

Clinigen Holdings Limited

Annual Report and Financial Statements

for the year ended 30 June 2020

Company registered number 10618229

MONDAY



A09

AAØAMPHK

15/03/2021

COMPANIES HOUSE

#58

Directors and other information

Directors

S Chilton

N Keher

Company secretary

A Miller

Registered office

Pitcairn House

Crown Square

First Avenue

Centrum 100

Burton-on-Trent

Staffordshire

DE14 2WW

Registered number

10618229

Strategic report

The directors present their Strategic report for the year ended 30 June 2020.

Principal activity

The Company is a wholly owned subsidiary of Clinigen Group plc and its principal activity is to act as an intermediate holding company.

Review of the business and future developments

The Company generated revenue of £2,377,000 (2019: £nil) and profit before tax of £2,306,000 (2019: loss of £2,046,000). This year the Company has started generating royalties from the sale and distribution of Imukin (outside of the US, Canada and Japan) and Proleukin (outside of the US) for which it owns the licences. The Company's only customer is Clinigen Healthcare Limited, one of its subsidiary undertakings which is the sole distributor of the two products.

Going forward the directors intend for the Company to continue acting as an intermediate holding company and to generate royalties from the out-licence of the two products it owns.

Key performance indicators

The directors view underlying earnings before interest and tax ('EBIT') as the best measure of underlying performance of the Company as it reflects the profit generated from the ownership of product licences after taking account of the cost which comes through amortisation of the assets. Underlying EBIT excludes exceptional or one-off income or expense.

EBIT for the year ended 30 June 2020 was £723,000 (2019: £nil). The directors believe that the performance of the business was in line with expectations.

Principal risks and uncertainties

The principal operational risks and uncertainties facing the wider Clinigen Group, together with the means by which they are managed or mitigated are set out in the Clinigen Group plc Annual Report.

On behalf of the Board

N Keher
Director

02 March 2021

DocuSigned by:

Nick Keher



Signer Name: Nick keher
Signing Reason: I approve this document
Signing Time: 03-Mar-2021 | 8:15:09 AM GMT
91628B8F0AE94E6EB3C725D71A070937

Directors' report

The directors present their report and audited financial statements for the year ended 30 June 2020. Clinigen Holdings Limited ('the Company') is a private company limited by shares, incorporated and domiciled in the United Kingdom. Its company number is 10618229.

Going concern

The Company has net current liabilities of £333,659,000 and is therefore reliant on continued support from its ultimate parent, Clinigen Group Plc to ensure it can pay its debts as they fall due. Clinigen Group Plc has confirmed that it will continue to support the Company for the next 12 months following approval of these financial statements and therefore for the foreseeable future, to allow the Company to meet its liabilities as they fall due and will not seek repayment of amounts currently made available to the Company by Group undertakings. On the basis of this support and their assessment of the Company's financial position, the Company's directors have a reasonable expectation that the Company will be able to continue in operational existence for the foreseeable future. The Company therefore continues to adopt the going concern basis of accounting in preparing its financial statements.

Directors

The directors who held office during the year and up to the date of signing the financial statements were:

S Chilton

N Keher

Directors' indemnity insurance

During the year and up to the date of signing of this report, the Company, through the Group, maintained liability insurance and third party indemnification provisions for its directors and the company secretary.

Dividend

The directors do not propose a dividend for the current financial year (2019: none).

Audit exemption

For the year ended 30 June 2020, the Company was entitled to exemption from audit under s479A of the Companies Act 2006 relating to subsidiary companies.

In respect of this exemption, the directors confirm that the members have not required the Company to obtain an audit of its accounts in accordance with s476 of the Companies Act 2006.

