL GUIDANCE

In 2021, at constant exchange rates, net sales are expected to grow at a low-to-mid single digit rate, and EBITDA to grow at a high single digit rate.<sup>1</sup>

## 3. OUTLOOK 2021

### Market Access

- Ferinject® – Expected approval in China
- Avacopan – Expected approval in Europe and Japan; partnering in China
- Difelikefalin – Expected approval in the US; partnering in China

## Clinical trials

- Vamifeport – Topline data from the phase-II study in non-transfusion dependent beta-thalassemia, and a phase-IIb trial in transfusion-dependent beta-thalassemia to be initiated
- ANG-3777 – Data readout of a phase-II trial for treatment of CSA-AKI and of a phase-III trial in transplant-associated acute kidney injury/delayed graft function

## Business development

In line with our ambition to strengthen our product pipeline, we aim to complete at least two in-licensing deals, product acquisitions or corporate transactions.

For further details, please see the Vifor Pharma 2021 Half-year Report at [www.viforpharma.com](http://www.viforpharma.com).

## Live conference call and webcast

A live webcast and conference call will be held on 5 August 2021 at 14:00 (CET).

Access to live webcast → [link](#)

Pin code and phone numbers for the live conference call:

**Pin code: 9368891**

Country	Phone number
Switzerland	+41 31 580 0059
France	+33 17 670 0794
Germany	+49 692 443 7351
United Kingdom	+44 207 192 8000
United States of America	+1 631 510 7495
Other countries	+44 207 192 8000

## Replay

A webcast replay ([link](#)) will be available shortly after the end of the live conference.

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## About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit [viforpharma.com](http://viforpharma.com).

<sup>1</sup> Subject to no worsening of the situation due to COVID-19 in H2 2021.

<sup>2</sup> Figures of 2020 are restated to reflect the sale of OM Pharma business which was completed on 30 September 2020.