

# Clinuvel (UK) Limited

Annual Report and Financial Statements

For the year ended 30 June 2021

Company Registration No. 05414157 (England and Wales)

# Clinuvel (UK) Limited

## Company Information

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<b>Director</b>	P J Wolgen
<b>Secretary</b>	D Keamy
<b>Company number</b>	05414157
<b>Registered office</b>	Devonshire House 60 Goswell Road London EC1M 7AD
<b>Auditor</b>	Moore Kingston Smith LLP Devonshire House 60 Goswell Road London EC1M 7AD

# Clinuvel (UK) Limited

## Contents

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	<b>Page</b>
Strategic report	1 - 3
Director's report	4
Independent auditor's report	6 - 9
Profit and loss account	10
Statement of comprehensive income	11
Balance sheet	12
Statement of changes in equity	13
Notes to the financial statements	14 - 21

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# Clinuvel (UK) Limited

## Strategic Report

For the year ended 30 June 2021

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The director presents the strategic report for the year ended 30 June 2021.

### **Fair review of the business**

Since June 2016 until the Brexit date of 31 December 2020, the core focus of CLINUVEL (UK) Ltd was to facilitate the distribution of its commercial pharmaceutical product called SCENESSE. As the European entity for the CLINUVEL Group of companies prior to Brexit, it held the European marketing authorisation licence to distribute SCENESSE® in Europe. Upon Brexit, the license to distribute SCENESSE® was transferred to another CLINUVEL entity residing in the EU. As a result of the transfer of the marketing authorisation licence, commercial sales of SCENESSE® in Europe recorded by CLINUVEL (UK) Ltd totalled £4.5 million for 2020/21, compared to £13.5 million for 2019/20, £14.5 million in 2018/19 and £12.2 million for 2017/18. Unit sales decreased by 68% year on year. All sales after the Brexit date of 31 December 2020 were recorded in a new European subsidiary. Ignoring the change in reporting entities, unit sales in Europe increased 9% year on year.

The price of SCENESSE® remained constant throughout 2020/21, in line with CLINUVEL's policy to charge a uniform price across all European countries. EPP Expert Centres in Europe continued to prescribe SCENESSE® to existing and new patients receptive to the treatment.

However CLINUVEL (UK) Ltd continues to be a critical function in the CLINUVEL Group of companies. It:

1. Continues to be responsible for many of the commitments agreed with the European Medicines Agency (EMA) to operate a risk management plan, as well as performing Quality, Pharmacovigilance and Market Access functions for the new European entity to support EU sales.
2. Provides communications, branding and marketing services for the CLINUVEL Group of companies.
3. Employs personnel who manage the clinical affairs of the SCENESSE development program.

Notwithstanding the change of licence holder resulting in loss of sales by CLINUVEL (UK) Ltd, the commitments made by the CLINUVEL Group to operate a long-term risk management plan under the supervision of the EMA has remained the responsibility of CLINUVEL (UK) Ltd. The commitments made under the risk management plan include conducting an ongoing non-interventional study whereby anonymised patient data is entered into a disease registry and the results provided to the EMA at least annually.

The Company is assisted by third parties to support the commitments made under the risk management plan to monitor long-term safety and it will continue to invest in existing and new personnel with the appropriate skills and expertise to maintain the ongoing requirements of the post-authorisation program in Europe. This has been demonstrated by the entity headcount increasing from 16 at July 2019 to 24 at June 2021. These ongoing requirements will remain in place until such time the EMA decides they are no longer necessary. The company may continue to increase staff numbers as more pricing agreements per country are established with payers allowing more patients to be treated and increasing the effort required to fulfil the commitments under the long-term risk management plan.

A reference price for SCENESSE® as part of a uniform pricing strategy has been established with several countries across Europe, including both state and private insurance groups. The UK is currently not one of these countries. During the year, first sales were made to sites in Slovenia, and a pricing agreement was established with the Scottish NHS. In addition to regulatory affairs and market access, CLINUVEL (UK) Ltd personnel are also engaged to fulfil Quality and Pharmacovigilance responsibilities on behalf of the new European entity licence holder.

As a result of CLINUVEL (UK) Ltd incurring expenses and engaging in activities to directly support the operations of the new European subsidiary entity which is now responsible for selling the goods into Europe, CLINUVEL (UK) Ltd derives a revenue stream by service charging the European sister subsidiary on an at-arm's length principle.