On behalf of the board

N Keher

Director

02 March 2021

DocuSigned by:

Nick Keher



Signer Name: Nick keher

Signing Reason: I approve this document

Signing Time: 03-Mar-2021 | 8:15:16 AM GMT

91628B8F0AE94E6EB3C725D71A070937

Statement of directors' responsibilities in respect of the strategic report, the directors' report and the financial statements

The directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the directors to prepare financial statements for each financial year. Under that law the directors have prepared the financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 102 'The Financial Standard applicable in the UK and Republic of Ireland', and applicable law). Under company law the directors must not approve the financial statements unless they are 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 the financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- state whether applicable United Kingdom Accounting Standards, comprising FRS 102 have been followed, subject to any material departures disclosed and explained in the financial statements;
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are 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.

The directors are 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.

Profit and loss account
for the year ended 30 June 2020

	Notes	2020 £000	2019 £000
Revenue	3	2,377	–
Gross profit		2,377	–
Administrative expenses		(1,654)	(1,622)
Operating profit / (loss)	4	723	(1,622)
Net finance income / (expense)	6	1,583	(424)
Profit / (loss) before taxation		2,306	(2,046)
Tax on profit / (loss) for the financial year	7	–	–
Profit / (loss) for the financial year		2,306	(2,046)

There were no items relating to components of other comprehensive income.

Balance sheet

as at 30 June 2020

	Notes	2020 £000	2019 £000
Assets			
Fixed assets			
Investments	8	830,546	830,546
Intangible assets	9	21,059	22,338
		851,605	852,884
Current assets			
Debtors	10	1,909	7
Total assets		853,514	852,891
Current liabilities			
Creditors – amounts falling due within one year	11	(335,568)	(337,251)
Net assets		517,946	515,640
Capital and reserves			
Called up share capital	12	18,000	18,000
Share premium		124,119	124,119
Profit and loss account		375,827	373,521
Total shareholders' funds		517,946	515,640

Company number: 10618229

The notes on pages 8 to 16 form an integral part of these financial statements.

Audit exemption

For the year ended 30 June 2020, the Company was entitled to exemption from audit under s479A of the Companies Act 2006 relating to subsidiary companies.

In respect of this exemption, the directors confirm that the members have not required the Company to obtain an audit of its accounts in accordance with s476 of the Companies Act 2006.

The directors acknowledge their responsibilities for complying with the requirements of the Companies Act 2006 with respect to accounting records and the preparation of accounts.

These financial statements were approved and authorised for issue by the Board of Directors on 02 March 2021 and were signed on its behalf by:

DocuSigned by:

 Signer Name: Nick keher
 Signing Reason: I approve this document
 Signing Time: 03-Mar-2021 | 8:15:22 AM GMT
 91628B8F0AE94E6EB3C725D71A070937

N Keher
Director

Statement of changes in equity

for the year ended 30 June 2020

	Called up share capital (note 12) £000	Share premium £000	Profit and loss account £000	Total shareholders' funds £000
At 1 July 2018	–	–	375,567	375,567
Loss for the year	–	–	(2,046)	(2,046)
Issue of share capital	18,000	124,119	–	142,119
At 30 June 2019	18,000	124,119	373,521	515,640
Profit for the year	–	–	2,306	2,306
At 30 June 2020	18,000	124,119	375,827	517,946

Notes to the financial statements

for the year ended 30 June 2020

1. Authorisation of financial statements and statement of compliance with FRS 102

The financial statements of Clinigen Holdings Limited (the 'Company') for the year ended 30 June 2020 were authorised for issue by the board of directors on 02 March 2021 and the balance sheet was signed on the board's behalf by N Keher.

The Company is a subsidiary undertaking of Clinigen Group plc, incorporated and domiciled in the United Kingdom. Clinigen Group plc is the ultimate parent company and controlling party.

The principal accounting policies adopted by the Company are set out in note 2.

2. Accounting policies

Basis of preparation

The financial statements have been prepared on the historical cost basis, as explained in the accounting policies below. Historical cost is generally based on the fair value of the consideration given in exchange for the goods and services. The financial statements are presented in sterling.

The Company is a wholly owned subsidiary of Clinigen Group plc and is included in its consolidated group financial statements which are publicly available. The Company is therefore exempt from the requirement to prepare consolidated financial statements under the Companies Act 2006. Accordingly, these financial statements present information about the Company as an individual undertaking and not about its group.

