

# CLINIGEN

## Year End Trading Update

Clinigen Group plc (AIM: CLIN, 'Clinigen' or the 'Group'), the global pharmaceutical Products and Services company, today provides an unaudited trading update for the year ended 30 June 2021. The Group expects to publish its final results for the year ended 30 June 2021 on Thursday 16 September 2021.

### Financial Highlights

- Net revenue<sup>1</sup> expected to be £455m representing an increase of 12% on a constant currency<sup>2</sup> and organic<sup>3</sup> basis. Including the contribution from the UK Specials and Aseptics compounding business (the "UK Compounding Business"), which was divested on 30 June 2021, reported net revenue is expected to be £495m.
- Adjusted EBITDA<sup>4</sup> is expected to be £116m, in line with guidance provided in June of £114-£117m, representing a decline of 10% on a reported basis and 6% on a constant currency<sup>2</sup> and organic<sup>3</sup> basis. Including the UK Compounding Business adjusted EBITDA expected to be £117m.
- Net debt of no more than £317m (excluding IFRS 16) representing net debt leverage<sup>5</sup> of 2.8x, meaningfully below the Group's temporary banking covenant of 3.5x.
- Clinigen expects to achieve double digit EBITDA growth in FY2022 and remains focused on debt paydown.

### Operational Highlights

- Reorganisation of Group into two divisions ("Products" and "Services") and divestment of the UK Compounding Business simplifies operational structure and aligns platform to end-market customer. Post these changes a further review of the cost base has begun to target new cost saving initiatives.
- Strong new business activity in Services, with \$100m of business won in Clinical Services and net 30 Managed Access Programs added. The Services business margin weakened in the period due to a higher proportion of Sourcing wins and delays to key contracts in Clinical that have now started.
- In Products, demand for Proleukin and On-Demand products remains weak due to the continued impact of COVID-19 on hospital-based treatments, whilst the developed portfolio of products performed strongly and the Erwinase global roll-out is progressing ahead of plan.

### Shaun Chilton, Chief Executive Officer of Clinigen, said:

*"Like many other companies operating in the clinical trial and hospital-based products area, Clinigen this year has seen an impact on demand from COVID-19. Nevertheless, we anticipate a return to double-digit growth in the next financial year driven by the strength of our underlying business and activity levels across the Group."*

*"We are seeing significant activity in Services, with strong business wins across the division in both COVID and non-COVID related areas that will fuel growth over the coming year. In Products, the roll-out of Erwinase is ahead of expectations, and we continue to add to our Partnered portfolio to support future growth."*

*“More broadly, Clinigen’s strong platform across the product lifecycle and synergies across the business give us confidence in our ability to deliver value for patients, customers and investors in the coming year and beyond.”*

## **Financials**

The positive cash generation seen in H1 2021 continued into the second half, equating to cash conversion of over 85% for the full year in spite of a £15m investment in working capital for Erwinase onboarding.

In spite of the working capital investment in H2 2021, net debt is expected to have decreased to £317m at end-June from £330m at end December 2020 (excluding IFRS 16), with net debt leverage of 2.8x well within the Group’s 3.5x net debt / adjusted EBITDA temporary banking covenant.

With the Group having made a \$89.5m deferred payment for CSM in September 2020 there are no material deferred payments to make on prior acquisitions. The Group aims to pay down debt to a leverage ratio well below 2.5x on an ordinary basis by end of FY2022 and within our stated target of below 2.0x within FY2023.

## **Simplified operations and a synergistic platform**

Clinigen has simplified and streamlined the organization to better align with customers by reorganizing the business into two divisions and more recently (announced June 30) disposing of the non-core, low margin UK Compounding Business which had two separate facilities in the UK and 198 employees.

Clinigen is confident that this will help to deliver further synergies across the platform, bringing clear benefit to our customers, patients and ultimately to the Group.

During the year the Group’s ‘Join The Dots’ initiative, focused on driving referrals and collaboration across the two business divisions, continued to show steady progress, with an increase in cross divisional referrals from its 579 Pharma & Biotech client list (10 business wins closed in the period, up from 4 in FY2020).