## Clinuvel (UK) Limited

### Strategic Report (Continued)

For the year ended 30 June 2021

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The CLINUVEL group has identified the UK as having the necessary talent pool to establish a Communications, Marketing and Branding division. This division is responsible for the Group's global communication and branding activities which includes the branding of new products currently under development by related parties. These activities also generate an at-arm's length service charges to its global parent.

Additionally, the Group of companies is expanding its overall research and development capabilities to further investigate the use of SCENESSE® in other disease indications, as a means of organically growing the company.

During 2020/21, the UK employed more R&D staff and made strong progress in identifying and recruiting hospital sites in Europe, North Africa and the US for future clinical studies. These clinical activities are performed on behalf of other CLINUVEL entities and are also service-charged out under at-arm's length principles.

Ultimately, the long-term financial objective of the Clinuvel (UK) Ltd is to achieve and maintain sustainable profitability to the benefit of the wider CLINUVEL Group. Key to longer-term profitability is to ensure a highly efficient and skilled workforce is operating to directly support the increase in Group sales of SCENESSE® in countries across Europe who have not yet agreed to the uniform price and to also reach new patients and increase the market penetration in those countries currently receiving SCENESSE®. Further successful research and development and commercialisation of SCENESSE® to treat other disease states and the commercialisation of the portfolio of assets across the CLINUVEL Group will also be integral to achieving this financial objective.

Hence management supports the ongoing operations of CLINUVEL (UK) Ltd.

# Clinuvel (UK) Limited

## Strategic Report (Continued)

For the year ended 30 June 2021

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### Principal Risks and uncertainties

The following specific business risks are reviewed continually by the Board of the company and its management, as they have the potential to affect its achievement of the business goals detailed above. This list is not exhaustive.

- Technology – there is a risk that despite obtaining marketing authorisations, that SCENESSE® may ultimately prove not to be safe and/or of clinical benefit.
- Supply – there is a risk that the manufacturing process may not result in product batches meeting minimum specification levels, that raw material components could not be sourced to specification, that the manufacturing process may encounter process issues not previously identified and controlled, and of non-controllable disruptions to the operations of the products' contract manufacturers. These factors may lead to non-supply of product and/or adverse regulatory outcomes.
- Clinical & Regulatory – there is a risk that clinical trials of SCENESSE®, whether or not the trials are sponsored by Clinuvel (UK) Ltd or by another Clinuvel entity, will not yield the expected and desired results for the investigational medicinal product(s) to obtain further regulatory approvals.
- Drug pricing – there is a risk that third-party payors will not provide coverage or will not be willing to accept the prices agreed with other third-party payors, adversely affecting revenues and profitability. Furthermore, reductions in government insurance programs may result in lower prices for SCENESSE® and could materially adversely affect our ability to operate profitably or to sustain profitability.
- Intellectual Property (IP) and market entry – future sales could be impacted to the extent that there is not sufficiently robust patent protection around SCENESSE® that will prevent competitors from entering the marketplace to compete. Also, competitors infringing the Group's IP rights may adversely impact the Group's ability to maximise the value to be made from product commercialisation.
- Funding – cash outflows from its operations over the long term may be higher than cash inflows over the long term across the CLINUVEL Group, and this could impact its ability to ensure its subsidiary entities such as CLINUVEL (UK) Ltd to be adequately funded. Therefore, the ability of the Group to successfully bring its products to market and achieve a state of consistent positive cash flow is dependent on its ability to maintain a revenue stream and to access sources of funding while containing its expenditures.
- Management – the success of the company could be impacted adversely if it was not able to retain its specialised knowledge and areas of expertise, of its key management personnel and members of staff over the longer term.
- Foreign exchange – there is a risk that movements in exchange rates of foreign currencies against the British Pound could adversely impact the recognition of sales and expenses when translated from their functional currency to the presentation currency of CLINUVEL (UK) Ltd.

On behalf of the board

P J Wolgen  
**Director**  
4 April 2022

# Clinuvel (UK) Limited

## Director's Report

For the year ended 30 June 2021

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The director presents his annual report and financial statements for the year ended 30 June 2021.