The financial statements have been prepared in compliance with United Kingdom Accounting Standards, including Financial Reporting Standard 102, "The Financial Reporting Standard applicable in the United Kingdom and the Republic of Ireland" ("FRS 102") and the Companies Act 2006.

As the Company is a wholly owned subsidiary of Clinigen Group plc, it is a qualifying entity as defined by FRS 102 and therefore the Company has taken advantage of the following exemptions in these financial statements:

- Reconciliation of number of shares outstanding at the beginning and end of the period;
- Cash flow statement and related notes; and
- Key management personnel compensation.

As the consolidated financial statements of Clinigen Group plc include the equivalent disclosures, the Company has also taken the exemptions under FRS 102 available in respect of the following disclosures:

- Certain disclosures required by FRS 102.26 *Share-based payments*; and
- Certain disclosures required by FRS 102.11 *Basic Financial Instruments* and FRS 102.12 *Other Financial Instrument Issues* in respect of financial instruments.

Going concern

The Company has net current liabilities of £333,659,000 and is therefore reliant on continued support from its ultimate parent, Clinigen Group Plc to ensure it can pay its debts as they fall due. Clinigen Group Plc has confirmed that it will continue to support the Company for the next 12 months following approval of these financial statements and therefore for the foreseeable future, to allow the Company to meet its liabilities as they fall due and will not seek repayment of amounts currently made available to the Company by Group undertakings. On the basis of this support and their assessment of the Company's financial position, the Company's directors have a reasonable expectation that the Company will be able to continue in operational existence for the foreseeable future. The Company therefore continues to adopt the going concern basis of accounting in preparing its financial statements.

Notes to the financial statements (continued)

for the year ended 30 June 2020

2. Accounting policies (continued)

Foreign currency translation

The Company's functional currency and presentation currency is sterling. Transactions in foreign currencies are initially recorded in the functional currency by applying the spot exchange rate ruling at the date of the transaction.

Monetary assets and liabilities denominated in foreign currencies are retranslated at the functional currency rate of exchange ruling at the balance sheet date. All differences are recognised in the profit and loss account within interest payable and similar charges.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

The Company does not apply hedge accounting of foreign exchange risks in its company financial statements.

Valuation of investments

Investments held as fixed assets are stated at cost less any provision for impairment. Investments held as current assets are stated at the lower of cost and net realisable value.

Intangible assets

Separately acquired trademarks and licences are initially recorded at cost, being the purchase price of the asset, which comprises the purchase price and any directly attributable cost of preparing the asset for its intended use, including the assignment of trademarks in different territories.

The carrying value of trademarks and licences is calculated as cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of the trademarks and licences over their estimated useful lives of between seven and fifteen years. The amortisation expense is recognised within administrative expenses in the profit and loss account.

The residual value and useful life of each intangible asset is reviewed at each financial year end and, if expectations differ from previous estimates, the changes are accounted for prospectively in the profit and loss account in the year of the change and future years. An increase in the residual value of an asset will decrease the amortisation charge for the year and future years and vice versa.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing the proceeds less cost of sale with the carrying amount and are recognised in the profit and loss account.

Intangible assets are derecognised upon disposal or when no future economic benefits are expected from their use or disposal.

Impairment of non-financial assets

The Company assesses at each reporting date whether there is an indication that an asset may be impaired. If any such indication exists, or when annual impairment testing for an asset is required, the Company makes an estimate of the asset's recoverable amount in order to determine the extent of the impairment loss.

An asset's recoverable amount is the higher of an asset's or cash-generating unit's fair value less costs to sell and its value in use and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or company of assets. Where the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. Impairment losses on continuing operations are recognised in the profit and loss account in those expense categories consistent with the function of the impaired asset.

Notes to the financial statements (continued)

for the year ended 30 June 2020

2. Accounting policies (continued)

Impairment of non-financial assets (continued)

For assets where an impairment loss subsequently reverses (excluding goodwill), the carrying amount of the asset or cash generating unit is increased to the revised estimate of its recoverable amount, not to exceed the carrying amount that would have been determined, net of amortisation, had no impairment losses been recognised for the asset or cash generating unit in prior years. A reversal of impairment loss is recognised immediately in the profit and loss account, unless the asset is carried at a revalued amount when it is treated as a revaluation increase.