## **Products**

As previously announced, Proleukin was negatively impacted by COVID-19 in H2 2021 with a significant reduction in US prescriptions for on-label indications, resulting in a key order from a US wholesaler not being placed in Q4. Management believe it is prudent to expect this reduced level of demand for Proleukin to remain until revitalisation efforts into new indications alongside novel cell therapies are successful and normal Hospital and Cancer Centre Services have resumed. Additional analysis on the prescribing patterns in the US will be presented at the update today and will be available online on the Clinigen website afterwards. Management remains confident in the outlook for Proleukin and the original investment case for revitalization into new indications, either alongside novel cell therapies or as a single agent in autoimmune diseases.

Outside of Proleukin, the Owned Products portfolio delivered a robust performance thanks to growth from key developed assets Glycopyrronium and Melatonin offsetting declines elsewhere with the loss of Ethylol in the year due to previously disclosed manufacturing difficulties. Foscavir performed well in spite of the launch of generic versions in both the US and EU due to the implementation of defensive strategies such as the launch of the bag formulation.

The Partnered portfolio performed strongly whilst the onboarding and roll-out of Erwinase is progressing ahead of plan, with sales already initiated in the UK on a commercial basis and into ex-UK markets on an unlicensed basis.

On-Demand revenues were materially impacted by COVID-19 with hospitals prioritising treating patients more directly affected by the pandemic.

## Services

The impact of COVID-19 has continued to cause delays to clinical trials and reduced hospital activity and, whilst activity levels are not back to pre-pandemic levels they are beginning to increase. In spite of the impact of COVID-19, net revenue increased strongly in the year thanks to new Sourcing contract wins, albeit these were at a lower overall margin.

The division also saw a strong period of new business wins, with \$100m worth of signings overall in Clinical Services and more Managed Access Programs being won than in any prior year (30 net). It is anticipated that these business wins, which are across the higher margin Clinical and MA services, will help drive strong EBITDA growth in FY2022.

## Board update

Peter Allen, Independent Non-Executive Chairman (“Chairman”) will not stand for re-election to the Board at the AGM in November. Peter has served as Chairman since the Group’s IPO in September 2012, steering the Group through a period of exponential growth, and Clinigen is enormously grateful to him for his leadership and guidance. The Group is in advanced discussions with a potential successor who would bring to Clinigen significant international experience in pharmaceutical products and services, and will provide an update in due course.

## Outlook

As the Group heads into FY2022 and the market begins to slowly recover from the pandemic, Clinigen sees evidence of strong momentum in its Services business and progress in the Products business laying the foundations for future growth. Clinigen is confident that our simplified operating structure will deliver further synergies across the platform, bringing clear benefit to our customers, patients and ultimately to the Group.

Clinigen expects to achieve double digit EBITDA growth in FY2022, with continued strong cash generation, and remains focused on debt paydown.

<sup>1</sup> Net revenue evaluates the Group’s revenue performance excluding the impact of pass through revenue in the Managed Access business which varies each period dependant on the mix of programs.

<sup>2</sup> Constant currency evaluates growth by applying the prior period’s actual exchange rate to this period’s result.

<sup>3</sup> Year on year comparisons referred to as ‘organic’ are a measure of growth on a constant currency basis, excluding the impact of acquisitions and disposals. There were no acquisitions within the last 12 months of the reporting date and one disposal relating to the UK Compounding Business. Organic growth is presented to aid the reader’s understanding of the underlying performance of the business.

<sup>4</sup> Group results on an adjusted basis exclude amortization of acquired intangibles and products and other non underlying items.

<sup>5</sup> Bank covenant leverage is calculated by dividing adjusted EBITDA of the Group for the last 12 months by net debt at the period end, excluding the impact of IFRS 16. Adjusted EBITDA excludes the EBITDA from businesses disposed of during the last 12 months.

Members of the management team at Clinigen will hold a webcast for analysts and investors, followed by a live Q&A, at 9:00am BST today. Please find a link to this webcast [here](#). If you would like to join the live Q&A, please register [here](#).

- Ends -

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**About Clinigen Group**

Clinigen Group plc (AIM: CLIN) is a global, specialist pharmaceutical services and products platform focused on providing ethical access to medicines. Its' mission is to deliver the right medicine to the right patient at the right time. The Group operates from sites in North America, Europe, Africa and the Asia Pacific.

Clinigen has more than 1,000 employees across five continents in 16 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 34 of the top 50 pharmaceutical companies; interacting with over 5,000 hospitals across more than 115 countries.

For more information on Clinigen, please visit <http://www.clinigen.com>

**Cautionary statement**

*This announcement contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Clinigen Group plc. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Except as required by law, Clinigen undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.*

*The information contained in this statement has not been audited and may be subject to further review.*