### **Principal activities**

The principal activity of the company continued to be that of developing, commercialising and distributing drugs as a pharmaceutical company.

### **Director**

The director who held office during the year and up to the date of signature of the financial statements was as follows:

P J Wolgen

### **Results and dividends**

The results for the year are set out on page 10.

No ordinary dividends were paid. The director does not recommend payment of a final dividend.

### **Auditor**

In accordance with the company's articles, a resolution proposing that Moore Kingston Smith LLP be reappointed as auditor of the company will be put at a General Meeting.

### **Statement of disclosure to auditor**

So far as each person who was a director at the date of approving this report is aware, there is no relevant audit information of which the company's auditor is unaware. Additionally, the directors individually have taken all the necessary steps that they ought to have taken as directors in order to make themselves aware of all relevant audit information and to establish that the company's auditor is aware of that information.

On behalf of the board

P J Wolgen

**Director**

4 April 2022

# Clinuvel (UK) Limited

## Director's Responsibilities Statement

For the year ended 30 June 2021

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The director is responsible for preparing the annual report and the financial statements in accordance with applicable law and regulations.

Company law requires the director to prepare financial statements for each financial year. Under that law the director has elected to prepare the financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards and applicable law). Under company law the director must not approve the financial statements unless he is satisfied that they give a true and fair view of the state of affairs of the company and of the profit or loss of the company for that period. In preparing these financial statements, the director is required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether applicable UK Accounting Standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The director is responsible for keeping adequate accounting records that are sufficient to show and explain the company's transactions and disclose with reasonable accuracy at any time the financial position of the company and enable them to ensure that the financial statements comply with the Companies Act 2006. He is also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.



# Clinuvel (UK) Limited

## Independent Auditor's Report

To the Member of Clinuvel (UK) Limited

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### Opinion

We have audited the financial statements of Clinuvel (UK) Limited (the 'company') for the year ended 30 June 2021 which comprise the Profit and Loss Account, the Statement of Comprehensive Income, the Balance Sheet, the Statement of Changes in Equity and notes to the financial statements, including significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards, including FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (United Kingdom Generally Accepted Accounting Practice).

In our opinion the financial statements:

- give a true and fair view of the state of the company's affairs as at 30 June 2021 and of its loss for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial statements* section of our report. We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Conclusions relating to going concern

In auditing the financial statements, we have concluded that the director's use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the director with respect to going concern are described in the relevant sections of this report.

### Other information

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The director is responsible for the other information contained within the annual report. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of the audit, or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

# Clinuvel (UK) Limited

## Independent Auditor's Report (Continued)

To the Member of Clinuvel (UK) Limited

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### **Opinions on other matters prescribed by the Companies Act 2006**

In our opinion, based on the work undertaken in the course of our audit:

- the information given in the Strategic Report and the Director's Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Strategic Report and the Director's Report have been prepared in accordance with applicable legal requirements.

### **Matters on which we are required to report by exception**

In the light of the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report and the Director's Report.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

### **Responsibilities of director**

As explained more fully in the Director's Responsibilities Statement, the director is responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the director determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the director is responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the director either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

# Clinuvel (UK) Limited

## Independent Auditor's Report (Continued)

To the Member of Clinuvel (UK) Limited

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### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (UK) we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

# Clinuvel (UK) Limited

## Independent Auditor's Report (Continued)

### To the Member of Clinuvel (UK) Limited

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#### **Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud**

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud.

The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below.

The objectives of our audit in respect of fraud, are; to identify and assess the risks of material misstatement of the financial statements due to fraud; to obtain sufficient appropriate audit evidence regarding the assessed risks of material misstatement due to fraud, through designing and implementing appropriate responses to those assessed risks; and to respond appropriately to instances of fraud or suspected fraud identified during the audit. However, the primary responsibility for the prevention and detection of fraud rests with both management and those charged with governance of the company.

Our approach was as follows:

- We obtained an understanding of the legal and regulatory requirements applicable to the company and considered that the most significant are the Companies Act 2006, UK financial reporting standards as issued by the Financial Reporting Council, and UK taxation legislation.
- We obtained an understanding of how the company complies with these requirements by discussions with management and those charged with governance.
- We assessed the risk of material misstatement of the financial statements, including the risk of material misstatement due to fraud and how it might occur, by holding discussions with management and those charged with governance.
- We inquired of management and those charged with governance as to any known instances of non-compliance or suspected non-compliance with laws and regulations.
- Based on this understanding, we designed specific appropriate audit procedures to identify instances of non-compliance with laws and regulations. This included making enquiries of management and those charged with governance and obtaining additional corroborative evidence as required.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

#### **Use of our report**

This report is made solely to the company's member in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's member those matters we are required to state to the member in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's member for our audit work, for this report, or for the opinions we have formed.

**Jonathan Sutcliffe (Senior Statutory Auditor)**  
for and on behalf of Moore Kingston Smith LLP

4 April 2022

**Chartered Accountants**  
**Statutory Auditor**

Devonshire House  
60 Goswell Road  
London  
EC1M 7AD

# Clinuvel (UK) Limited

## Profit and Loss Account

For the year ended 30 June 2021

	Notes	2021 £	2020 £
<b>Turnover</b>	<b>3</b>	4,481,559	13,482,174
Cost of sales		(2,717,673)	(12,030,270)
<b>Gross profit</b>		<u>1,763,886</u>	<u>1,451,904</u>
Administrative expenses		(2,657,217)	(2,221,407)
Exceptional item	<b>4</b>	-	(119,236)
<b>Loss before taxation</b>		<u>(893,331)</u>	<u>(888,739)</u>
Tax on loss	<b>7</b>	-	-
<b>Loss for the financial year</b>		<u><u>(893,331)</u></u>	<u><u>(888,739)</u></u>

The Profit and Loss Account has been prepared on the basis that all operations are continuing operations.

# Clinuvel (UK) Limited

## Statement of Comprehensive Income

For the year ended 30 June 2021

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	2021 £	2020 £
Loss for the year	(893,331)	(888,739)
Other comprehensive income	-	-
Total comprehensive income for the year	<u>(893,331)</u>	<u>(888,739)</u>

# Clinuvel (UK) Limited

## Balance Sheet

As at 30 June 2021

	Notes	2021 £	£	2020 £	£
<b>Fixed assets</b>					
Tangible assets	8		48,512		27,606
Investments	9		68,581		68,581
			<u>117,093</u>		<u>96,187</u>
<b>Current assets</b>					
Debtors	11	124,639		2,683,633	
Cash at bank and in hand	12	5,584,388		5,735,152	
		<u>5,709,027</u>		<u>8,418,785</u>	
<b>Creditors: amounts falling due within one year</b>	13	(8,070,919)		(9,905,509)	
<b>Net current liabilities</b>			<u>(2,361,892)</u>		<u>(1,486,724)</u>
<b>Net liabilities</b>			<u>(2,244,799)</u>		<u>(1,390,537)</u>
<b>Capital and reserves</b>					
Called up share capital	15		1		1
Other reserves			128,358		89,289
Profit and loss reserves			<u>(2,373,158)</u>		<u>(1,479,827)</u>
<b>Total equity</b>			<u>(2,244,799)</u>		<u>(1,390,537)</u>

The financial statements were approved and signed by the director and authorised for issue on 4 April 2022

P J Wolgen  
Director

Company Registration No. 05414157

# Clinuvel (UK) Limited

## Statement of Changes in Equity

For the year ended 30 June 2021

	Share capital	Capital contribution	Profit and loss reserves	Total
	£	£	£	£
<b>Balance at 1 July 2019</b>	1	87,949	(591,088)	(503,138)
<b>Year ended 30 June 2020:</b>				
Loss and total comprehensive income for the year	-	-	(888,739)	(888,739)
Transfers	-	1,340	-	1,340
<b>Balance at 30 June 2020</b>	1	89,289	(1,479,827)	(1,390,537)
<b>Year ended 30 June 2021:</b>				
Loss and total comprehensive income for the year	-	-	(893,331)	(893,331)
Transfers	-	39,069	-	39,069
<b>Balance at 30 June 2021</b>	1	128,358	(2,373,158)	(2,244,799)



# Clinuvel (UK) Limited

## Notes to the Financial Statements

For the year ended 30 June 2021

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### 1 Accounting policies

#### Company information

Clinuvel (UK) Limited is a private company limited by shares incorporated in England and Wales. The registered office is Devonshire House, 60 Goswell Road, London, EC1M 7AD.

#### 1.1 Accounting convention

These financial statements have been prepared in accordance with FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" ("FRS 102") and the requirements of the Companies Act 2006.

The financial statements are prepared in sterling, which is the functional currency of the company. Monetary amounts in these financial statements are rounded to the nearest £.

The financial statements have been prepared under the historical cost convention. The principal accounting policies adopted are set out below.

The company has taken advantage of the exemption under section 399 of the Companies Act 2006 not to prepare consolidated accounts, on the basis that the group of which this is the parent qualifies as a small group. The financial statements present information about the company as an individual entity and not about its group.

#### 1.2 Going concern

The company made a loss of £893,331 (2020: £888,739) for the year and held net liabilities at the balance sheet date of £2,244,739 (2020: £1,390,537). As at the date of approval of the financial statements, the directors are continuing to assess the impact of the outbreak of COVID-19 and the measures taken to contain it on the company's activities. COVID-19 is an adjusting event occurring before the reporting date of 30 June 2021. At the date of approval of the financial statements, there was no material effect on the value of the company's asset base. During the pandemic the majority of EPP Expert Centres continued prescription of SCENESSE® due to the ongoing clinical demand, while a small number of Centres either deferred orders or reduced order sizes in the initial months of the COVID-19 infections. These few Centres were not able to provide treatment access to patients, or patients were unable to travel to Centres. Despite the uncertainty surrounding the pandemic, patient demand for SCENESSE® remained high, with existing patients continuing to seek treatment and new patients receiving treatment for the first time. The directors expect that sales to the few centres affected will return to pre-COVID-19 levels in FY2022. As a result, the directors do not believe that the COVID-19 will affect the ability of the company to continue its operations and meet its liabilities as they fall due.

In addition, the company is supported by its ultimate parent company, Clinuvel Pharmaceuticals Limited, which has confirmed in writing that it will continue to provide financial support to the company as required, in order to enable it to continue to trade and meet its liabilities as they fall due for at least twelve months from the date of approval of the financial statements. The majority of the liabilities relate to amounts due to group entities which are covered by this support. On this basis the directors consider it appropriate to prepare the financial statements on the going concern basis.

#### 1.3 Turnover

Turnover is recognised at the fair value of the consideration received or receivable for goods and services provided in the normal course of business, and is shown net of VAT and other sales related taxes.

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

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### 1 Accounting policies

(Continued)

#### 1.4 Tangible fixed assets

Tangible fixed assets are initially measured at cost and subsequently measured at cost or valuation, net of depreciation and any impairment losses.

Depreciation is recognised so as to write off the cost or valuation of assets less their residual values over their useful lives on the following bases:

Computer equipment	40% diminishing value
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The gain or loss arising on the disposal of an asset is determined as the difference between the sale proceeds and the carrying value of the asset, and is credited or charged to profit or loss.

#### 1.5 Fixed asset investments

Interests in subsidiaries, associates and jointly controlled entities are initially measured at cost and subsequently measured at cost less any accumulated impairment losses. The investments are assessed for impairment at each reporting date and any impairment losses or reversals of impairment losses are recognised immediately in profit or loss.

A subsidiary is an entity controlled by the company. Control is the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

#### 1.6 Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short-term liquid investments with original maturities of three months or less.

#### 1.7 Financial instruments

Basic financial instruments are measured at cost. The company has no other financial instruments or basic financial instruments measured at fair value.

##### *Other financial assets*

Other financial assets, including investments in equity instruments which are not subsidiaries, associates or joint ventures, are initially measured at fair value, which is normally the transaction price. Such assets are subsequently carried at fair value and the changes in fair value are recognised in profit or loss, except that investments in equity instruments that are not publicly traded and whose fair values cannot be measured reliably are measured at cost less impairment.

##### *Impairment of financial assets*

Financial assets, other than those held at fair value through profit and loss, are assessed for indicators of impairment at each reporting end date.

Financial assets are impaired where there is objective evidence that, as a result of one or more events that occurred after the initial recognition of the financial asset, the estimated future cash flows have been affected. If an asset is impaired, the impairment loss is the difference between the carrying amount and the present value of the estimated cash flows discounted at the asset's original effective interest rate. The impairment loss is recognised in profit or loss.

If there is a decrease in the impairment loss arising from an event occurring after the impairment was recognised, the impairment is reversed. The reversal is such that the current carrying amount does not exceed what the carrying amount would have been, had the impairment not previously been recognised. The impairment reversal is recognised in profit or loss.

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

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### 1 Accounting policies

(Continued)

#### ***Derecognition of financial assets***

Financial assets are derecognised only when the contractual rights to the cash flows from the asset expire or are settled, or when the company transfers the financial asset and substantially all the risks and rewards of ownership to another entity, or if some significant risks and rewards of ownership are retained but control of the asset has transferred to another party that is able to sell the asset in its entirety to an unrelated third party.

#### ***Other financial liabilities***

Debt instruments that do not meet the conditions in FRS 102 paragraph 11.9 are subsequently measured at fair value through profit or loss. Debt instruments may be designated as being measured at fair value through profit or loss to eliminate or reduce an accounting mismatch or if the instruments are measured and their performance evaluated on a fair value basis in accordance with a documented risk management or investment strategy.

#### ***Derecognition of financial liabilities***

Financial liabilities are derecognised when the company's contractual obligations expire or are discharged or cancelled.

### 1.8 Equity instruments

Equity instruments issued by the company are recorded at the proceeds received, net of transaction costs. Dividends payable on equity instruments are recognised as liabilities once they are no longer at the discretion of the company.

Changes in the fair value of derivatives that are designated and qualify as fair value hedges are recognised in profit or loss immediately, together with any changes in the fair value of the hedged asset or liability that are attributable to the hedged risk.

### 1.9 Employee benefits

The costs of short-term employee benefits are recognised as a liability and an expense.

The cost of any unused holiday entitlement is recognised in the period in which the employee's services are received.

Termination benefits are recognised immediately as an expense when the company is demonstrably committed to terminate the employment of an employee or to provide termination benefits.

### 1.10 Retirement benefits

Payments to defined contribution retirement benefit schemes are charged as an expense as they fall due.

### 1.11 Foreign exchange

Transactions in currencies other than pounds sterling are recorded at the rates of exchange prevailing at the dates of the transactions. At each reporting end date, monetary assets and liabilities that are denominated in foreign currencies are retranslated at the rates prevailing on the reporting end date. Gains and losses arising on translation in the period are included in profit or loss.

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

### 2 Judgements and key sources of estimation uncertainty

In the application of the company's accounting policies, the director is required to make judgements, estimates and assumptions about the carrying amount of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised where the revision affects only that period, or in the period of the revision and future periods where the revision affects both current and future periods.

#### Critical judgements

The following judgements (apart from those involving estimates) have had the most significant effect on amounts recognised in the financial statements.

#### Tax losses

The company has significant tax losses for which no deferred tax asset has been recognised in the financial statements. The director and management do not consider that there is sufficient certainty on either the timing of any future profits or the future availability of these losses.

#### Key sources of estimation uncertainty

The estimates and assumptions which have a significant risk of causing a material adjustment to the carrying amount of assets and liabilities are as follows.

#### Share-based payment transactions

Certain of the company's employees are eligible for incentives including the award of equity settled transactions in respect of shares in the parent company. The company recognises a cost in respect of these transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted with a equal and opposite adjustment to the capital contribution reserve. The fair value is determined by using either a binomial or trinomial model on a group basis and recharged to the company. The total expense is accounted for over the vesting period which requires judgements associated with the timing and probability of the vesting conditions.

### 3 Turnover and other revenue

An analysis of the company's turnover is as follows:

	2021	2020
	£	£
Turnover analysed by geographical market		
Europe	4,481,559	13,482,174

### 4 Exceptional item

	2021	2020
	£	£
Expenditure		
Exceptional costs	-	119,236

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

(Continued)

### 4 Exceptional item

Exceptional costs recognised in 2020 related to unpaid employers national insurance on employee share options. The company made a voluntary disclosure to HMRC for these costs which was accepted and subsequently paid. No further expenses have arisen.

### 5 Operating loss

	2021 £	2020 £
Operating loss for the year is stated after charging/(crediting):		
Exchange differences apart from those arising on financial instruments measured at fair value through profit or loss	420,056	(211,453)
Fees payable to the company's auditor for the audit of the company's financial statements	18,058	9,450
Depreciation of owned tangible fixed assets	17,511	12,436
	<u>          </u>	<u>          </u>

### 6 Employees

The average monthly number of persons employed by the company during the year was:

2021 Number	2020 Number
22	17
<u>          </u>	<u>          </u>

Their aggregate remuneration comprised:

	2021 £	2020 £
Wages and salaries	1,051,072	847,629
Social security costs	100,649	96,151
Pension costs	39,927	28,029
	<u>          </u>	<u>          </u>
	1,191,648	971,809
	<u>          </u>	<u>          </u>

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

### 7 Taxation

The actual charge for the year can be reconciled to the expected credit for the year based on the profit or loss and the standard rate of tax as follows:

	2021 £	2020 £
Loss before taxation	(893,331)	(888,739)
<i>Expected tax credit based on the standard rate of corporation tax in the UK of 19.00% (2020: 19.00%)</i>	(169,733)	(168,860)
Tax effect of expenses that are not deductible in determining taxable profit	2,081	4,029
Unutilised tax losses carried forward	172,407	173,412
Permanent capital allowances in excess of depreciation	(4,755)	(8,581)
Taxation charge for the year	-	-

### 8 Tangible fixed assets

	Computer equipment £
<b>Cost</b>	
At 1 July 2020	49,076
Additions	38,417
At 30 June 2021	87,493
<b>Depreciation and impairment</b>	
At 1 July 2020	21,470
Depreciation charged in the year	17,511
At 30 June 2021	38,981
<b>Carrying amount</b>	
At 30 June 2021	48,512
At 30 June 2020	27,606

### 9 Fixed asset investments

	Notes	2021 £	2020 £
Investments in subsidiaries	10	68,581	68,581

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

### 10 Subsidiaries

These financial statements are separate company financial statements for Clinuvel (UK) Limited

Details of the company's subsidiaries at 30 June 2021 are as follows:

Name of undertaking	Registered office	Class of shares held	% Held Direct
Clinuvel AG	Switzerland	Class A	100.00

The aggregate capital and reserves and the result for the year of the subsidiaries noted above was as follows:

Name of undertaking	Capital and Reserves	Profit/(Loss)
	£	£
Clinuvel AG	(7,037,600)	(69,950)

### 11 Debtors

	2021	2020
Amounts falling due within one year:	£	£
Trade debtors	24,187	2,251,599
Other debtors	69,207	408,797
Prepayments and accrued income	31,245	23,237
	<u>124,639</u>	<u>2,683,633</u>

### 12 Security over cash deposit

There is a fixed charge in favour of HSBC UK Bank Plc for a total of £41,000 in respect of a legal case in which Clinuvel (UK) Limited is the plaintiff.

### 13 Creditors: amounts falling due within one year

	2021	2020
	£	£
Trade creditors	75,958	201,618
Amounts owed to group undertakings	7,617,440	8,821,695
Other creditors	31,991	533,363
Accruals and deferred income	345,530	348,833
	<u>8,070,919</u>	<u>9,905,509</u>

# Clinuvel (UK) Limited

## Notes to the Financial Statements (Continued)

For the year ended 30 June 2021

### 14 Retirement benefit schemes

	2021	2020
Defined contribution schemes	£	£
Charge to profit or loss in respect of defined contribution schemes	39,927	28,029

The company operates a defined contribution pension scheme for all qualifying employees. The assets of the scheme are held separately from those of the company in an independently administered fund.

### 15 Share capital

	2021	2020
Ordinary share capital Issued and fully paid	£	£
1 ordinary share of £1 each	1	1

### 16 Operating lease commitments

At the reporting end date the company had outstanding commitments for future minimum lease payments under non-cancellable operating leases, which fall due as follows:

	2021	2020
	£	£
Within one year	32,250	27,975

### 17 Control

The ultimate controlling party is Clinuvel Pharmaceuticals Limited, a company incorporated in Australia, by virtue of holding the entire share capital of Clinuvel (UK) Limited. The parent is registered at Level 11, 535 Bourke Street, Melbourne, VIC 3000.

The accounts of Clinuvel (UK) Limited are included within the publicly available consolidated accounts of Clinuvel Pharmaceuticals Limited.



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