Financial instruments

a. Financial assets

Trade and other receivables

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. Trade receivables are recognised initially at the amount of consideration that is unconditional, unless they contain significant financing components, where they are recognised at fair value. The Company holds trade receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method.

The Company applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. The expected loss rates are based on payment profiles and historic credit losses. The historic loss rates are adjusted to reflect current and forward looking information on macro-economic factors to the extent they are relevant to the customers' ability to settle. For trade receivables, which are reported net, such provisions are recorded in a separate allowance account with the movement in the provision being recognised within administrative expenses in the income statement. The gross carrying value of the asset is written off against the associated provision when the Company's right to the cash flows expires.

Financial liabilities

Trade and other payables

Trade and other payables are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest rate method.

b. Fair values

The Company measures non-financial assets, at fair value at each balance sheet date.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Notes to the financial statements (continued)

for the year ended 30 June 2020

2. Accounting policies (continued)

b. Fair values (continued)

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 - Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 - Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 - Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Company determines whether transfers have occurred between levels in the hierarchy by re-assessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

The fair value of financial instruments that are traded in active markets at the reporting date is determined by reference to quoted market prices or dealer price quotations, without any deduction for transaction costs.

For financial instruments not traded in an active market, the fair value is determined using appropriate valuation techniques.

External valuers are involved for valuation of significant assets, such as licences. Involvement of external valuers is decided upon annually by the management. Selection criteria include market knowledge, reputation, independence and whether professional standards are maintained.

For the purpose of fair value disclosures, the Company has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy as explained above.

c. Derecognition of financial instruments

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or it expires.

A financial asset is derecognised when the rights to receive cash flows from the asset have expired.

Taxes

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Company operates and generates taxable income.

Current income tax related to items recognised directly in other comprehensive income or equity is recognised in other comprehensive income or equity not in the profit or loss account.

Revenue

Revenue represents amounts receivable for goods and services provided in the normal course of business, net of trade discounts, VAT and other sales-related taxes.

Royalty income is earned on product distribution agreements. Revenue is recognised on an accruals basis based on the sales of the distributor.

Notes to the financial statements (continued)

for the year ended 30 June 2020

2. Accounting policies (continued)

Significant accounting judgements, estimates and assumptions

The preparation of the Company's financial statements in conformity with FRS 102 requires management to make judgements, estimates and assumptions at the date of the financial statements. Estimates and assumptions are continuously evaluated and are based on management experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the assets or liabilities affected in future periods.

In particular the Company has identified the following areas where significant judgement, estimates and assumptions are required.

a. Judgements

In the process of applying the Company's accounting policies, management has made the following judgements, which have the most significant effect on the amounts recognised in the financial statements.

Carrying value of investments

The carrying value of investments is at cost less any impairment. Annual impairment trigger reviews are undertaken at the end of the financial year or more frequently if events or changes in circumstances indicate a potential impairment. Investments are not traded in an active market, hence the fair value of the asset is determined using discounted cash flows which requires the Company to use judgement and assumptions.

b. Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below:

Fair value measurement

The fair value of an asset or a liability is measured using the assumption that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest. The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data is available to measure fair value.

3. Revenue

The revenue earned in the period was £2,377,000 (2019: £nil) in relation to royalties earned from the product distribution licence for the Company's owned products granted to Clinigen Healthcare Limited, a fellow Group company based in the United Kingdom.

Notes to the financial statements (continued)

for the year ended 30 June 2020

4. Operating loss

The operating loss is stated after charging:

	2020 £000	2019 £000
Amortisation of intangible assets (note 9)	1,600	1,450
Foreign exchange gains on financial liabilities	55	172
	<u>1,655</u>	<u>1,622</u>

The audit fee in relation to these financial statements was borne by the ultimate parent company, Clinigen Group plc.

5. Staff cost and directors remuneration

The Company had no employees during the year (2019: nil) and accordingly no employee costs are included in these financial statements.

6. Net finance income / (expense)

	2020 £000	2019 £000
Unwind of discount on deferred consideration	(68)	(424)
Foreign exchange adjustments on loans	1,651	—
	<u>1,583</u>	<u>(424)</u>

7. Tax on profit / (loss) for the financial year**(a) Tax charged in the profit and loss account**

The tax charge on profit for the financial year was £nil (2019: £nil).

(b) Reconciliation of the total tax charge

Reconciliation between tax expense and the accounting loss multiplied by the UK standard rate of corporation tax is as follows:

	2020 £000	2019 £000
Profit / (loss) before taxation	2,306	(2,046)
Tax calculated at UK standard rate of corporation tax of 19.0% (2019: 19.0%)	438	(389)
Effects of:		
Expenses not deductible for tax purposes	—	81
Transfer pricing adjustment	(1,755)	(1,308)
Group relief not paid for	1,317	1,616
Total tax expense reported in the profit and loss account	<u>—</u>	<u>—</u>

Notes to the financial statements (continued)

for the year ended 30 June 2020

8. Investments

	2020 £000	2019 £000
<i>Cost or valuation</i>		
At 30 June	830,546	830,546

The Company's subsidiary undertakings are listed below. The Company directly owns 100% of their ordinary share capital. They are incorporated and registered in England and Wales, and their registered office address is Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW.

Name	Nature of business
Clinigen Healthcare Limited	Supply of specialty pharmaceutical products and provision of healthcare services
Clinigen SP Limited	Supply of specialty pharmaceutical products
Clinigen International Holdings Limited	Holding company
Idis Group Holdings Limited	Holding company

9. Intangible assets

	Trademarks & Licences £000	Total £000
Cost:		
At 1 July 2019	23,788	23,788
Additions	321	321
At 30 June 2020	24,109	24,109
Accumulated amortisation:		
At 1 July 2019	1,450	1,450
Charge for the year	1,600	1,600
At 30 June 2020	3,050	3,050
Net book value:		
At 30 June 2019	22,338	22,338
At 30 June 2020	21,059	21,059

Notes to the financial statements (continued)

for the year ended 30 June 2020

10. Debtors

	2020 £000	2019 £000
Amounts owed by Group undertakings	1,902	3
Tax receivables	7	4
	<u>1,909</u>	<u>7</u>

The amounts owed by Group undertakings are non-interest bearing and receivable on demand.

11. Creditors – amounts due within one year

	2020 £000	2019 £000
Trade creditors	5	6
Amounts owed to group undertakings	335,558	334,624
Accruals	5	–
Deferred consideration	–	2,621
	<u>335,568</u>	<u>337,251</u>

The amounts owed to group undertakings are non-interest bearing and payable on demand.

The deferred consideration in the prior year relates to the final payment for Imukin which was paid in September 2019.

12. Called up share capital

	2020 No.	2019 No.	2020 £000	2019 £000
<i>Issued and fully paid</i>				
Ordinary shares of £1 each	18,000,003	18,000,003	18,000	18,000

The balance classified as equity share capital includes the total net proceeds (nominal value) on issue of the Company's equity share capital. The holders of each class of ordinary shares are entitled to receive dividends as declared from time to time and are entitled to one vote per share at meetings of the Company. The shares are not redeemable.

Notes to the financial statements (continued)

for the year ended 30 June 2020

13. Capital commitments and contingent liabilities

The Company guarantees the borrowing facilities of its ultimate parent company Clinigen Group plc. The balance of the facilities at 30 June 2020 was £433.8m (2019: £338.1m).

14. Ultimate parent undertaking and controlling party

The Company is a wholly owned subsidiary undertaking of Clinigen Group plc. The Company's ultimate parent undertaking and controlling party is Clinigen Group plc, a company registered in England and Wales.

Clinigen Group plc is the parent undertaking of the smallest and largest group of which the Company is a member. The consolidated financial statements of this group may be obtained from Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW.