

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 20-F**

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2020

OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

OR
☐ SHELL COMPANY PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report _____

Commission File Number **001-37652**

MIDATECH PHARMA PLC

(Exact name of registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

Oddfellows House

19 Newport Road

Cardiff, CF24 0AA

United Kingdom

(Address of principal executive offices)

Stephen Stamp, Chief Executive Officer and Chief Financial Officer

Oddfellows House

19 Newport Road

Cardiff, CF24 0AA

United Kingdom

Tel: +44 1235 888 300

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Ordinary Shares, nominal value 0.1p each		
American Depositary Shares, each representing five ordinary shares	MTP	NASDAQ Capital Market

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Securities registered or to be registered pursuant to Section 12(g) of the Act.

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

(Title of Class)

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2020 was: 63,073,852 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer", and "emerging growth company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting

firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by the

Other ☐

International Accounting Standards Board ☒

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

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GENERAL INFORMATION

Midatech Pharma PLC is a public limited company organized under the laws of England and Wales under registered number 09216368. In this annual report, references to “we,” “us,” “our,” “the Group,” “Company,” “company” or “Midatech” means Midatech Pharma PLC and our consolidated subsidiaries.

Our principal executive offices are located at Oddfellows House, 19 Newport Road, Cardiff, CF24 0AA, United Kingdom. The telephone number at our principal executive office is +44 1235 888 300.

We maintain an Internet website at www.midatechpharma.com. None of the information contained on our website, or on any other website linked to our website, will be incorporated in this annual report by reference or otherwise be deemed to be a part of this annual report.

The trademarks, trade names and service marks appearing in this Annual Report on Form 20-F are the property of their respective owners.

PRESENTATION OF FINANCIAL AND OTHER DATA

The consolidated financial statement data as of December 31, 2020, 2019 and 2018 and for the years ended December 31, 2020, 2019 and 2018 have been derived from our consolidated financial statements, as presented at the end of this annual report, which have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We prepare our consolidated financial statements in British pounds sterling. Except as otherwise stated, all monetary amounts in this annual report are presented in British pounds sterling. Solely for the convenience of the reader, unless otherwise indicated, all British pounds sterling amounts as of and for the year ended December 31, 2020 have been translated into United States dollars at the rate as of December 31, 2020, of £1.00 to \$1.3662, based on noon buying rates published by the Federal Reserve Bank of New York for the British pound sterling on such date. These translations should not be considered representations that any such amounts have been, could have been or could be converted into United States dollars at that or any other exchange rate as of that or any other date.

In this annual report, unless otherwise specified or the context otherwise requires:

- “\$” and “U.S. dollar” each refer to the United States dollar (or units thereof); and
- “£,” “pence” and “p” each refer to the British pound sterling (or units thereof).

References to a particular “fiscal” year are to our fiscal year ended December 31 of such year. References to years not specified as being fiscal years are to calendar years.

On March 3, 2020, following shareholder approval, we effected a one-for-20 reverse split of our ordinary shares, nominal value 0.1p per share, or Ordinary Shares, and our Ordinary Shares began trading on AIM, a market operated by the London Stock Exchange plc, or AIM, on a split-adjusted basis as of such date. No fractional shares were issued in connection with the reverse stock split. As a result of the reverse stock split, the number of issued and outstanding Ordinary Shares was reduced to 23,494,981 shares as of March 3, 2020.

Concurrently with the reverse split, and in an effort to bring our Depositary Share price into compliance with The NASDAQ Stock Market LLC's, or NASDAQ, minimum bid price per share requirement, on March 3, 2020 we effected a ratio change in the number of Ordinary Shares represented by our American depositary shares, or Depositary Shares, from 20 Ordinary Shares per Depositary Share to five Ordinary Shares per Depositary Share, reducing the number of outstanding Depositary Shares, as of the close of business on March 3, 2020 to 988,656.

The change in the number of shares resulting from the reverse stock split and change in the number of Depositary Shares resulting from the change in ratio has been applied retroactively to all share and per share amounts presented in this annual report, to the extent applicable.

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As reference, the following provides a description of the different phases of clinical trials, as may be used in this annual report:

- *Phase I* clinical trials involve the assessment of the safety, pharmacodynamics and pharmacokinetics of a drug candidate in a small group of healthy human subjects (typically 20 to 100 patients), or in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- *Phase II* clinical trials involve the assessment in patients of a drug to determine its safety, dose range, possible side effects and preliminary efficacy (typically 100 to 300 patients).
- *Phase III* is a clinical trial involving the assessment of the efficacy and safety of a drug, usually in comparison with a marketed product or a placebo, in the patient population for which it is intended (typically 1,000 to 3,000 patients).

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains certain forward-looking information about the Company that is intended to be covered by the safe harbor for “forward-looking statements” provided by the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this annual report or may be incorporated into this annual report by reference to other documents. Our representatives may also make forward-looking statements. Forward-looking statements are statements that are not historical facts. Words such as “expect,” “believe,” “will,” “may,” “anticipate,” “plan,” “estimate,” “intend,” “should,” “can,” “likely,” “could” and similar expressions are intended to identify forward-looking statements. Forward-looking statements appear in a number of places throughout this annual report and include statements regarding our intentions, beliefs, assumptions, projections, outlook, analyses or current expectations concerning, among other things, our intellectual property position, research and development projects, results of operations, cash needs, capital expenditures, financial condition, liquidity, prospects, growth and strategies, regulatory approvals and clearances, the markets and industry in which we operate and the trends and competition that may affect the markets, industry or us.

These forward-looking statements are based on currently available competitive, financial and economic data together with management's views and assumptions regarding future events and business performance as of the time the statements are made and are subject to risks and uncertainties. We wish to caution you that there are some known and unknown factors that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements, including but not limited to risks related to:

- our requirement for additional financing and our ability to continue as a going concern;
- our estimates regarding losses, expenses, future revenues, and capital requirements;
- our ability to successfully develop, test, and partner with a licensee to manufacture or commercialize products for conditions using our technology platforms;
- the successful commercialization and manufacturing of our any future product candidate we may commercialize or license;
- the outcome of our remediation plan and approach to the material weaknesses in internal control over financial reporting;
- our indemnity obligations;
- the success and timing of preclinical studies and clinical trials, if any;
- shifts in our business and commercial strategy;
- the filing and timing of regulatory filings, including Investigational New Drug applications, with respect to any of our products and the receipt of any regulatory approvals;
- the anticipated medical benefits of our products;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- the success and timing of the potential commercial development of our product candidates and any product candidates we may acquire in the future;
- our plans and ability to develop and commercialize our product candidates and any product candidates we may acquire in the future;
- the ability to manufacture products in third-party facilities;
- the rate and degree of market acceptance of any of our product candidates;
- the successful development of our commercialization capabilities, including our internal sales and marketing capabilities;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the success of competing therapies and products that are or become available;

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- the success of any future acquisitions;
- cybersecurity and other cyber incidents;
- industry trends;
- the impact of government laws and regulations;
- regulatory, economic and political developments in the United Kingdom, the European Union, the United States and other foreign countries, including any impact from the United Kingdom leaving the European Union;

- the difficulties doing business internationally, including any risks related to the novel strain of coronavirus, COVID-19;
- the ownership of our Ordinary Shares and Depositary Shares;
- our ability to continue to meet the listing criteria required to remain listed on the NASDAQ Capital Market;
- the status of our ongoing leadership transition and our failure to recruit or retain key scientific or management personnel or to retain our senior management;
- the impact and costs and expenses of any litigation we may be subject to now or in the future;
- the performance of third parties, including joint venture partners, our collaborators, third-party suppliers and parties to our licensing agreements; and
- other risks and uncertainties, including those described in “Risk Factors” in this annual report.

Any forward-looking statements that we make in this annual report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this annual report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this annual report. See “Item 10. Additional Information-H. Documents on Display.”

You should also read carefully the factors described in “Item 3. Key Information-D. Risk Factors” and elsewhere in this annual report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS.

Not Applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE.

Not Applicable.

ITEM 3. KEY INFORMATION.

A. Selected Financial Data.

We have elected to voluntarily comply with the amendments to Item 3.A of Form 20-F, effective February 10, 2021, contained in SEC Release No. 33-10890.

B.Capitalization and Indebtedness

Not Applicable

C.Reasons for the Offer and Use of Proceeds

Not Applicable

D.Risk Factors

Our business has significant risks. In addition to the other information included in this annual report, including the matters addressed in the section of the annual report entitled “Cautionary Note Regarding Forward-Looking Statements” and in our financial statements and the related notes, you should consider carefully the risks described below. The risks and uncertainties described below are not the only risks and uncertainties we may face. Additional risks and uncertainties not presently known to us, or that we currently consider immaterial could also negatively affect our business, financial condition, results of operations, prospects, profits and stock prices. If any of the risks described below actually occur, our business, financial condition, results of operations, prospects, profits and stock prices could be materially adversely affected.

Summary of Risk Factors

The occurrence of one or more of the events or circumstances described in this section titled “Risk Factors,” alone or in combination with other events or circumstances, may materially adversely affect our business, financial condition and operating results. In that event, the trading price of our securities could decline, and you could lose all or part of your investment. Such risks include, but are not limited to:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future;
- Our requirement for additional financing in the short-term represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern.
- The effects of health epidemics, including the ongoing global coronavirus COVID-19 pandemic, in regions where we, or the third parties on which we rely, have business operations could adversely impact our business, including our clinical trials, preclinical studies and supply chains, depending on the location, duration and severity of disruptions to the systems affecting our business.
- Our operations are in early-stage development with no sources of recurring revenue and there is no assurance that we will successfully develop and license our product candidates or ever become profitable.
- We are exposed to political, regulatory, social and economic risk relating to the United Kingdom’s exit from the European Union.
- We recognized a material intangible asset impairment loss as of December 31, 2020, and we may be required to recognize additional non-cash impairment losses in the future.

- We are in receipt of a letter purporting to terminate our license agreement related to panobinostat, the active pharmaceutical ingredient in our MTX110 product. If we are unsuccessful in challenging this termination, our business, financial condition and results of operations could be materially adversely affected.
- Our future success is dependent on product development and the ability to successfully license our product candidates to partners who can seek regulatory approval and commercialization of our product candidates.
- Clinical drug development involves a risky, lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- We expect to seek to establish agreements with potential licensing partners and collaborators and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost for us to commercialize our product candidates.

- Our success depends in part on our ability to protect rights in our intellectual property, which cannot be assured.
- We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We are dependent on third party suppliers, and if we experience problems with any of these third parties, the manufacturing of our product candidates could be delayed, which could harm our results of operations.
- We are currently undergoing a leadership transition and this transition, along with the possibility that we may in the future be unable to retain and recruit qualified scientists, key executives, key employees or key consultants, may delay our development efforts or otherwise harm our business.
- Our strategic review and the associated workforce reduction announced in March 2020 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
- The price of our Ordinary Shares and Depositary Shares may be volatile.
- Shareholder ownership interests in the Company may be diluted as a result of future financings, additional acquisitions or the exercise of our options and warrants, and may have a material negative effect on the market price of our securities.
- The rights of holders of Depositary Shares are not the same as the rights of holders of Ordinary Shares.
- It may be difficult for you to bring any action or enforce any judgment obtained in the United States against us or members of our Board of Directors, which may limit the remedies otherwise available to you.
- We are a “foreign private issuer” under the rules and regulations of the SEC and, as a result, are exempt from a number of rules under the Exchange Act and are permitted to file less information with the SEC than a company incorporated in the United States.

Risks Related to Our Financial Operations and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are an early-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because we entail substantial upfront capital expenditures and significant risk that a product candidate will fail in development, will fail to gain regulatory approval or otherwise fail to become commercially viable. We continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred substantial losses since our inception. For the year ended December 31, 2020, we had a net loss of £22.19 million and an accumulated deficit of £122.43 million. For the years ended December 31, 2019 and 2018 we had a net loss of £10.09 million and £15.03 million, respectively.

We expect to continue to incur losses for the foreseeable future, and do not expect these losses to reduce as we continue our development of, and work with any licensing partners to seek regulatory approvals for, our product candidates.

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We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we fail to find licensing partners, if we abandon any development programs, or if any of our licensed product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders’ equity and working capital.

In 2020, we undertook a strategic review of our operations, which may yield uncertain results.

On March 31, 2020, we announced that, due to the prevailing conditions in the capital markets and the prospect of raising additional funds and finding a partner for our assets, the Board of Directors initiated a strategic review of our operations. The objective of the review was to identify ways to maximize value for our stakeholders given the significant challenges faced by our business. We have formed a Finance Committee comprised of Mr. Stamp and Rolf Stahel, our Chairman, to review, analyze and make recommendations to the Board of Directors regarding a possible sale of our business or other strategic transactions, and hired an outside advisor to assist us. We entered into an “offer period” under United Kingdom rules and regulations, which placed certain restrictions and obligations on us. In January 2021, we announced that the strategic review had completed, although the impact of the uncertainty created by the process on all stakeholders, including employees, vendors and shareholders, may not be apparent for some time.

Our requirement for additional financing in the short-term represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern.

We have experienced net losses and significant cash outflows from cash used in operating activities over the past years as we develop our portfolio. For the year ended December 31, 2020, the Company incurred a consolidated loss from operations of £22.2 million and negative cash flows from operations of £9.3 million. As of December 31, 2020, we had an accumulated deficit of £122.4 million.

Our future viability is dependent on our ability to generate cash from operating activities, to raise additional capital to finance our operations and to successfully obtain regulatory approval to allow marketing of our development products. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies.

Our consolidated financial statements have been presented on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As at December 31, 2020, we had cash and cash equivalents of £7.5 million. We believe we currently have enough cash to fund our planned operations into the fourth quarter of 2021.

We have prepared cash flow forecasts and considered the cash flow requirement for our next three years, including the period twelve months from the date of the approval of the financial statements. These forecasts show that further financing will be required during the course of the next 12 months, assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2020 with respect to this uncertainty.

In addition, the global spread of pandemic novel coronavirus, COVID-19, places increased uncertainty over our forecasts. The restrictions placed and being placed on the movement of people will likely cause delays to some of our plans. We have established a COVID-19 task force internally to monitor the impact of COVID-19 on our business and prioritize activities to minimize its effect.

In addition to utilizing the existing cash reserves, we are evaluating a number of near-term funding options potentially available to us, including fundraising and/or the partnering of assets or technologies. After considering the uncertainties, we considered it appropriate to continue to adopt the going concern basis in preparing the financial information.

Our ability to continue as a going concern is dependent upon our ability to obtain additional capital and/or dispose of assets, for which there can be no assurance we will be able to do on a timely basis, on favorable terms or at all.

Our operations are in early-stage development with no sources of recurring revenue and there is no assurance that we will successfully develop and license our product candidates or ever become profitable.

We are at a relatively early stage of our commercial development. To date, we have generated a minimal amount of revenue from our product candidates. Our ability to generate revenue and become and remain profitable depends, in part, on our ability to successfully find a licensing partner for our product candidates, or other product candidates we may in-license or acquire, and have such candidates successfully commercialized. Our current strategy is, once proof-of-concept of our product candidates has been established, to generate revenue via a partner, thereby earning royalty and/or milestone income; however, this is not expected to materialize in the foreseeable future, and there can be no guarantee we will be able to find a licensing partner for our product candidates. Even if our product candidates were to successfully achieve regulatory approval, we do not know when any of the product candidates will generate revenue, if at all. Our ability to generate revenue from our product candidates also depends on a number of additional factors, including our ability, and the ability of any licensing partners, to:

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- successfully complete development activities;
- complete and submit new drug applications to the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, or the MHRA, the United States Food and Drug Administration, or the FDA, and any other foreign regulatory authorities, and obtain regulatory approval for products for which there is a commercial market;
- set a commercially viable price;
- obtain commercial quantities of the products at acceptable cost levels;
- develop and maintain a commercial organization capable of sales, marketing and distribution in the markets where the product is to be sold; and
- obtain adequate reimbursement from third-parties, including government, departments and healthcare payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the process described above, we anticipate incurring significant costs.

Even if we are able to generate royalty and/or milestone revenues from the sale of product candidates, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to cease or reduce our operations.

There can be no assurance that we will operate profitably, produce a reasonable return, if any, on investment, or remain solvent. If our strategy proves unsuccessful, stockholders could lose all or part of their investment.

If we require or seek to raise additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the development of our product candidates.

We expect to continue to spend substantial amounts of our cash resources going forward in order to advance the development of our product candidates.

Until such time as we can generate a sufficient amount of revenue from the product candidates we license, if ever, we expect that we may finance future cash needs through, among other things, public or private equity or debt offerings. Such offerings may take place in the United Kingdom, the United States or other foreign countries. However, if we are unable to raise capital when needed, or on terms acceptable to us, our business could be significantly harmed. If we raise additional funds through the issuance of debt or additional equity securities, such issuance could result in dilution to our existing shareholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our Ordinary Shares and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- any acquisitions and the commercialization of other assets, including licensed assets;
- the initiation, progress, timing, costs and results of clinical trials for any product candidates we advance to clinical trials;
- the attainment of milestones and the need to make any royalty payments on any of our product candidates or any other future product candidates, including any product candidates derived from our license with Secura Bio;

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- the number and characteristics of product candidates we in-license or acquire and develop;
- the outcome, timing and cost of regulatory approvals by the EMA, the MHRA, the FDA and any other comparable foreign regulatory authorities, including the potential for such regulatory authorities to require that we perform more studies, or more costly studies, than those we currently expect;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights; and
- the effect of competing technological and market developments.

If a lack of available capital means that we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

We are exposed to political, regulatory, social and economic risk relating to the United Kingdom’s exit from the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, during which European Union rules continued to apply. The Trade and Cooperation Agreement between the United Kingdom and the European Union, which outlines the future trading relationship between the United Kingdom and the European Union, was agreed in December 2020. The impact of the new trade agreement on the general and economic conditions in the United Kingdom remains uncertain. There may be, for example, additional costs in materials and equipment sourced from the European Union and/or delays that could have a material adverse effect on our business, financial condition and results of operations.

From a regulatory perspective, the United Kingdom's withdrawal from the European Union could bear significant complexity and risks. A basic requirement of European Union law relating to the grant of a marketing authorization for a medicinal product in the European Union is that the applicant is established in the European Union. Following the withdrawal of the United Kingdom from the European Union, marketing authorizations previously granted to applicants established in the United Kingdom may no longer be valid. Moreover, the scope of a marketing authorization for a medicinal product granted by the European Commission pursuant to the centralized procedure might not, in the future, include the United Kingdom. In these circumstances, an authorization granted by competent United Kingdom authorities would be required to place medicinal products on the United Kingdom market. In addition, the laws and regulations that will apply after the United Kingdom withdraws from the European Union would affect the manufacturing sites that hold a certification issued by the United Kingdom competent authorities, and vice versa. Our capability to rely on these manufacturing sites for products intended for the European Union market would also depend upon the exact terms of the United Kingdom withdrawal.

Any of these factors could significantly increase the complexity of our activities in the European Union and in the United Kingdom, could depress our economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our Ordinary Shares and Depositary Shares.

In previous years, we and our independent registered public accounting firm have identified material weaknesses in our internal control over financial reporting, and any failure by us to maintain an effective system of internal controls or provide reliable financial and other information in the future, may cause investors to lose confidence in our financial statements and SEC filings and the market price of our securities may be materially and adversely affected.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosures of any material weaknesses identified by management in its internal control over financial reporting.

A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain a non-accelerated filer, we are not required to comply with the independent registered public accounting firm attestation requirement.

In preparing our interim financial statements for the six months ending June 30, 2019, we and our independent registered public accounting firm identified a material weakness in the effectiveness of our internal controls over financial reporting, specifically that we had expensed a deposit in our income statement, as opposed to classifying it as a recoverable financial asset in other receivables during the six months ended June 30, 2019. As previously disclosed, in October 2018, pursuant to the terms of a Stock Purchase Agreement dated September 26, 2018, or Purchase Agreement, by and among the Company, Midatech Pharma US, Inc., our former wholly owned subsidiary, or Midatech US, and Kanwa Holdings, LP, an affiliate of Barings LLC, we sold Midatech US to Kanwa Holdings, LP. During the fiscal year ended December 31, 2019, following a request by Midatech US, we paid a deposit of £947,000 in connection with a certain indemnity obligation set forth in the Purchase Agreement. The deposit was originally expensed in the income statement. Following a review by our independent registered public accounting firm of the interim financial information for the six months ended June 30, 2019, this deposit was reclassified as a recoverable financial asset in other receivables.

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Furthermore, as part of their audit procedures for 2019, BDO LLP, our independent registered public accounting firm at the time, identified the following material weaknesses in our internal control environment:

- Regarding our IT general controls environment material weaknesses included an absence of new vendor approval, inappropriate access to administration accounts of finance systems, password segregation and access security which were not designed or operating effectively. The lack of appropriate IT general controls could lead to a material misstatement of our financial statements that will not be prevented or detected in a timely manner.
- Several control deficiencies were identified related to the consolidation and financial reporting close functions including; the adoption of IFRS 16, adjustments required to align the results of foreign subsidiaries prepared under Spanish GAAP to IFRS, the recognition of certain costs not yet incurred that occurred during the process of preparing our financial information during the period that, when considered in aggregate, would be considered a material weakness.
- The design and operation of our revenue recognition process, in which required policies and procedures either were not designed or were not operating effectively at the period end. While no adjustments to our consolidated financial statements during the course of the audit were required, there were no mitigating controls that would have prevented or detected such a material error should it have occurred.

During 2020, we took corrective measures to address the material weaknesses identified by BDO LLP as follows:

- Regarding IT general controls environment, we introduced a new vendor approval process, carried out reorganization of administration access accounts and introduced regular user access reviews;
- Regarding previous deficiencies identified in the consolidation and financial reporting close process, robust processes and greater oversight have been introduced to provide greater assurance. External technical accounting advice has also been sought during the year when necessary; and
- Regarding the revenue recognition process, we carried out a review and introduced additional steps within the process to ensure revenue is recognized appropriately.

Although we have instituted these remedial measures to address the material weaknesses identified and to continually review and evaluate our internal control systems to allow management to report on the sufficiency of our internal control over financial reporting, we cannot assure you that we will not discover additional weaknesses in our internal control over financial reporting. Any such additional weaknesses or failure to adequately remediate any existing weakness could materially and adversely affect our financial condition and results of operations, as well as our ability to accurately report our financial condition and results of operations in a timely and reliable manner.

Additionally, the material weaknesses described above, or other material weaknesses or significant deficiencies we may become aware of in the future, could result in our determining that our controls and procedures are not effective in future periods or could result in a material misstatement of the consolidated financial statements that would not be prevented or detected.

Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial

statements and reports, the market price of our ordinary shares and/or Depositary Shares could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We recognized a material intangible asset impairment loss as of December 31, 2020, and we may be required to recognize additional non-cash impairment losses in the future.

As of December 31, 2020, in connection with our decision to terminate further in-house development of MTD201, our Q-Sphera formulation of octreotide, we recognized an impairment loss for in-process research and development of £9.3 million. In addition, because no other Q-Sphera products were advanced beyond the formulation stage as of December 31, 2020, we recognized an impairment of goodwill arising from our acquisition of Q Chip Limited in December 2014 of £2.3 million. Further, in connection with the purported termination of our license to panobinostat, the active ingredient for our MTX110 product, by Secura Bio, Inc. in June 2020, we recognized an impairment of an intangible asset of £0.8 million as of December 31, 2020.

These charges discussed above and any future impairment charges could materially increase our expenses and reduce our profitability. The process of testing goodwill and intangible assets for impairment involves numerous judgments, assumptions and estimates made by our management including expected future profitability, cash flows and the fair values of assets and liabilities, which inherently reflect a high degree of uncertainty and may be affected by significant variability. If the business climate deteriorates, including the markets in which certain of our product candidates may be sold, then actual results may not be consistent with these judgments, assumptions and estimates, and our goodwill and intangible assets, to the extent not impaired at the time, may become impaired in future periods. This would in turn have an adverse impact on our financial position and results of operations.

Risks Related to Our Business and Industry

The effects of health epidemics, including the ongoing global coronavirus COVID-19 pandemic, in regions where we, or the third parties on which we rely, have business operations could adversely impact our business, including our clinical trials, preclinical studies and supply chains, depending on the location, duration and severity of disruptions to the systems affecting our business.

Beginning in late 2019, the outbreak of a novel strain of coronavirus, COVID-19, has evolved into a global pandemic and in March 2020, the World Health Organization characterized COVID-19 as a pandemic. The COVID-19 pandemic, which has continued to spread, and the related adverse public health developments, including orders to shelter-in-place, travel restrictions, and the imposition of additional requirements on businesses, have adversely affected workforces, organizations, healthcare communities, economies, and financial markets globally, leading to an economic downturn and increased market volatility. The United States government and the United Kingdom government also has imposed travel restrictions international travel. It has also disrupted the normal operations of businesses across industries, including ours, and caused significant disruption in the operations of third party manufacturers and CROs upon whom we rely.

In response to the spread of COVID-19 as well as public health directives and orders, we have implemented work-from-home policies to support the community efforts to reduce the transmission of COVID-19 and protect employees, complying with guidance from government authorities in the countries within which we operate. We have implemented a number of measures to ensure employee safety and business continuity, including limiting access to our facilities to only those individuals required to execute their job responsibilities and restricted the number of staff working concurrently in our laboratories. In addition, we have suspended all non-essential travel for our employees and have discouraged employee attendance at industry events and in-person work-related meetings, all of which could negatively affect our business.

We are currently conducting clinical trials in the United States. Timely enrollment in our clinical trials is dependent upon capacity at our clinical trial sites, some of which have been and are currently adversely affected by COVID-19. Due to the uneven geographic impact of the pandemic, these localized disruptions are difficult to predict. Shutdowns or other restrictions related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities, which, in turn, could impact the availability or cost of materials and disrupt our supply chain. Additionally, clinical trials may involve immunocompromised patients who are at higher risk for COVID-19 and who are therefore more likely to avoid hospitals or other high-risk areas.

The effects of the governmental restrictions and guidelines, and the measures we have implemented to comply with them, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. The magnitude of these potential disruptions will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business and drug development activities, including:

- delays or difficulties in enrolling patients in our clinical trials, including travel restrictions on patients and constraints on the capacity of our clinical trial sites;
- delays or difficulties in clinical site initiation, including difficulties in training clinical site investigators and clinical site staff;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances in supply chain;
- delays or disruptions in our manufacturing abilities to due to supply chain and transportation system disruptions or lack of manufacturing staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, or being unable to visit clinical trial locations;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, particularly for clinical trials that require in-patient monitoring following administration of the product candidate;
- delays or disruptions in the availability of clinical site staff, who, as healthcare providers, may have heightened exposure to COVID-19, which, in turn, could adversely impact our clinical trial operations;

- interruption of our key clinical trial activities, such as clinical assessments at pre-specified time points during the trial and clinical trial site data monitoring, due to limitations on travel imposed or recommended by governmental entities, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, EMA and comparable foreign regulatory agencies or their refusal to accept data

from clinical trials in affected geographies, which may impact approval timelines;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions; and
- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could continue to adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading price for our Ordinary Shares and Depositary Shares, as well as trading price for the publicly traded securities of other biopharmaceutical companies, as well as the broader global financial markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on United Kingdom and United States economic activities. As a result, we may face difficulties raising capital when needed, and any such sales may be on unfavorable terms to us. Further, to the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing shareholders will be diluted.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments which are difficult to predict, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and other actions taken to contain or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our licensing efforts, our clinical studies, our research programs, healthcare systems or the global economy, and if the ultimate impact of the COVID-19 pandemic and the resulting uncertain economic and healthcare environment is more severe than we anticipated, we may not be able to execute on our current operating plan or on our strategy. If the duration of the COVID-19 pandemic and the associated period of business and social restrictions and economic uncertainty is longer than we anticipated, our cash, cash equivalents, and marketable securities may not be sufficient to fund the activities under our operating plan for the time period that we anticipated, and we may be required to revise our operating plan further. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

We are in receipt of a letter purporting to terminate our license agreement related to panobinostat, the active pharmaceutical ingredient in our MTX110 product. If we are unsuccessful in challenging this termination, our business, financial condition and results of operations could be materially adversely affected.

On June 8, 2020, we received a letter sent on behalf of Secura Bio. Inc., or Secura Bio, dated June 1, 2020, purporting to terminate a License Agreement, executed on or about June 6, 2017, or the License Agreement, by and between Midatech Limited and Novartis AG, or Novartis, which Novartis subsequently transferred to Secura Bio, or the Secura License Agreement. Pursuant to the Secura License Agreement, Midatech Limited was granted a worldwide, sublicenseable license to certain patents of panobinostat, the active pharmaceutical ingredient of Midatech’s development product MTX110. Midatech Limited’s rights are limited to the treatment of brain cancer in humans, administered by convection-enhanced delivery. We view MTX110 as an important asset and currently have two ongoing clinical trials for MTX110 and intend to commence two further clinical trials as part of our MTX110 clinical program.

We plan to continue to pursue development of MTX110 and the strategic review process previously disclosed. We are also reviewing with our outside counsel remedies we may have if Secura Bio does not withdraw the notice and otherwise cease to interfere with our ongoing business and strategic review process, which we have formally requested. We are evaluating available actions to protect our rights under the Secura License Agreement and our assets. Notwithstanding the foregoing, if Secura Bio does not withdraw its notice, the uncertainty and diversion of time and resources associated could have a material adverse effect on our business, financial condition and prospects, and we cannot assure you that we would be successful in resolving such dispute.

Our future success is dependent on product development and the ability to successfully license our product candidates to partners who can seek regulatory approval and commercialization of our product candidates.

We continue to conduct research and development for our product candidates and, to a lesser extent, clinical trials for certain of our product candidates; however there can be no assurance that any of our targeted developments will be successful. We must develop functional products that address specific market needs. We must therefore engage in new development activities, which may not produce innovative, commercially viable results in a timely manner or at all. In addition, we may not be able to develop new technologies or identify specific market needs that are addressable by our technologies, or technologies available to us. We may encounter delays and incur additional development and production costs and expenses, over and above those expected, in order to develop technologies and products suitable for licensing. If any of our development programs are curtailed, this may have a material adverse effect on our business and financial conditions.

Our business is dependent on our ability to complete the development of product candidates, and license our product candidates to partners who will seek to obtain regulatory approval for and commercialize our product candidates in a timely manner. Any licensing partner cannot commercialize a product without first obtaining regulatory approval from the appropriate regulatory authorities in a country. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, it must be demonstrated with substantial evidence gathered in preclinical and well-controlled clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. The process of developing, obtaining regulatory approval for and commercializing product candidates is long, complex and costly. Even if a product candidate were to successfully obtain approval from the EMA, the MHRA, the FDA and/or comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If our product candidates are unable to obtain regulatory approval in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other product candidate. Furthermore, even if a product candidate obtains approval from the regulatory authorities, it is likely that, in order to obtain royalty and/or milestone revenue from any of our licensing partners, our licensing partners may need to expand their commercial operations, establish commercially viable pricing and obtain approval for adequate reimbursement from third parties and government departments and healthcare payors for such products. If our product candidates are unable to successfully be commercialized, we may not be able to earn sufficient revenues to continue our business.

Clinical drug development involves a risky, lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials

may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of any preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, even after seeing promising results in earlier clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry, including many with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

In 2018, we embarked on first-in-human clinical trial program for our MTD201 and MTX110 products, with MTD201 completing our Phase I study in the third quarter of 2018, with an additional Phase I study completed in the third quarter of 2019. The MTX110 Phase I clinical study completed in the fourth quarter of 2020. In 2020, Phase I clinical trials of MTX110 were initiated by the University of Texas in medulloblastoma, and by Columbia University in diffuse intrinsic pontine glioma. In connection with the termination of our MTD201 program, we have determined not to conduct additional clinical trials in humans, other than clinical trials for which funding is provided by third parties or via grants. We expect our licensing partners will be responsible for any future clinical trials. We and any of our licensing partners may experience delays in ongoing or future clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- restrictions related to COVID-19;
- delay or failure in reaching agreement with the applicable regulatory authorities on a trial design;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;

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- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial providers and sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board, or IRB, or the approval of other reviewing entities, including foreign regulatory authorities, to conduct a clinical trial at each site;
- failure to recruit, or subsequent withdrawal of, clinical trial sites from clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of third party clinical trial managers or clinical sites to satisfy contractual duties or meet expected deadlines;
- failure to receive the recommendation of health technology assessment bodies such as the U.S. Agency for Healthcare Research and Quality, and other relevant international bodies or agencies responsible for pricing and utilization determinations;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- from the EMA, the MHRA, the FDA, the IRB, data safety monitoring boards, or other regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, which might require modification to the protocol for a given study;
- decisions by the EMA, the MHRA, the FDA, the IRB, other regulatory authorities, or us, or recommendation by a data safety monitoring board or other regulatory authority, to suspend or terminate a clinical trial at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a drug over existing marketed products;
- manufacturing issues, including problems with manufacturing or obtaining from third parties sufficient quantities of raw materials, active pharmaceutical ingredients, or API, or product candidates for use in clinical trials; and
- changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Patient and/or volunteer enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the ability to obtain and maintain patient consents, whether enrolled subjects drop out before completion, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on contract research organizations and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their activities, we have limited influence over their actual performance.

If we experience delays in the completion of, or termination of, any ongoing or future clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing clinical trials may slow down our product candidate development and approval process and jeopardize the ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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The regulatory approval processes in the United States and Europe are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business may be substantially harmed.

The time required to obtain approval for a product candidate by the EMA, the MHRA, the FDA and other comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among

jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the EMA, the MHRA, the FDA and other comparable foreign regulatory authorities for many reasons, including:

- disagreement with the design or implementation of the clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a new drug application or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third party manufacturers with whom we or any licensing partner contracts with for clinical and commercial supplies; or
- changes in approval policies or regulations that render the preclinical and clinical data insufficient for approval.

In addition, the EMA, the MHRA, the FDA and other comparable foreign regulatory authorities may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and any commercialization plans, or we or any licensing partner may decide to abandon the development program. If approval were to be obtained, regulatory authorities may approve any of our product candidates for fewer or more limited indications than is requested, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the regulatory authorities (the FDA, MHRA, EMA or a comparable foreign regulatory authority) may require the establishment of Risk Evaluation and Mitigation Strategy, or REMS, which may, for instance, restrict distribution of the products and impose burdensome implementation requirements on us or any licensing partner. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval and limit the commercial profile of an approved label, and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates.

Undesirable side effects caused by any of our product candidates could cause us, our licensing partner, if any, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the EMA, the MHRA, the FDA or other comparable foreign regulatory authority. Results of the clinical trials could reveal a high and unacceptable severity and prevalence of side effects or risks associated with a product candidate's use. In such an event, our trials could be suspended or terminated and the regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if undesirable side effects of our products are identified following marketing approval, a number of potentially significant negative consequences could result, including:

- marketing of such product may be suspended;

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- a product recall or product withdrawal;
- regulatory authorities may withdraw approvals of such product or may require additional warnings on the label;
- the requirement to develop a REMS for each product or, if a strategy is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority;
- the requirement to conduct additional post-market studies; and
- being sued and held liable for harm caused to subjects or patients.

Consequently, our reputation and business operations may suffer.

Any of these events could prevent the achievement or maintaining of market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Even if our product candidates receive regulatory approval, they may still face future development, manufacturing and regulatory difficulties.

Our product candidates, if they receive regulatory approval, will be subject to the ongoing requirements of the EMA, the MHRA, the FDA and other regulatory agencies governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product is closely monitored by the EMA, the MHRA, the FDA and other regulatory authorities after approval. If the EMA, the MHRA, the FDA or other regulatory authorities become aware of new safety information after approval of any of our products or product candidates, regulatory authorities may require labeling changes or establishment of a risk mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug and biological products and their facilities are subject to continual review and periodic inspections by the EMA, the MHRA, the FDA and other governmental regulatory authorities for compliance with current good manufacturing practices, or cGMP, regulations. If a previously unknown problem with a product, such as adverse events of unanticipated severity or frequency, or a problem with the facility where the product is manufactured is discovered, a regulatory agency may impose restrictions on that product, the manufacturing facility or the party commercializing the product, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to, or the withdrawal of, marketing and promotional materials or require corrective information to be provided to healthcare practitioners;
- require the violating party to enter into a consent decree, which can include the imposition of various fines, reimbursements of inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, vary or withdraw regulatory approval;
- suspend any ongoing clinical studies;

- refuse to approve pending applications or supplements to applications filed by us or any licensing partner;
- suspend or impose restrictions on operations, the products, manufacturing or ourselves;
- require a change to the product labeling; or
- seize or detain products, refuse to permit the import or export of products or require a product recall.

The occurrence of any of these events or penalties described above may inhibit our ability to generate revenue from product candidates that are commercialized by any of our licensing partners.

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We expect to seek to establish agreements with potential licensing partners and collaborators and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our current commercialization strategy is to deploy our proprietary drug delivery technologies to formulate a compelling portfolio of novel first-in-class sustained release formulations of products with significant commercial potential for licensing to pharmaceutical company partners at proof-of-concept stage, which would potentially result in revenue generation from product royalty and/or milestone deals. We expect to seek to work with licensing or collaboration partners for the development and commercialization of one or more of our product candidates. For example, in January 2019, we entered into that certain Licensing, Collaboration and Distribution Agreement, or the CMS License Agreement, with China Medical Systems Holdings Limited, or CMS, as guarantor, and two of its wholly owned subsidiaries, CMS Bridging Limited, or CMS Bridging, and CMS Medical Hong Kong Limited, or CMS Medical HK, each a CMS Party, pursuant to which, among other things, we agreed to license certain of our products to the CMS Parties in exchange for, among other things, royalty revenue. Likely future collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We face significant competition in seeking appropriate licensing or collaboration partners. Whether we reach a definitive agreement will depend, among other things, upon our assessment of the partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate.

These agreements are complex and time consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future licensing and collaboration partners.

We may not be able to negotiate agreements with these potential partners on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs.

If we enter into agreements with a licensing or collaboration partner for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

Some of our revenues are currently derived from licensing or collaboration agreements with other biopharmaceutical companies, research institutes and universities, and we expect a material amount of our revenue in the future will be derived from these and similar agreement. We may enter into additional agreements with a licensing or collaboration partner for the development and commercialization of certain of our product candidates. If we enter into such agreements, we will have limited control over the amount and timing of resources that our partners will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future licensing partners' ability to successfully perform the functions assigned to them in these arrangements. In addition, any future licensing or collaboration partner may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Agreements involving our product candidates pose a number of risks, including:

- partners have significant discretion in determining the efforts and resources that they will apply to these matters;
- partners may not perform their obligations as expected;
- partners may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the their strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- a partner with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

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- disagreements with partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any future partners of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

The commercial success of any of our product candidates is not guaranteed.

There can be no assurance that any of our product candidates currently in development will be successfully developed into any commercially

viable product or products and/or be manufactured in commercial quantities at an acceptable cost or be marketed successfully and profitably. If we, or our partners, encounter delays at any stage, and fail successfully to address such delays, it may have a material adverse effect on our business, financial condition and prospects. In addition, our success will depend on the market's acceptance of these products and there can be no guarantee that this acceptance will be forthcoming or that our technologies will succeed as an alternative to competing products. If a market fails to develop or develops more slowly than anticipated, we may be unable to recover the costs we may have incurred in the development of particular products and may never achieve profitable royalty or licensing revenues from that product.

The pharmaceutical and biotechnology industries are highly competitive.

The development and commercialization of new drug products is highly competitive. Our business faces competition from a range of major and specialty pharmaceutical and biotechnology companies worldwide with respect to our product candidates, and will face competition in the future with respect to any product candidates that we may seek to develop or commercialize.

There are a number of pharmaceutical and biotechnology companies that currently market and sell products or are pursuing development of products similar to our technology and product candidates. With respect to our product candidates, from a technology perspective, we believe other companies in the sustained release space include MedinCell S.A., GP Pharm, S.A., Peptron, Inc., Graybug Inc. and Nanomi B.V. In addition, other companies using gold nanoparticle technologies include CytImmune Sciences, Inc., and Nanospectra Biosciences, Inc.

Some of these competitive products and therapies are based on scientific approaches that are the same or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our competitors in the biotechnology and pharmaceutical industries may have superior research and development capabilities, products, manufacturing capability or sales and marketing expertise. Many of our competitors may have significantly greater financial and human resources and may have more experience in research and development.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection of other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop products that are more effective, more widely used and less costly than our own product candidates, and may be more successful in commercializing their products.

We anticipate that we will face increased competition in the future as new companies enter our markets and alternative products and technologies become available. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs.

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Our product candidates may be subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the United Kingdom, United States, European Union and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed. On November 20, 2020, the Centers for Medicare and Medicaid Services issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost for us to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which has resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we obtain marketing approval. For a detailed discussion of healthcare reform initiatives of importance to the pharmaceutical industry, see "Item 4. Information on the Group-B. Business Overview-Government Regulations."

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, was enacted in the United States in March 2010 with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change healthcare delivery, increase the number of individuals with insurance, ensure access to certain basic healthcare services, and contain the rising cost of care. There have been executive, judicial and Congressional challenges to certain aspects of the

ACA. While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. H.R. 1: An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, or the Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program, or Quality Payment Program, under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. The Quality Payment Program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, the Centers for Medicare and Medicaid Services issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of or reimbursement and access to pharmaceutical products, may limit or delay our ability to generate revenue, attain profitability, or commercialize our products.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor’s determination to provide coverage for a drug does not assure that other payors will also provide coverage for the drug. Additionally, a third-party payor’s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor’s formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

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We are subject to environmental laws and regulations that govern the use, storage, handling and disposal of hazardous materials and other waste products.

We are subject to environmental laws and regulations governing the use, storage, handling and disposal of hazardous materials and other waste products. We have health and safety policies and procedures in place to assess the risks associated with use of hazardous materials, and the

assessment includes information for employees on how the substances should be used to avoid contamination of the environment and inadvertent exposure to themselves and their colleagues. Despite our precautions for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure. If we fail to comply with any laws or regulations, or if an accident occurs, we may have to pay significant penalties and may be held liable for any damages that result. This liability could exceed our financial resources and could harm our reputation. We may also have to incur significant additional costs to comply with current or future environmental laws and regulations. Our failure to comply with any government regulation applicable to our laboratory and the materials used in our laboratory may adversely affect our ability to develop, produce, market or partner any products we may commercialize or develop.

Our success depends in part on our ability to protect rights in our intellectual property, which cannot be assured.

Our success and ability to compete effectively are in large part dependent upon exploitation of proprietary technologies and products that we have developed internally or have acquired or in-licensed. To date, we have relied on copyright, trademark and trade secret laws, as well as confidentiality procedures, non-compete and/or work for hire invention assignment agreements and licensing arrangements with our employees, consultants, contractors, customers and vendors, to establish and protect our rights to our technology and, to the best extent possible, control the access to and distribution of our technology, software, documentation and other proprietary information, all of which offer only limited protection. Where we have the right to do so under our agreements, we seek to protect our proprietary position by filing patent applications in the United States, the United Kingdom and worldwide related to our novel technologies and products that are important to our business. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. There can be no assurance that:

- the scope of our patents provides and will provide us with exclusivity with respect to any or all of our product candidates and technologies, as well as any other technologies and/or products that address the same problems as our technologies and product candidates by a different means, whether in the same manner as us or not;
- pending or future patent applications will be issued as patents;
- our patents, and/or those patents to which we are licensed, are and will remain valid and enforceable and will not be subject to invalidity or revocation proceedings and that such proceedings will not result in a complete or partial loss of rights;
- our entitlement to exploit patents from time to time (including patents registered solely in our name or our affiliates' name or in the joint names of Midatech or an affiliate and a third party or patents which are licensed to us) is and will be sufficient to protect our core intellectual property rights against third parties, our commercial activities from competition or to support comprehensively our ability to develop and market our proposed products either now or in the future;
- the lack of any particular patents or rights to exploit any particular patents, and the scope of our patents, will not have a material adverse effect on our ability to develop and market our proposed product candidates, either now or in the future;
- we have or will have the resources to pursue any infringer of: (i) patents registered in our name (whether solely or jointly with a third party) from time to time; or (ii) patents licensed to us where we or an affiliate have the financial responsibility to bring such infringement actions pursuant to the relevant license agreement;
- we will develop technologies or product candidates which are patentable, either alone or in conjunction with third parties;
- the ownership, scope or validity of any patents registered in our name (either solely or jointly) from time to time will not be challenged by third parties, including parties with whom we, or any affiliate, have entered into collaboration projects or co-ownership arrangements and that any such challenge will not be successful;
- any patent or patent application owned solely or jointly by us will not be challenged on grounds that we failed to identify the correct inventors or that we failed to comply with our duty of disclosure to the United States Patent and Trademark Office or any equivalent office in a foreign jurisdiction having a disclosure requirement;

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- any issued patent in our sole or joint name from time to time will not be challenged in one or more post-grant proceedings, including but not limited to *inter partes* review, derivation proceedings, interferences, and that like; and that any such challenge will not result in a complete or partial loss of rights to such issued patent or patents;
- any patent applications in our sole or joint name from time to time will not be opposed by any third party, including parties to collaboration, co-existence and any other contractual relationship with us or any of its members;
- the license agreements between us and third parties are and will be valid and subsisting in the future or until their expiry dates, and that we have complied with our contractual obligations under the license agreements;
- all intellectual property capable of being commercialized that is or has been generated pursuant to collaboration agreements between us and third parties will be or has been identified;
- all intellectual property generated pursuant to collaboration agreements and to which we have a contractual entitlement or generated by employees has been lawfully assigned into our sole name (or to one of our subsidiaries);
- in respect of all intellectual property generated pursuant to a collaboration agreement between us and a third party to which we and that third party have a joint contractual entitlement, that such intellectual property has been lawfully assigned into joint names and the rights between us and that third party are properly regulated by a co-ownership agreement; and
- beyond contractual warranties, the licensors of intellectual property to us or our affiliates own the relevant patents and that those patents have not and will not be the subject of, or subject to, infringement, invalidity or revocation actions.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United Kingdom and United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our licensed compounds will result in the issuance of patents that protect our technology or products, or which will effectively prevent others from commercializing competitive technologies and products. Although we have a number of issued patents covering our technology, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us to narrow the claims, which may limit the scope of patent protection that may be obtained. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the European Union, United Kingdom, the United States and other foreign jurisdictions. Overall, such

challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms where they are available in any countries where we are prosecuting patents. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes in either the patent laws or interpretation of the patent laws in the European Union, the United Kingdom, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United Kingdom or the United States, and these foreign laws may also be subject to change. Publication of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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Previously, in the United States, assuming the other requirements for patentability are met, the first to make the claimed invention was entitled to the patent. Outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States transitioned to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Under either the previous or current system, third parties will be allowed to submit prior art prior to the issuance of a patent by the United States Patent and Trademark Office, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

Our commercial success depends, in part, upon our not infringing intellectual property rights owned by others.

Although we believe that we have proprietary platforms for our technologies and product candidates, we cannot determine with certainty whether any existing third party patents or the issuance of any third party patents in the future would require us to alter our technology, obtain licenses or cease certain activities. We may become subject to claims by third parties that our technology infringes their intellectual property rights, in which case we will have no option other than to defend the allegation, which may be possible to resolve through negotiation or which might result in court proceedings. An adverse outcome in any of these circumstances is that we might be subject to significant liabilities, be required to cease using a technology or to pay license fees (both prospectively and retrospectively); and may be subject to the payment of significant damages. We could incur substantial costs in any litigation or other proceedings relating to patent rights, even if it is resolved in our favor. If the proceedings occur in the United States, it is likely that we will be responsible for our own legal costs, no matter the outcome of the litigation. In contrast, in the United Kingdom, the losing party typically is ordered to pay the winning party’s costs, although it is rare to have a complete recovery of all costs from the losing side. Some of our competitors may be able to sustain the costs of complex litigation more effectively or for a longer time than we can because of their substantially greater resources. In addition, uncertainties or threatened or actual disputes relating to any patent, patent application or other intellectual property right (including confidential information) could have a material adverse effect on our ability to market a product, enter into collaborations in respect of the affected products, or raise additional funds.

The policing of unauthorized use of our patented technologies and product candidates is difficult and expensive. There can be no assurance that the steps we take will prevent misappropriation of, or prevent an unauthorized third party from obtaining or using, the technologies, know-how and products we rely on. In addition, effective protection may be unavailable or limited in some jurisdictions. Any misappropriation of our proprietary technology, product candidates and intellectual property could have a negative impact on our business and our operating results. Litigation may be necessary in the future to enforce or protect our rights or to determine the validity or scope of the proprietary rights of others. Litigation could cause us to incur substantial costs and divert resources and management attention away from our daily business and there can be no guarantees as to the outcome of any such litigation. In addition, a defendant in any such litigation may counterclaim against us, resulting in additional time and expense to defend against such a counterclaim, which defense may not be successful.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe on our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend our intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

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Our commercial success depends upon our ability and the ability of our collaborators and licensing partners to develop, manufacture, market and

sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated our confidential information or trade secrets could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a potential distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, a court may determine that we failed to take adequate steps to protect our trade secrets, in which case it may not be possible to enforce our trade secret rights. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

We may face product liability claims stemming from product candidates.

In carrying out our activities, we may potentially face contractual and statutory claims, or other types of claims from customers, suppliers and/or investors. In addition, we are exposed to potential product liability risks that are inherent in the research, development, production and supply of products. Subjects enrolled in our clinical trials, consumers, healthcare providers or other persons administering or selling products based on our and our collaborators' technology may be able to bring claims against us based on the use of such products. If we cannot successfully defend ourselves against claims that any product candidates commercialized caused injuries, we could incur substantial costs and liabilities. Irrespective of their merits or actual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- significant negative media attention and injury to our reputation;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

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We have obtained product liability insurance coverage with a £8.0 million annual aggregate coverage. Our insurance coverage may not be sufficient to cover our entire product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that may be less severe than those of our products. A successful product liability claim or series of claims brought against us could cause the price of the Ordinary Shares and/or Depositary Shares to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We are, and may continue to be, reliant on other parties for the successful development and commercialization of many of our product candidates. We rely upon CROs for the conduct of our clinical studies. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs or collaboration partners does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices and requirements with respect to animal welfare. We and our CROs or collaboration or licensing partners are required to comply with Good Clinical Practices, or GCP, which are regulations and guidelines enforced by the MHRA, the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or partners fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, the MHPA, the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be assured that upon inspection by a given regulatory authority,

such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under such agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, then our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third party providers. To the extent we are unable to identify and successfully manage the performance of third party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We are dependent on third party suppliers, and if we experience problems with any of these third parties, the manufacturing of our product candidates could be delayed, which could harm our results of operations.

We are dependent upon certain qualified suppliers, of which there are a limited number, for the supply of raw materials, components, devices and manufacturing equipment. Additionally, these suppliers may also have downstream suppliers who supply materials, components, devices and manufacturing equipment, which may indirectly impact our business operations. We may also become dependent in the future on third party contract manufacturing organizations for the production of our product candidates for commercial sale. Thus, the success of our business may be adversely affected by the underperformance of third parties, exploitation by third parties of our commercial dependence and by unforeseen interruptions to third parties' businesses. Although the existence of several alternative suppliers for each function mitigates the risks associated with this dependence, as does the availability of commercial insurance in respect of the impact of accidental events, the failure of a third party to properly to carry out their contractual duties or regulatory obligations could be highly disruptive to our business. Supply chain failures can result in significant clinical or commercial supply interruptions which could materially hamper our ability to conduct clinical trials or to supply adequate commercial supplies, and efforts to qualify new suppliers can be costly and time consuming. Further, any action taken by a third party that is detrimental to our reputation could have a negative impact on our ability to register our trademarks and/or market and sell our products.

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In the future, we intend to license certain of our products to other companies for later stages of development and subsequent marketing, and consequently we will be increasingly reliant on securing and retaining such partners once our products advance through the development process. There can be no assurance that we will be able to secure such partners or that, once secured, our partners will continue to make the necessary and timely investments in our products to complete their development in the expected time and achieve commercial success.

Our counterparties may become insolvent.

There is a risk that parties with whom we trade or have other business relationships with (including partners, joint venturers, customers, suppliers, subcontractors and other parties) may become insolvent. This may be due to general economic conditions or factors specific to that company. In the event that a party with whom we trade becomes insolvent, this could have an adverse impact on our revenues and profitability.

Our relationships with customers and third party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of any of our products or any product candidate for which we obtain marketing approval. Our arrangements with third party payors and customers exposes us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products for which we obtain marketing approval.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with such laws and regulations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the United States, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

We are subject to cybersecurity risks and other cyber incidents, including the misappropriation of our information and other breaches of information security that may result in disruption and the incurrence of costs in an effort to minimize those risks.

In the normal course of conducting our business, we collect and store sensitive data on our networks, including intellectual property, personal information of our employees, and our proprietary business information and that of our customers, vendors and business partners. Despite the security measures we have in place and any additional measures we may implement in the future to safeguard our systems and to mitigate potential security risks, our facilities and systems, and those of our third-party service providers, could be vulnerable to security breaches, computer viruses, lost or misplaced data, programming errors, human errors, acts of vandalism or other events. Any steps we take to deter and mitigate these risks may not be successful and may cause us to incur increasing costs. Any disruption of our systems or security breach or event resulting in the misappropriation, loss or other unauthorized disclosure of confidential information, whether by us directly or by our third-party service providers, could damage our reputation, result in the incurrence of costs, expose us to the risks of litigation and liability, result in regulatory penalties under laws that protect privacy of personal information, disrupt our business or otherwise affect our results of operations.

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In the European Union, the General Data Protection Regulation (EU) 2016/679, or GDPR, lays down the legal framework for data protection and privacy. The GDPR applies directly in all European Union member states (until December 31, 2020, this included the United Kingdom) and applies to companies with an establishment in the European Economic Area, or EEA, and to certain other companies not in the EEA that offer or provide goods or services to individuals located in the EEA or monitor the behavior of individuals located in the EEA. In the United Kingdom, the GDPR has been converted into United Kingdom domestic law, pursuant to the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (as amended), which makes some minor technical amendments to ensure the GDPR is operable in the United Kingdom, or the UK GDPR. The UK GDPR is also supplemented by the Data Protection Act 2018. United Kingdom and European Union data protection law is therefore aligned. The GDPR and UK GDPR implement stringent operational requirements for controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, increased cyber security requirements, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained a valid legal basis for certain data processing activities. The GDPR provides that European Union member states may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between member states, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Failure to comply with European Union laws, including failure under the GDPR and UK GDPR, Data Protection Act 2018, ePrivacy Directive and other laws relating to the security of personal data may result in fines up to €20 million (or £17.5 million under the UK GDPR) or up to 4% of the total worldwide annual turnover of the preceding financial year, if greater, and other administrative penalties including criminal liability, which may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the GDPR and related laws may also give risk to increase risk of private actions from data subjects and consumer not-for-profit organizations, including a new form of class action that is available under the GDPR. While we do not routinely handle or process personal data, we do maintain a database of employee information; however, since the GDPR and UK GDPR only came into effect recently, the potential risks associated with non-compliance therewith are uniquely difficult to predict.

We are currently undergoing a leadership transition and this transition, along with the possibility that we may in the future be unable to retain and recruit qualified scientists, key executives, key employees or key consultants, may delay our development efforts or otherwise harm our business.

On May 31, 2018, Dr. James Phillips, our then-Chief Executive Officer and member of the Board of Directors, stepped down from all of his positions with the Company and its subsidiaries. Dr. Craig Cook, formerly our Chief Operating Officer and Head of Research and Development, was appointed by the Board of Directors to succeed Dr. Phillips. Further, on February 26, 2019, three of our non-executive directors, John Johnston, Michele Luzi, and Pavlo Protopapa, resigned, and we appointed Dr. Huaizheng Peng to the Board of Directors. In July 2019, we appointed Frédéric Duchesne to our Board of Directors. In September 2019, our then-Chief Financial Officer and member of our Board of Directors, Nicholas Robbins-Cherry, stepped down from all of his positions with the Company and its subsidiaries. Stephen Stamp was appointed by the Board of Directors to succeed Mr. Robbins-Cherry. In March 2020, Dr. Cook stepped down from all of his positions with the Company and its subsidiaries and two of our non-executive directors, Dr. Huaizheng Peng and Frédéric Duchesne, resigned from the Board of Directors. Mr. Stamp was appointed our Chief Executive Officer upon Dr. Cook's resignation, in addition to his continued service as our Chief Financial Officer. While we have confidence in Mr. Stamp and our remaining leadership team, including the Board of Directors, the uncertainty inherent in this ongoing leadership transition may be difficult to manage, may cause concerns from third parties with whom we do business, and may increase the likelihood of turnover of other key officers and employees.

In addition, our future development and prospects depend to a large degree on the experience, performance and continued service of our senior management team, including members of our Board of Directors. We have invested in our management team at all levels. We have entered into contractual arrangements with our directors and senior management team with the aim of securing the services of each of them. However, retention of these services or the identification of suitable replacements cannot be guaranteed. There can be no guarantee that the services of the current directors and senior management team will be retained, or that suitably skilled and qualified individuals can be identified and employed, which may adversely impact our ability to develop our technologies and/or provide our services at the time requested by our customers or our ability to market our services and technologies, and otherwise to grow our business, could be impaired. The loss of the services of any of the directors or other members of the senior management team and the costs of recruiting replacements may have a material adverse effect on us and our commercial and financial performance.

The ability to continue to attract and retain employees with the appropriate expertise and skills also cannot be guaranteed. Finding and hiring any additional personnel and replacements could be costly and might require us to grant significant equity awards or other incentive compensation, which could adversely impact our financial results, and there can be no assurance that we will have sufficient financial resources to do so. Effective product development and innovation, upon which our success is dependent, is in turn dependent upon attracting and retaining talented technical and scientific personnel, who represent a significant asset and serve as the source of our technological and product innovations. If we are unable to hire, train and retain such personnel in a timely manner, the development and introduction of our products could be delayed and our ability to sell our products and otherwise to grow our business will be impaired and the delay and inability may have a detrimental effect upon our performance.

Our strategic review and the associated workforce reduction announced in March 2020 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In March 2020, we announced a reduction in workforce as part of the termination of the MTD201 program and closing of our Bilbao, Spain manufacturing facilities. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, these changes may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific and medical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with applicable regulations, provide accurate information to regulatory authorities, comply with manufacturing standards, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we have taken to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Unexpected facility shutdowns or system failures may occur and our disaster recovery plans may not be sufficient.

We depend on the performance, reliability and availability of our properties, machinery, and laboratory equipment and information technology systems. We may not be able to access our facilities as a result of events beyond our control, such as extreme weather conditions, quarantines, flood, fire, theft, terrorism and acts of God. Currently, England and Wales are in a lockdown due to COVID-19 and our facilities, including laboratory facilities in Cardiff, Wales, are working at a reduced capacity in order to conform to social distancing policies, which has resulted in a disruption in our current operations and which could have a material adverse effect on our business.

Further, any damage to or failure of our equipment and/or systems could also result in disruptions to our operations. A complete or partial failure of our information technology systems, or those of our CROs and other third parties on which we rely, or corruption of data could result in our inability to access information that we need in order to meet our obligations to our customers or a breach of confidentiality with respect to our or our customers' proprietary information. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Our disaster recovery plans may not adequately address every potential event and our insurance policies may not cover any loss in full or in part (including losses resulting from business interruptions) or damage that we suffer fully or at all. The occurrence of one or more of these events could have a material adverse effect on our business, financial position, reputation or prospects, and might lead to a claim for damages.

Our business may be adversely affected by economic conditions and current economic weakness.

Any economic downturn either globally, regionally or locally, including the economic downturn due to COVID-19, in any country in which we operate may have an adverse effect on the demand for any products derived from our product candidates. A more prolonged economic downturn may lead to an overall decline in our sales, limiting our ability to generate a profit and positive cash flow. The markets in which we expect the products to be offered are directly affected by many national and international factors that are beyond our control, such as political, economic, currency, social and other factors.

We are exposed to the risks of doing business internationally.

We have in the past, and may in the future, operate outside of the United Kingdom. These international operations are subject to a number of risks inherent in operating in different countries. These include, but are not limited to, risks regarding:

- currency exchange rate fluctuations;
- restrictions on repatriation of earnings;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property (including confidentiality) protection in foreign countries;

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- public health epidemics or outbreaks, such as COVID-19;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges; and
- changes in a specific country's or a region's political or economic conditions, including the implications of the United Kingdom's withdrawal from the European Union.

The occurrence of any of these events or conditions could adversely affect our ability to increase or maintain our operations in various countries.

We have undertaken, and may in the future undertake, additional strategic acquisitions. Failure to integrate acquisitions could adversely affect our value.

One of the ways we have grown our pipeline and business in the past is through strategic acquisitions, such as our acquisition of DARA. We may, from time to time, evaluate additional acquisition opportunities, and may, in the future, strategically make further acquisitions of, and investments in, businesses and technologies when we believe the opportunity is advantageous to our prospects. There can be no assurance that in the future we will be able to find appropriate acquisitions or investments. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our shareholders' percentage of ownership;
- be obligated to make milestone or other contingent or non-contingent payments;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, this may not ultimately strengthen our competitive position or ensure that we will not be viewed negatively by customers, financial markets or investors. Further, acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies, including the failure to achieve the expected benefits and synergies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

We are exposed to risks related to currency exchange rates.

We currently conduct a portion of our operations outside of the United Kingdom. Because we use the British pound sterling as our financial statement reporting currency, changes in currency exchange rates have had and could have a significant effect on our operating results when our operating results are translated from the local currency into the British pound sterling. Exchange rate fluctuations between local currencies and the British pound sterling create risk in several ways, including the following: weakening of the British pound sterling, as seen, for example, following the results of the Brexit referendum, may increase the British pound sterling cost of overseas research and development expenses and the cost of sourced product components outside the United Kingdom; strengthening of the British pound sterling may decrease the value of our revenues denominated in other currencies; the exchange rates on non-sterling transactions and cash deposits can distort our financial results; and commercial pricing and profit margins are affected by currency fluctuations. Future changes in currency exchange rates could have a material adverse effect on our financial results.

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The ownership of a significant portion of our outstanding Ordinary Shares by Chinese entities may expose us to greater regulatory scrutiny.

At various times during recent years, the governments of the United States and China have had disagreements over political and economic issues. Controversies may arise in the future between these two countries. Any political or trade controversies between the United States and China could adversely affect our ability to successfully conduct our business in China or the United States, the market price of our Ordinary Shares or Depositary Shares and our ability to access the capital markets in the United States. Also, as a result of recent controversies involving Chinese controlled companies, it is possible that such companies have come under increased scrutiny in the United States and other countries, including the United Kingdom. If we become subject to enhanced regulatory review and oversight, responding to such review and oversight may be expensive and time consuming and may have a material adverse effect on our operations, even if we otherwise have complied with all legal and regulatory requirements.

Risks Related to Ownership of Our Securities

The price of our Ordinary Shares and Depositary Shares may be volatile.

Each Depositary Share represents five Ordinary Shares. A public market has only been established for the Depositary Shares since December 2015, and such a market may not be sustained. Both the United States and United Kingdom stock markets have experienced significant volatility, including in pharmaceutical and biotechnology stocks. In particular, the closing prices of our Ordinary Shares on AIM and our Depositary Shares on the NASDAQ Capital Market have fluctuated significantly in the prior few years.

In addition to the factors discussed in this “*Risk Factors*” section and elsewhere in this annual report, the factors that could cause volatility in the market price of each ordinary share and the Depositary Shares include:

- the success of competitive products or technologies;
- regulatory actions;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of new products, significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the progress of preclinical development, laboratory testing and clinical trials of our product candidates or those of our competitors;
- the results from our clinical programs and any future trials we may conduct;
- developments in the clinical trials of potentially similar competitive products;
- EMA, MHRA, FDA or international regulatory or legal developments;
- failure of any of our product candidates, if approved, to achieve commercial success;
- developments or disputes concerning patent applications, issued patents or other proprietary intellectual property rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- litigation or public concern about the safety of our products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our operating results;
- variations in our financial results or those of companies that are perceived to be similar to us;

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- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcements or expectations of additional financing efforts;
- rumors relating to us or our competitors;
- sales of our Ordinary Shares or Depositary Shares by us, our insiders or our other shareholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors, or general volatility in the market due to other factors, such as the recent volatility attributed to COVID-19;
- third party reimbursement policies;
- Brexit and any resulting economic or currency volatility;
- developments concerning current or future collaborations, strategic alliances, joint ventures or similar relationships; and
- reviews of long-term values of our assets, which could lead to impairment charges that could reduce our earnings.

In addition, the stock market in general, NASDAQ, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Ordinary Shares, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these “*Risk Factors*,” could have a dramatic and material adverse impact on the market price of our Ordinary Shares and Depositary Shares.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Ordinary Shares and Depositary Shares may be volatile, and in the past, some companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could

seriously harm our business.

The liquidity of our Depositary Shares and Ordinary Shares may have an adverse effect on our share price.

As at April 15, 2021, we had 63,380,667 Ordinary Shares outstanding. Of these shares, 39,227,410 of our Ordinary Shares were held as Depositary Shares. Some companies that have issued American depositary shares on United States stock exchanges have experienced lower levels of liquidity in their American depositary shares than is the case for their ordinary shares listed on their domestic exchange. Our Depositary Shares are traded on the NASDAQ Capital Market and our Ordinary Shares are traded on AIM. We cannot predict the effect of this dual listing on the value of our Ordinary Shares and Depositary Shares. However, the dual listing of our Ordinary Shares and Depositary Shares may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the Depositary Shares in the United States. The price of the Depositary Shares could also be adversely affected by trading in our Ordinary Shares on AIM. As a result of these and other factors, you may not be able to sell your Depositary Shares. In addition, investors may incur higher transaction costs when buying and selling Depositary Shares than they would incur in buying and selling common stock. An inactive market may also impair our ability to raise capital by selling Depositary Shares and Ordinary Shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our Ordinary Shares as consideration.

Our Ordinary Shares and Depositary Shares trade on two different markets, and this may result in price variations and regulatory compliance issues.

Depositary Shares representing our Ordinary Shares are listed for trading on the NASDAQ Capital Market and our Ordinary Shares are traded on AIM. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the U.S. and the United Kingdom. Consequently, the effective trading prices of our securities on these two markets may differ. Any decrease in the trading price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

Shareholder ownership interests in the Company may be diluted as a result of future financings, additional acquisitions or the exercise of our options and warrants, and may have a material negative effect on the market price of our securities.

We may seek to raise additional funds from time to time in public or private issuances of equity and such financings may take place in the near future or over the longer term. Sales of our securities offered through future equity offerings may result in substantial dilution to the interests of our current shareholders. The sale of a substantial number of securities to investors, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

As of April 15, 2021, we had issued 1,356,052 options under the Midatech Pharma PLC Enterprise Management Incentive Plan, and 129,926 non-EMI options. In addition, we assumed options in connection with our acquisition of DARA in 2015, of which 2,835 were still outstanding. Further, as of April 15, 2021, we had issued outstanding warrants exercisable for (i) 15,692,276 Ordinary Shares with an exercise price of £10.00 per share, (ii) 630,000 Depositary Shares with an exercise price of \$6.25 each (representing 3,150,000 Ordinary Shares), (iii) 1,318,182 Depositary Shares with an exercise price of \$2.05 each (representing 6,590,910 Ordinary Shares), (iv) 29,546 Depositary Shares with an exercise price of \$2.0625 each (representing 147,730 Ordinary Shares), (v) 6,999,999 Ordinary Shares with an exercise price of £0.34 each, and (vi) 4,624 Ordinary Shares with a weighted average exercise price of \$110.51 per share (assumed pursuant to the acquisition of DARA in 2015). We may also issue Ordinary Shares (and Depositary Shares underlying such Ordinary Shares) or other securities convertible into Ordinary Shares from time to time for future acquisition. The issuance of the securities underlying these instruments, or perception that issuance may occur, will have a dilutive impact on other shareholders and could have a material negative effect on the market price of our Ordinary Shares and Depositary Shares.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Ordinary Shares and Depositary Shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, the price of our Ordinary Shares and Depositary Shares would likely decline. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, demand for our securities could decrease, which might cause the price of our Ordinary Shares and Depositary Shares and our trading volume to decline.

The rights of holders of Depositary Shares are not the same as the rights of holders of Ordinary Shares.

We are a public limited company incorporated under the laws of England and Wales. The Depositary Shares represent a beneficial ownership interest in our Ordinary Shares. The rights of holders of Depositary Shares will be governed by English law, our constitutional documents, the listing rules of AIM, or AIM Rules, and the deposit agreement pursuant to which the Depositary Shares are issued. The rights and terms of the Depositary Shares are designed to replicate, to the extent reasonably practicable, the rights attendant to the Ordinary Shares, for which there is currently no active trading market in the United States. However, because of aspects of United Kingdom law, our constitutional documents and the terms of the deposit agreement, the rights of holders of Depositary Shares will not be identical to and, in some respects, may be less favorable than, the rights of holders of Ordinary Shares.

You may not have the same voting rights as the holders of our Ordinary Shares and may not receive voting materials in time to be able to exercise your right to vote.

As a holder of Depositary Shares, you will not have the right to vote the shares underlying the Depositary Shares directly unless you cancel the Depositary Shares in accordance with the terms of the related deposit agreement and vote the underlying shares at the applicable shareholders meeting. Holders of the Depositary Shares will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the Ordinary Shares represented by the Depositary Shares. You may not receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their Depositary Shares through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

You may not receive distributions on Ordinary Shares represented by Depositary Shares or any value for them if it is illegal or impractical to make them available to holders of Depositary Shares.

The depositary of the Depositary Shares has agreed to pay to you distributions with respect to cash or other distributions it or the custodian receives on Ordinary Shares or other deposited securities after deducting its agreed fees and expenses. You will receive these distributions in proportion to the number of Ordinary Shares your Depositary Shares represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Depositary Shares. We have no obligation to take any other action to permit the distribution of our Depositary Shares, Ordinary Shares, rights or anything else to holders of our Depositary Shares. As a result, you may not receive the distributions made on Ordinary Shares or any value from them if it is illegal or impractical for us to make them available to you. These restrictions may have a material adverse effect on the value of your Depositary Shares.

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You may be subject to limitations on transfer of your Depositary Shares.

Your Depositary Shares are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your Depositary Shares generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Securities traded on AIM may carry a higher risk than shares traded on other exchanges that may impact the value of your investment.

Our Ordinary Shares are currently traded on the AIM. Investment in equities traded on the AIM is perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the Main Market of the London Stock Exchange, New York Stock Exchange or NASDAQ. This is because the AIM imposes less stringent corporate governance and ongoing reporting requirements than those other exchanges. In addition, the AIM requires only semi-annual, rather than quarterly, financial reporting. You should be aware that the value of our Ordinary Shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM-listed companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our Ordinary Shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the market price of our Ordinary Shares underlying the Depositary Shares may not reflect the underlying value of the Company.

It may be difficult for you to bring any action or enforce any judgment obtained in the United States against us or members of our Board of Directors, which may limit the remedies otherwise available to you.

We are incorporated as a public limited company in England and Wales. In addition, all of the members of our Board of Directors are nationals and residents of countries, including the United Kingdom, outside of the United States. Most or all of the assets of these individuals are located outside the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States if you believe your rights have been infringed under the securities laws or otherwise. In addition, a United Kingdom court may prevent you from enforcing a judgment of a United States court against us or these individuals based on the securities laws of the United States or any state thereof. A United Kingdom court may not allow you to bring an action against us or our directors based on the securities laws of the United States or any state thereof.

We have no present intention to pay dividends on our Ordinary Shares in the foreseeable future and, consequently, your only opportunity to achieve a return on your investment during that time may be if the price of Depositary Shares appreciates.

We have no present intention to pay dividends on our Ordinary Shares in the foreseeable future. Any determination by our Board of Directors to pay dividends will depend on many factors, including our financial condition, results of operations, legal requirements and other factors. Accordingly, if the price of the Depositary Shares falls in the foreseeable future and you sell your Depositary Shares, you will lose money on your investment, without the likelihood that this loss will be offset in part or at all by cash dividends.

We are a “foreign private issuer” under the rules and regulations of the SEC and, as a result, are exempt from a number of rules under the Exchange Act and are permitted to file less information with the SEC than a company incorporated in the United States.

We are incorporated as a public limited company in England and Wales and are deemed to be a “foreign private issuer” under the rules and regulations of the SEC. As a foreign private issuer, we are exempt from certain rules under the Exchange Act that would otherwise apply if we were a company incorporated in the United States, including:

- the requirement to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies with securities registered under the Exchange Act;
- the requirement to file financial statements prepared in accordance with U.S. GAAP;
- the proxy rules, which impose certain disclosure and procedural requirements for proxy solicitations; and
- the requirement to comply with Regulation FD, which imposes certain restrictions on the selective disclosure of material information.

In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the related rules with respect to their purchases and sales of Ordinary Shares and Depositary Shares. Accordingly, you may receive less information about us than you would receive about a public company incorporated in the United States and may be afforded less protection under the United States federal securities laws than you would be if we were incorporated in the United States.

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Additional reporting requirements may apply if we lose our status as a foreign private issuer.

If we lose our status as a foreign private issuer at some future time, then we will no longer be exempt from such rules and, among other things, will be required to file periodic reports and financial statements as if we were a company incorporated in the United States. The costs incurred in fulfilling these additional regulatory requirements could be substantial.

As a foreign private issuer, we are not required to comply with many of the corporate governance standards of NASDAQ applicable to companies incorporated in the United States.

Our Board of Directors is required to maintain an audit committee comprised solely of three or more directors satisfying the independence standards of NASDAQ applicable to audit committee members. As a foreign private issuer, however, we are not required to comply with most of the other corporate governance rules of NASDAQ, including the requirement to maintain a majority of independent directors, and nominating and compensation committees of our Board of Directors comprised solely of independent directors. Although United Kingdom corporate governance rules which we abide by have comparable requirements, holders of Depositary Shares may not be afforded the benefits of the corporate governance standards of NASDAQ to the same extent applicable to companies incorporated in the United States.

We are no longer an “emerging growth company” but remain a non-accelerated filer, and the reduced reporting obligations applicable non-accelerated filers may make our securities less attractive to investors.

We are no longer an “emerging growth company,” as defined under the Jumpstart Our Business Startups Act. However, for as long as we remain a “non-accelerated filer” under the rules of the SEC, our independent registered public accounting firm is not required to deliver an annual attestation report on the effectiveness of our internal control over financial reporting. We will cease to be a non-accelerated filer if (a) the aggregate market value of our outstanding Ordinary Shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is \$75 million or more and we reported annual net revenues of greater than \$100 million for our most recently completed fiscal year or (b) the aggregate market value of our outstanding Ordinary Shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter is \$700 million or more, regardless of annual net revenues. If we cease to be a non-accelerated filer, we would be subject to the requirement

for an annual attestation report by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. We cannot predict whether investors will find our securities less attractive if we rely on this exemption. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and our stock price may be more volatile and may decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We design our disclosure controls and procedures to reasonably assure that information we are required to disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and we may not detect them.

Any failure to maintain effective internal controls and procedures over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows.

We are incurring increased costs as a result of operating as a public company, and management will be required to devote substantial time to new compliance initiatives.

As a public company in the United Kingdom and United States, we are incurring significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of, in the United Kingdom, the AIM Rules, the Market Abuse Regulation, or MAR, and the Disclosure Guidance and Transparency Rules, and in the United States, the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and the NASDAQ. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as members of our senior management.

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Regulations related to “conflict minerals” may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

In August 2012, the SEC adopted a rule requiring disclosures of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured by U.S. public companies. The conflict minerals rule requires companies annually to diligence, disclose and report whether or not such minerals originate from the Democratic Republic of Congo and other specified countries. The rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, including gold. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. Since our supply chain is complex, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. In addition, we may encounter challenges to satisfy those customers who require that all of the components of our products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so.

If we cannot continue to meet NASDAQ’s continued listing requirements, NASDAQ may delist our Depositary Shares, which could have an adverse impact on the liquidity and market price of our Depositary Shares.

Our Depositary Shares are currently listed on the NASDAQ Capital Market. We are required to meet certain qualitative and financial tests to maintain the listing of our Depositary Shares on NASDAQ. On December 11, 2019, we received a letter from NASDAQ stating that, for the previous 30 consecutive business days, the bid price for our Depositary Shares had closed below the minimum \$1.00 bid price per share requirement for continued listing on The NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). On March 18, 2020, we received written notice from NASDAQ notifying us that for the preceding 10 consecutive business days the closing bid price for our Depositary Shares had been \$1.00 or greater. Accordingly, NASDAQ determined that we had regained compliance with NASDAQ Listing Rule 5550(a)(2).

Having regained compliance with these rules, we are now in compliance with all applicable requirements for continued listing on the NASDAQ Capital Market. However, we cannot assure you that we will remain in compliance with all applicable requirements for continued listing on the NASDAQ Capital Market. If, in the future, we fail to sustain compliance with all applicable requirements for continued listing on NASDAQ, our Depositary Shares may be subject to delisting by NASDAQ. This could inhibit the ability of our holders of Depositary Shares to trade their shares in the open market, thereby severely limiting the liquidity of such shares. Although stockholders may be able to trade their shares of Depositary Shares on the over-the-counter market, there can be no assurance that this would occur. Further, the over-the-counter market provides significantly less liquidity than NASDAQ and other national securities exchanges, is thinly traded and highly volatile, has fewer market makers and is not followed by analysts. As a result, your ability to trade or obtain quotations for these securities may be more limited than if they were quoted on NASDAQ or other national securities exchanges.

The change in ratio of our Ordinary Shares to Depositary Shares may not increase our Depositary Share price over the long-term.

On March 3, 2020, in an effort to bring our Depositary Share price into compliance with NASDAQ’s minimum bid price per share requirement, we effected a ratio change in the number of Ordinary Shares represented by our Depositary Shares from 20 Ordinary Shares per Depositary Share to five Ordinary Shares per Depositary Share. We cannot assure you, however, that the ratio change will accomplish this objective for any meaningful period of time, or result in any permanent or sustained increase in the market price of our Depositary Shares, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success.

The change in ratio of our Ordinary Shares to Depositary Shares may decrease the liquidity of our Depositary Shares.

Although the Board of Directors believes that the increase in the market price of our Depositary Shares could encourage interest in our Depositary Shares and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of Depositary Shares outstanding after the ratio change. A reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our Depositary Shares. In addition, the ratio change may increase the number of stockholders who own odd lots (less

than 100 shares) of our Depositary Shares, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales.

We intend to operate so as to be treated exclusively as a resident of the United Kingdom for tax purposes, but the relevant tax authorities may treat us as also being a resident of another jurisdiction for tax purposes.

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We are a public limited company incorporated under the laws of England and Wales. Under current English law, the decisions of the English courts and the published practice of Her Majesty's Revenue and Customs suggest that we are likely to be regarded as being a United Kingdom resident and should remain so if, as we intend that, (i) all major meetings of our Board of Directors and most routine meetings are held in the United Kingdom with a majority of directors present in the United Kingdom for those meetings; (ii) at those meetings there are full discussions of, and decisions are made regarding, the key strategic issues affecting us and our subsidiaries; (iii) those meetings are properly minuted; (iv) at least some of our directors, together with supporting staff, are based in the United Kingdom; and (v) we have permanent staffed office premises in the United Kingdom sufficient to discharge our functions.

Even if we are considered by Her Majesty's Revenue and Customs as resident in the United Kingdom for United Kingdom tax purposes, as expected, we would nevertheless not be treated as resident in the United Kingdom if (a) we were concurrently resident in another jurisdiction (applying the tax residence rules of that jurisdiction) that has a double tax treaty with the United Kingdom and (b) there is a tiebreaker provision in that tax treaty which allocates exclusive residence to that other jurisdiction. Because this analysis is highly factual and may depend on future changes in our management and organizational structure, there can be no assurance regarding the final determination of our tax residence. Should we be treated as resident for tax purposes in another jurisdiction other than the United Kingdom, we would be subject to taxation in such jurisdiction in accordance with such jurisdiction's laws, which could result in additional costs and expenses.

If we are deemed or become a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2021 or in any prior or subsequent year, this may result in adverse U.S. federal income tax consequences for U.S. taxpayers that are holders of our securities.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

We do not believe we were a PFIC for 2020, but there can be no assurance that we will not be a PFIC in 2021 or for any other taxable year, as our operating results for any such years may cause us to be a PFIC. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. shareholder owns our securities, and such U.S. shareholder does not make an election to treat us as a "qualified electing fund," or a QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our securities will be subject to special rules. Under these rules: (1) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for the securities; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the United States Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold or have held our securities during a period when we were or are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. However, because we do not intend to prepare or provide the information that would permit the making of a valid QEF election, such an election will not be available to United States holders.

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our Company and holders of our Ordinary Shares and the Depositary Shares.

The Tax Cut Act, which was legislation bringing about broad changes in the existing U.S. corporate tax system, was enacted in the United States in December 2017. The Tax Cut Act made significant changes to the U.S. federal income tax laws. Certain provisions of the Tax Cut Act could have an adverse effect on the Company or holders of our Ordinary Shares or Depositary Shares. The U.S. Treasury Department and the IRS continue to interpret and issue guidance on how provisions of the Tax Cut Act will be applied and administered. The interpretations of many provisions of the Tax Cut Act are still unclear. We cannot predict when or to what extent any additional U.S. federal tax laws, regulations, interpretations, or rulings clarifying the Tax Cut Act will be issued or the impact of any such guidance on investors or the Company. Holders of Ordinary Shares and Depositary Shares are urged to consult their own tax advisors regarding the effect of the Tax Cut Act and other potential changes to the U.S. federal tax laws.

We are unable to predict what tax changes may be enacted in the future or what effect such changes would have on our business, but such changes could affect our effective tax rates in countries where we have operations and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden and cost of tax compliance. In addition, such changes could impact the holders of Ordinary Shares or Depositary Shares.

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ITEM 4. INFORMATION ON THE GROUP.

A. History and Development of the Group

We were originally formed as a limited liability company under the laws of England and Wales in 2000 under the name Midatech Limited, which acquired its base nanoparticle technology through an assignment of worldwide commercialization rights and joint ownership of patent rights from Consejo Superior de Investigaciones Científicas, or CSIC, in Madrid, Spain. Midatech Limited was a research and development focused biotech company which subsequently advanced and developed this gold nanoparticle drug delivery platform technology to enhance the delivery of medicines for major therapeutic indications where clinical therapeutic options are limited, with a particular focus on certain cancers, such as liver and brain cancer.

To better be able to continue the commercial development of the research and development programs of Midatech Limited, Midatech Pharma PLC was incorporated on September 12, 2014 under the laws of England and Wales, to be the public holding company of Midatech Limited and Midatech Pharma (Wales) Limited, or Midatech Wales, under registered number 09216368. On December 8, 2014, we completed our initial public

offering of our Ordinary Shares in the United Kingdom.

Also on December 8, 2014, we acquired Midatech Wales (formerly known as Q Chip Limited) and its subsidiaries in exchange for approximately 5.4 million Ordinary Shares. Founded in 2003 with the acquisition of core intellectual property around micro-fluidics from Cardiff University, Midatech Wales develops a complementary technology and products that allow sustained delivery of substances over extended periods of time. We believe that this technology provides an additional drug delivery platform to improve biodelivery and biodistribution of existing drugs.

On December 4, 2015, in to establish a presence in the United States, we acquired DARA (including its commercial products) and its subsidiaries pursuant to an Agreement and Plan of Merger entered into on June 4, 2015. As a result, DARA became a wholly owned subsidiary of Midatech, and was subsequently renamed Midatech US.

On December 24, 2015, we expanded our commercial product portfolio by acquiring Zuplenz® (ondansetron) Oral Soluble Film, or Zuplenz, a marketed anti-emetic oral soluble film from Galena Biopharma, Inc. for the prevention of chemotherapy-induced nausea and vomiting, radiotherapy-induced nausea and vomiting, and post-operative nausea and vomiting. Zuplenz was subsequently contributed to Midatech US in April 2018.

Effective November 1, 2018, and pursuant to the Purchase Agreement, we sold 100% of the outstanding equity interests of Midatech US to an affiliate of Barings LLC for initial consideration of \$13.0 million, and up to \$6.0 million of additional payments subject to the achievement of 2018 and 2019 net sales performance targets with respect to certain Midatech US products, both individually and in the aggregate. These target were not met and no additional payments were received.

On March 31, 2020 we announced that, in the context of prevailing conditions in the capital markets, we did not expect to be able to raise capital to fund the continued development of MTD201, including scale-up of MTD201 manufacturing at our Bilbao facilities. We determined to conduct a strategic review of our operations, cease further investment in MTD201 and close our operations in Bilbao, Spain, including making all our employees in Bilbao redundant.

On April 20, 2020, we announced an update to the strategic review of operations including the appointment of Noble Capital Markets, Inc. to advise us on options for extracting value from its technologies, including partnering our clinical stage assets, partnering existing and upcoming proof of concept formulations, partnering or selling one or more of our technologies or selling the entire Company.

On January 26, 2021, we announced, among other things, that the strategic review had completed and that we were now focused on executing our realigned strategy of deploying our technologies to develop more early stage products and seeking licensing partners at proof of concept stage.

Our principal executive office and registered offices are located at Oddfellows House, 19 Newport Road, Cardiff, United Kingdom CF24 0AA, and our telephone number is +44 1235 888 300. Our authorized representative in the United States is Donald J. Puglisi of Puglisi and Associates. Our agent for service in the United States is Donald J. Puglisi of Puglisi and Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711. Our Ordinary Shares are traded on AIM under the symbol “MTPH,” and our Depositary Shares are traded on the NASDAQ Capital Market under the symbol “MTP.”

We file reports and other information with the SEC. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. Our filings with the SEC are available to the public through the SEC’s website at <http://www.sec.gov>. Our corporate website is located at www.midatechpharma.com. Information contained on our website is not part of, or incorporated in, this annual report.

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Capital Expenditures

Our capital expenditures amounted to £0.21 million, £0.31 million and £0.24 million for the years ended December 31, 2020, 2019 and 2018, respectively.

For the year ended December 31, 2020, our principal capital expenditures largely related to investment in our laboratory and pilot-scale manufacturing facility in Cardiff, Wales.

For the year ended December 31, 2019, our principal capital expenditures largely related to the purchase of laboratory equipment for our former manufacturing facility in Bilbao, Spain.

For the year ended December 31, 2018, our principal capital expenditures largely related to expansion of our pharmaceutical development capability in our Cardiff research and development facility, and production capability at our Bilbao, Spain manufacturing facility.

B. Business Overview

Business Overview

We are focused on the research and development of medicines which we believe would benefit from improved bio-delivery and/or bio-distribution using our using our proprietary platform drug delivery technologies:

- Q-Sphera™ platform: Our disruptive polymer microsphere microtechnology is used for sustained delivery to prolong and control the release of therapeutics over an extended period of time, from weeks to months.
- MidaSolve™ platform: Our innovative oligosaccharide nanotechnology is used to solubilize drugs so that they can be administered in liquid form directly and locally into tumors.
- MidaCore™ platform: Our leading-edge gold nanoparticle, or GNP, nanotechnology is used for targeting sites of disease by using either chemotherapeutic agents or immunotherapeutic agents

During the past three years we sold oncology treatment and supportive care products through our former subsidiary, Midatech US. With the sale of Midatech US in 2018, we no longer sell any products.

Intellectual Property. We have developed a strong intellectual property base and have a wide intellectual property portfolio of 108 granted patents, 57 applications in process and 35 patent families (a set of patents to protect a single invention in various countries covering a range of diverse technologies).

Revenue. Revenue from continuing and discontinued operations for the whole of the Group is set out below.

	Year ended December 31,		
(£ in thousands)	2020	2019	2018
Continuing Operations:			
Revenue (United States) (1)	–	60	–
Revenue (Europe, including United Kingdom)	118	252	149
Revenue (Rest of World)	62		
Discontinued Operations:			
Revenue (United States) (1)	–	–	3,882
Revenue (Europe, including United Kingdom)	–	–	–
Total Revenue from continuing and discontinued operations	180	312	4,031

(1) Revenue for Midatech US, which we divested in 2018, is included in the consolidated statement of comprehensive income within the

[Table of Contents](#)**Recent Developments*****Strategic Review***

In March 2020, we reviewed the remaining costs necessary to complete the Phase III clinical trial of MTD201, which uses our sustained release platform, Q-Sphera, to formulate a long acting dose of octreotide for the treatment of acromegaly and neuroendocrine tumors, as well as the manufacturing scale-up of our MTD201 manufacturing capabilities at our Bilbao, Spain facilities. We believed the remaining costs to be in the order of \$30 million (of which \$8.5 million had been raised in loans from the Spanish government, as discussed in more detail herein). Given the state of the financial markets at that time, and our cash runway, we determined we were unlikely to conclude a license transaction or raise sufficient funds to continue the required remaining investment in MTD201 in a timely manner. The Board of Directors made the determination to terminate the further in-house development of MTD201 and, on March 31, 2020, announced a strategic review of the Company's operations.

In connection with the decision to terminate the MTD201 program, we closed our MTD201-dedicated manufacturing facilities in Bilbao, Spain. We have made redundant all of our Midatech Pharma España S.L., or Midatech Spain, employees pursuant to a consultation process as required by Spanish law. We also made redundant five employees located in the United Kingdom in our clinical research and administrative departments.

Following these changes, our strategy has shifted to deploying our proprietary drug delivery technologies to formulate a compelling portfolio of novel first-in-class sustained release formulations of products with significant commercial potential for licensing to pharmaceutical company partners at a proof-of-concept stage. Other than with respect to MTX110, for which pilot clinical trials are required to demonstrate proof of concept due to the fact we are repurposing an existing medicine, we have no plans to undertake additional clinical trials in humans unless a license partner or grant funding has been secured. MTX110 is a direct delivery treatment for diffuse intrinsic pontine glioma, or DIPG, an ultra-rare brain cancer suffered by children, using our MidaSolve technology for direct delivery. For more information regarding our strategy, see “-Our Strategy.”

Additionally, on March 31, 2020, Dr. Craig Cook, our then-Chief Executive Officer, resigned from his position and as a director of Midatech, effective immediately. He was succeeded by Mr. Stephen Stamp, our current Chief Financial Officer, who now serves in the combined roles of Chief Executive Officer and Chief Financial Officer. Further, in line with our streamlined strategy and operations, each of Dr. Huaizheng Peng and Mr. Frederic Duchesne resigned from the Board of Directors, effective March 31, 2020.

On January 26, 2021, we announced, among other things, that the strategic review had been completed and that we were now focused on executing our realigned strategy of deploying our technologies to develop more early stage products and seeking licensing partners at proof of concept stage.

Secura License Agreement

On June 8, 2020, we received a letter sent on behalf of Secura Bio, dated June 1, 2020, purporting to terminate the Secura License Agreement. Pursuant to the Secura License Agreement, Midatech Limited was granted a non-exclusive worldwide, sublicenseable license to certain patents of panobinostat, the active pharmaceutical ingredient of our development product MTX110. Midatech Limited's rights are limited to the treatment of brain cancer in humans, administered by convection-enhanced delivery.

We view MTX110 as an important asset and currently have two ongoing clinical trials for MTX110 and intend to commence two further clinical trials as part of our MTX110 clinical program. We continue to enjoy freedom to use panobinostat for research purposes and we plan to continue to pursue development of MTX110. We believe that the relevant Secura Bio patents may delay a launch of MTX110 for use in patients with DIPG, however we do not anticipate it would have any impact on launching MTX110 for use in patients with glioblastoma multiforme. We continue to review with our outside counsel any cost-effective remedies we may have if Secura Bio does not withdraw the notice and otherwise cease to interfere with our ongoing business, which we have formally requested.

Notwithstanding the foregoing, if Secura Bio does not withdraw its notice, the uncertainty and diversion of time and resources associated could have a material adverse effect on our business, financial condition and prospects, and we cannot assure you that we would be successful in resolving such dispute.

Impact of COVID-19

With the global spread of the ongoing COVID-19 pandemic, we established a COVID-19 task force in mid-March 2020 with the objectives of safeguarding the health and wellbeing of our staff members and monitoring the impact on our vendors and collaborators. Beginning in mid-March 2020, our employees primarily worked from their homes. Since that time, we have formally implemented a work-from-home policy for our employees, with exceptions being made for essential laboratory personnel. To the extent possible, we have reorganized the layout of our offices and laboratories in Cardiff, Wales to conform to social distancing policies and allow laboratory employees to safely return to the workplace, if allowed by their local government.

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Our expectation is that the COVID-19 pandemic is likely to negatively affect businesses globally for an indeterminate period and that, once the pandemic is under control, recovery to normalization will not be instantaneous. Accordingly, we believe governmental limitations on travel will certainly cause delays to timelines. These delays may be the result of a limitation on the number of staff permitted in our facilities at any one time or delays in our vendor's supply chains. In addition, delays have occurred in the recruitment and execution of clinical trials as prospective and enrolled patients are unable to visit clinical sites.

It is not currently possible to quantify the impact of COVID-19 and resultant delays on the Company until it becomes clear that the global crisis has abated and a normalization of the business environment can be foreseen with confidence.

Registered Direct Offering and Private Placement

May 2020 Offering. On May 20, 2020, we completed the closing of a registered direct offering, or Registered Direct Offering, with certain institutional investors, or the Investors, for the sale of 1,818,182 Depositary Shares (representing 9,090,910 Ordinary Shares) at a price per Depositary Share of \$1.65, for aggregate gross proceeds of \$3.0 million.

In a concurrent private placement, we sold to the Investors warrants, or the Private Placement Warrants, to purchase a total of 1,818,182 Depositary Shares (representing 9,090,910 Ordinary Shares) at an exercise price of \$2.05 per Depositary Share. The Private Placement Warrants, which were immediately exercisable, will expire five and one-half years from the issuance date. The closing of the private placement occurred on May 20, 2020. As of December 31, 2020, Private Placement Warrants to purchase 500,000 Depositary Shares had been exercised for an aggregate exercise price of approximately \$1.0 million.

H.C. Wainwright & Co., LLC, or Wainwright, served as the sole placement agent for the transaction. In connection therewith, we also issued to certain designees of Wainwright warrants, or Wainwright Warrants, for the purchase of a total of 90,909 Depositary Shares (representing 454,546 Ordinary Shares) at an exercise price of \$2.0625 per Depositary Share pursuant to the terms of our engagement letter agreement with Wainwright.

The Wainwright Warrants became exercisable on May 18, 2020 and expire May 18, 2025.

United Kingdom Placings

May 2020 Placing. Concurrently with the Registered Direct Offering, on May 22, 2020, we, through Turner Pope Investments Limited, a United Kingdom Financial Conduct Authority registered broker, or TPI, completed a placing with certain investors in the United Kingdom, or the May Placing, of 6,666,666 units, or Units, with each Unit comprising one new Ordinary Share and one warrant exercisable for one new Ordinary Share, or UK Warrant, at an issue price of £0.27 per Unit. The exercise price of the UK Warrants is £0.34 per share, for aggregate gross proceed of £1.8 million. The UK Warrants expire five years and six months from the issuance date.

In connection with TPI acting as the placement agent for the May Placing, we issued to TPI UK Warrants to purchase an aggregate of 333,333 Ordinary Shares, or 5.0% of the aggregate UK Warrants issued in the May Placing.

July 2020 Placing. In July 2020, we, through TPI, completed a placing with certain investors in the United Kingdom, or the July Placing, of 18,518,518 Ordinary Shares, or the Placing Shares. A further 2,777,777 Ordinary Shares, or Broker Option Shares, were placed by TPI pursuant to a broker option. Each of the Placing Shares and the Broker Option Shares were sold at an issue price of £0.27 per share.

Each of the Units, the securities underlying the Units, the Placing Shares and the Broker Option Shares were offered only outside the United States in reliance upon Regulation S under the Securities Act in an offshore transaction.

MTD201 Program

MTD201 is for the treatment of chronic high morbidity neuro hormonal tumors in two indications - acromegaly and neuro endocrine tumors. Currently, this program has completed two Phase I clinical studies and we hope to license MTD201 to a partner for the pivotal registration studies for these two indications.

On January 8, 2020, we announced the positive results of our second Phase I clinical trial, confirming similar pharmacokinetics and bioavailability of octreotide for subcutaneous and intramuscular routes of administration.

As described herein, in light of the remaining costs to complete clinical trials and the manufacturing scale-up for MTD201, we have determined to terminate the further in-house development of MTD201, although the product remains available for licensing. We believe the data from our two Phase I clinical trials demonstrate the clinical utility of our Q-Sphera technology and a number of its features and benefits.

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MTX110 Updates

The first application of our MidaSolve technology is for the treatment of debilitating childhood brain cancers that have no approved therapies. DIPG is an ultra-rare brain cancer, most commonly found in children. We believe MTX110 (soluble panobinostat), which is a 'direct-to-brain' treatment for DIPG and is based on our MidaSolve technology for direct delivery, may be an important advancement in transforming outcomes for patients with this disease.

On October 19, 2020, we announced headline results from a Phase I study at the University of California, San Francisco, or UCSF, in seven DIPG patients. The UCSF study met its primary endpoint, supporting a dose of between 60µM and 90µM of MTX110, depending upon patient tolerance in Phase II. At the interim cut-off date of September 30, 2020, median overall survival based on Kaplan Meier analysis was 26.06 months and overall survival at 12 months was 71.4% (which translated to five of seven patients alive).

We plan to initiate a Phase II study in DIPG to examine efficacy and safety in a further 20 patients. The Phase II trial will also use a convection enhanced delivery, or CED, system, whereby MTX110 will be infused under slight pressure directly into and around the tumor. We believe the primary endpoint of the study is likely to be patient survival rates after 12 months. In addition, we are evaluating an expansion of our MTX110 clinical program to include a small pilot study in glioblastoma multiforme, or GBM.

On January 26, 2021, we announced that we were engaged in tentative discussions with a third party around the potential co-development of MTX110. On March 25, 2021, we announced these discussions had now advanced and a non-binding Heads of Terms had been agreed. The Heads of Terms envisage that, if the deal progresses to definitive agreements, the Company would expect to receive a modest upfront payment upon execution, success-based development and sales milestones and royalties typical for a licensing agreement with products in a similar stage of development. R&D expenses would be assumed by the two parties with the apportionment to be agreed based on their respective territories. There can be no assurance on the timing for concluding the discussions nor any assurance that the parties will enter into definitive agreements.

Governmental Loans and Grants

On September 11, 2019, Midatech Spain received a €6.6 million loan from the Spanish Ministry of Industry, Commerce and Tourism, under its Re-industrialisation Programme, or the REINDUS Loan. The loan was fully drawn down in September 2019, and was partially secured by a guarantee by the Company of €3.0 million in the form of a cash bond. The REINDUS Loan was intended to partially fund activities to scale-up the manufacturing capability of our MTD201 program, however, in connection with our decision to terminate the MTD201 program and shut down our Bilbao, Spain manufacturing facilities, we fully repaid this loan in August 2020. The total amount repaid was approximately €3.6 million (net of deposits returned to us). In addition, we repaid other loans from the Spanish government in connection with this termination. As of December 31, 2020, €119,000 of Spanish government loans remained outstanding. This remaining amount was repaid in February 2021. In February 2021, we received a fine of €149,835 from the Spanish tax authorities in relation to the purported late repayment of the loan. We consider the fine without foundation and are currently appealing it.

On December 5, 2019, we announced that confirmation had been received for a €2.7 million grant from the European Union to be used to conduct a clinical study designed to demonstrate the efficacy of MTX110 as a treatment for DIPG. The grant was subject to, among other things, the Company satisfying to the European Union that it meets the SME criteria of the European Union. Subsequently, the Company was notified that, due to its relationships with the CMS Parties, it did not qualify as an SME and was therefore not eligible to receive the grant.

Change in Executive Officers

On March 31, 2020, we announced that Dr. Craig Cook, our then-Chief Executive Officer and a member of the Board of Directors, resigned from all of his positions with the Company, effective as of such date. Mr. Stamp was appointed by the Board of Directors to succeed Dr. Cook, as well as maintain his position as Chief Financial Officer.

Our Strategy

Our development, manufacturing and commercialization strategy is based on advancing our proprietary technology platforms and programs with a view to partnering these assets during the course of their development. This is expected to drive a commercial pipeline of products with improved essential parameters, over and above the currently marketed source or parent compound, including safety, tolerability, efficacy and compliance profiles. We believe that our management team has significant industry and technical experience and is highly capable of, and committed to, building our value.

Since our announcement of a strategic review in March 2020 and the termination of further in-house development of MTD201, we have sought to broaden our research and development pipeline through technology collaborations with third party pharmaceutical companies, initiating new internal programs and adding new indications to MTX110. Our realigned strategy is to advance our development programs to proof-of-concept

stage, before seeking license partners to fund further development, manufacturing scale-up and commercialization of such programs.

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Development

Our intention is to build a balanced portfolio of Q-Sphera programs employing a strategy to create an:

- internal pipeline of long-acting, injectable products by re-formulating existing, approved therapies; and
- external pipeline by entering into research collaboration with partners to formulate their proprietary products into long-acting injectable products.

We have applied our MidaSolve technology to panobinostat to create our proprietary product MTX110. Our development strategy for MTX110 is to demonstrate its utility in a range of intractable brain cancers with a series of pilot proof-of-concept studies before seeking licensee partners. Once a licensing partner has been secured, we would expect any future development costs to be reimbursed by that partner.

Manufacturing

As part of our strategic review, we decided to close our operations in Bilbao, Spain, including our Q-Sphera dedicated manufacturing facility. To establish proof-of-concept in pre-clinical studies for potential licensees, we are able to manufacture non-GMP Q-Sphera products at pilot scale at our Cardiff, Wales facility. Our intention is to technology transfer manufacture of clinical trial supplies and, ultimately, full GMP commercial manufacture to a third party CMO. We would expect a licensee to assume the cost of manufacturing GMP product and commercial scale-up pursuant to a technology transfer agreement.

MTX110 is currently being manufactured to GMP standards at a CMO.

Commercialization

Once proof-of-concept has been established, we intend to seek to license our products to a partner who would complete the development, and subsequently market and sale, of the product in an agreed upon licensed territory. In addition to reimbursement of development costs, the partner would be expected to make milestone payments based on sales targets and royalty payments.

Our Platform Technologies and Pipeline

Central to our business are our three complementary platform technologies that enable the sustained release, direct local delivery, or targeted delivery improvement to previously approved therapeutic drugs. Individually, these platforms are expected to offer unique advantages that address current therapeutic challenges and needs. Our sustained release “Q-Sphera” technology platform is used for selected applications, and ensures consistently sized monodispersed polymer microparticles that may be engineered for precise and sustained release drug delivery. Our GNP “MidaCore” technology platform may provide improved targeting of chemotherapeutics agents to individual tumors using specific targeting agents in order to deliver a therapeutic payload into the tumor cell, while at the same time decreasing the side effect profile associated with off-target effects of these drugs. Our nano-inclusion technology platform, “MidaSolve,” used for local delivery of therapeutics, allows for the delivery of generally water insoluble drugs into the site of disease through the creation of water soluble complexes without the efficacy of the active drug compound being affected. Individually and collectively, we believe that these technologies provide platforms that improve bio-delivery and bio-distribution of therapeutic molecules to the right place of disease, at the right time.

In 2020, following our strategic review, we pivoted from a largely singular focus on the clinical development and manufacturing scale up of MTD201 to a strategy based on a broader, but earlier stage, pipeline designed to optimize opportunities for partnering success. Our development pipeline includes 10 projects, of which three are partnered with the European affiliate of a global healthcare company, and as set forth in more detail below:

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ID	API	Therapeutic Area	Administration	Formulation	Pre-clinical	Phase I	Phase II	Partnering Status
Q-Sphera								
MTD211	Small molecule	CNS	Long acting injectable					
MTD219	Small molecule	Anti-rejection	Long acting injectable					
MTD201	Octreotide	Carcinoid cancer and acromegaly	Long acting injectable	In-house development terminated				
MTX213	Undisclosed	Undisclosed	Undisclosed					Partnered
MTX214	Undisclosed	Undisclosed	Undisclosed					Partnered
MTX216	Undisclosed	Undisclosed	Undisclosed					Partnered
MidaSolve								
MTX110	Panobinostat	Brain cancer in children (DIPG)	Direct to tumour via CED					
MTX110	Panobinostat	Medulloblastoma	Direct to tumour					
MTX110	Panobinostat	Glioblastoma	Direct to tumour via CED					
MidaCore								
MTX114	Methotrexate	Psoriasis Immuno-rx	Topical					

Sustained Release Technology Platform: Q-Sphera

Technology. Our Q-Sphera technology employs 3-D printing techniques to encapsulate medicines in polymer-based bioresorbable microspheres. Q-Sphera is a precise, scalable, efficient, and environmentally friendly microparticle manufacturing platform. From a clinical perspective, Q-Sphera ensures monodispersed microparticles that release active drug compounds into the body in a tightly controlled, highly predictable and linear manner over an extended period of time.

Q-Sphera is the next generation polymer microsphere technology which simplifies manufacturing, facilitates the sustained release of previously unachievable products and delivers formulations with significant patient, healthcare professional and payor benefits. Our polymer microsphere platform has been developed to enable sustained release delivery solutions for peptide and small-molecule therapeutics through precise definition of the properties of polymer microparticles into which active compounds can be incorporated. Microspheres are small, spherical particles that can be utilized as a time release drug capsule. This technology contributes to our oncology franchise as well as potential applications in endocrinology

and other disease areas.

Current reactor-based emulsion manufacturing technology has been in use for over 20 years and, despite several issues, it continues to be used by the vast majority of the market as there are limited alternatives. Reactor-based emulsion processes, used by most existing products, require large infrastructure, are energy intensive, inefficient and wasteful, producing large quantities of unusable particles, and utilize large volumes of toxic organic solvents that are damaging to the environment.

The microspheres may be injected to form depots in the body, which release drugs over predictable, sustained periods from one week up to several months. We believe Q-Sphera offers numerous potential advantages to patients and payors compared with other immediate release products and polymer-based technologies, as set forth below:

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Features	Benefits	Advantages of Q-Sphera			
		For patients	For payors	Compared with immediate release products	Compared with other polymer-based systems
Biocompatible, bio-degradable microspheres	Safe, sustained release delivery of therapeutics with substantially increased dose intervals	•		•	
Homogenous, monodispersed microspheres	Lower dose to dose variability and improved injectability	•	•	•	•
Tunable, predictable drug release	Low variability plasma levels within a targeted therapeutic window	•	•	•	•
Easier reconstitution and adaptable to a wide range of presentations	Nurse or self-administration. Easy to use, safer pre-filled syringe and ‘pen’ presentations	•	•		•
Low viscosity, smaller gauge needles	Reduced severity and frequency of injection site reactions. Higher doses with subcutaneous and/or self-administration	•	•		•
Localized delivery, including intratumoral, intraocular, peritoneal and intraarticular	Reduced systemic side effects	•	•	•	
Small footprint, reliable and scalable manufacturing process	Lower cost of manufacture				•
Class 3 solvents in low volume	Less environmental impact and lower cost of manufacture				•

Pipeline. We have an internal Q-Sphera pipeline comprising MTD211 and MTD219 for central nervous system and transplant anti-rejection indications, respectively. The active pharmaceutical ingredients included in MTD211 and MTD219 are already marketed as immediate release products and both are currently undergoing pre-clinical in vivo studies to demonstrate proof-of-concept. If successful, MTD211 and MTD219 will be made available for licensing to partners for their continued clinical development.

MTD201. Following the announcement of a strategic review, we ceased further in-house development of MTD201, our Q-Sphera formulation of octreotide for acromegaly and neuroendocrine tumors. We completed two clinical trials for MTD201, a 2018 first-in-human Phase I study compared MTD201 with Novartis’ SLAR, and second Phase I study of MTD201 completed in January 2020 which compared subcutaneous administration with intramuscular administration in healthy volunteers and showed similar pharmacokinetics and bioavailability in healthy volunteers. Together, the two Phase I studies of MTD201 serve as clinical validation of the Q-Sphera technology, confirming many of Q-Sphera’s features and benefits for patients, payors and licensees.

MidaSolve: Local Delivery Technology Platform

Technology. Our MidaSolve nano inclusion technology is utilized for potent, small molecule chemotherapeutics that have minimal solubility in water at biological pH, which means they cannot normally be injected and limits them to oral administration in solid form. When reformulated with MidaSolve technology, the complexed molecules solubilize such that the molecule can be administered in liquid form into the body. This enables local infusion directly into the tumor, thus extending the available routes of administration for drugs that otherwise would be limited to oral forms only.

The complexed molecules comprise a hydrophobic (‘water-fearing’) inner surface and a hydrophilic (‘water-loving’) outer surface, and as a result are capable of forming host-guest complexes with normally water-insoluble molecules. A hydrophobic, poorly water-soluble drug can associate with the inner, more hydrophobic surface of the MidaSolve host, while the hydrophilic outer surface allows the complex to dissolve at biological pH.

MTX110. Using our MidaSolve technology in combination with panobinostat, an otherwise insoluble drug, MTX110 is designed for direct-to-tumor treatment of intractable brain cancers. The resulting complex is readily soluble in water at therapeutic concentrations, thus enabling liquid administration routes directly into the tumor that otherwise would not be possible. Panobinostat (Farydak®) is a potent, nonselective histone deacetylase inhibitor that was developed for the treatment of multiple myeloma. Given in its natural oral form, panobinostat does not cross the blood-brain barrier, and thus does not reach brain tumors. It is also a highly toxic substance and, when given orally, suffers from significant dose-limiting side effects. MidaSolve allows an alternate means of delivery in liquid form, and MTX110, our soluble form of panobinostat, is infused directly into the tumor. Direct delivery of MTX110 bypasses the blood-brain barrier and ensures adequate drug exposure to tumor cells without exposing the rest of the body to potentially toxic concentrations. MTX110’s intratumoral delivery thus provides a significant potential for treatment of DIPG and, potentially, other forms of brain cancer.

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We are currently researching the utility of MTX110 to proof-of-concept stage in the following three indications.

- **DIPG.** DIPG tumors are located in the pons (middle) of the brain stem and aggressively infiltrate the brainstem such that cancer tissue typically cannot be differentiated from normal brain tissue. Occurring mostly in children, approximately 1,000 patients are

diagnosed with DIPG per annum and median survival is approximately 10 months. There is no effective treatment as surgical resection is not possible, and radiotherapy and chemotherapy do not improve survival since anti-cancer drugs cannot cross the blood-brain barrier to access the tumor.

In October 2020, we reported the first-in-man study by UCSF of MTX110 in DIPG using a CED system. The Phase I study established a recommended dose for Phase II, a good safety and tolerability profile but also encouraging survival data in the seven patients treated. We are in the process of planning for a Phase II study to confirm the safety and efficacy of MTX110 in DIPG.

On October 24, 2019, we announced that the FDA has granted orphan drug designation for MTX110. Orphan drug designation is granted to support the development of drugs that target rare diseases with high unmet needs, affecting 200,000 or fewer U.S. patients annually, and that are expected to provide significant therapeutics advantages over existing treatments. Orphan designation qualifies a company for benefits that apply across all stages of drug development, including an accelerated approval process, seven years of market exclusivity upon regulatory approval, if received, tax credits for qualified U.S. clinical trials, eligibility for orphan drug grants and exemption from certain administrative fees.

- **Medulloblastoma.** Medulloblastomas are generally located in the fourth ventricle of the brain between the brainstem and the cerebellum. They are invasive and, unlike most brain tumors, spread through cerebrospinal fluid, or CSF, and frequently metastasize to different locations in the brain and spinal cord. Treatments include resection, radiation and chemotherapy. Approximately 350 patients are diagnosed with medulloblastoma per annum, and 3,800 people are living with the disease in the United States. The cumulative survival rate is 60%, 52% and 47% at five years, 10 years and 20 years, respectively. The University of Texas is undertaking a Phase I exploratory study in medulloblastoma using direct administration of MTX110 into the fourth ventricle of the brain, enabling it to circulate through the CSF.
- **Glioblastoma Multiforme.** Glioblastoma multiforme, or GBM, is one of the most aggressive forms of cancer and glioblastomas usually occur in the white matter of the cerebrum, although metastasis through the CSF to the spinal cord is rare. Treatments include radiation, surgical resection and chemotherapy although, in almost all cases, tumors recur. There are approximately two to three new cases of GBM per 100,000 people per annum, with median survival of approximately 12 months.

We are currently in the process of planning a Phase I exploratory study to assess the utility of MTX110 in GBM.

For additional information regarding MTX100, see “Recent Developments-MTX110 Updates.”

Secura Bio. On June 8, 2020, we received a letter sent on behalf of Secura Bio, dated June 1, 2020, purporting to terminate the Secura License Agreement. Pursuant to the Secura License Agreement, Midatech Limited was granted a non-exclusive worldwide, sublicenseable license to certain patents of panobinostat, the active pharmaceutical ingredient of our development product MTX110. Midatech Limited’s rights are limited to the treatment of brain cancer in humans, administered by convection-enhanced delivery. We plan to continue to pursue development of MTX110 and the strategic review process previously disclosed. For more information, see “Recent Developments-Secura License Agreement.”

MidaCore: Targeted Delivery Platform

Technology. MidaCore is a leading innovation in ‘ultra-small’ nanomedicine and is designed for targeted delivery to enable improved delivery of therapeutics to tumor cells and the immune system. In oncology treatments MidaCore provides a nano complex (less than 5nm in size, or approximately 80,000 times smaller than the width of a hair) that carries conventional small molecule chemo-therapeutic payloads and delivers these to the tumor site in high concentrations. In immunotherapy, treatments, MidaCore acts as a nanocarrier complex for synthetic immuno-peptides that stimulate the immune system to seek out and destroy cancer cells via immune mediated vaccine processes. These small complexes can enter immune processing cells to induce T-cell mediated immune responses specifically against tumor cells, viral infected host cells or autoimmune disease.

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The MidaCore technology platform is based upon ‘ultra-small’ nanoparticle drug conjugates, which at 2-4nm in size are among the smallest particles in biomedical use. They are composed of a core of gold atoms decorated with a permutation of therapeutic and/or targeting molecules. The small size and multi-functional arrangement around the gold core underpin the ability to improve biodistribution, and target tumor and/or immune sites providing a new generation of oncology drugs.

MidaCore design and synthesis GNP technology enables the production of 2nm to 5nm medications, which we believe is roughly five-to-tenfold smaller than any other delivery vehicle in clinical trials. MidaCore’s therapeutics are comprised of a core of gold atoms (approximately 100 gold atoms per GNP) surrounded by an organic layer of carbohydrates that stabilize the metallic core and make the particle water-soluble and biocompatible.

MTX114. Using MidaCore technology, we have developed a re-engineered version of methotrexate, an immuno-suppressant for topical application in psoriasis. If successful, MTX114 would be a first topical formulation of methotrexate, thus avoiding the need for potentially toxic systemic administration. Pre-clinical data suggest MTX114 may reduce inflammation in a psoriatic skin model. There are estimated to be over 100 million people who suffer from psoriasis worldwide.

Certain other indications using GNP technology have been licensed to Emergex Vaccines.

Commercial Agreements, Strategic Partnerships and Collaborations

We are currently collaborating with a number of biopharmaceutical companies, research institutes and universities on several of our development programs involving our core technologies.

Q-Sphera Collaborations. On June 8, 2020, we announced that we had entered into a research and development collaboration with Dr. Reddy’s Laboratories Ltd., or Dr. Reddy’s, to deploy our in-house expertise and proprietary drug delivery platforms towards comprehensive improvement of bio-delivery and bio-distribution of certain medicines nominated by Dr. Reddy’s. After some initial work, the collaboration was mutually terminated in January 2021 for reasons of technical feasibility.

On July 21, 2020, we announced a collaboration with the European affiliate of a global pharmaceutical company to deploy our in-house expertise and proprietary drug delivery platforms towards product candidates nominated by the collaborating company. This collaboration has, at the option of our partner, been subsequently expanded to three products.

CMS License Agreement. On January 29, 2019, we entered into the CMS License Agreement with CMS, as guarantor, and the Licensees. The CMS License Agreement was effective as of February 26, 2019. Pursuant to the terms of the CMS License Agreement, we agreed to license to the Licensees the exclusive right to use our technology and our intellectual property rights and information and data related to certain of our clinical and pre-clinical products (i.e. MTD201, MTX110, MTX102, MTR103 and MTD119), together with any other pipeline products or line extensions which are in or which enter pre-clinical or clinical development in the first three years following the effective time of the CMS License Agreement, together the Products, to develop and commercialize the Products in China, including Macau, Hong Kong and Taiwan, with the same rights in certain countries in south east Asia in respect of which the Licensees notifies us that such licensee wants a license after the grant of a regulatory approval of any of the Products by the FDA, EMA or by the regulatory authorities in the United Kingdom, France, Germany or Switzerland,

collectively the Territory, such activities to be conducted by the Licensee(s) and affiliates of CMS and local partners as permitted sub-licensees. The Licensees have the exclusive right to import, obtain market approvals and register, market, distribute, promote and sell the Products in the Territory at the Licensees' sole discretion, and in the event we choose not to or fail to meet the Licensees' binding orders for the Products under certain circumstances, will be granted the right to manufacture the Products itself. The Licensees will be restricted from supplying the Products to any customers outside of the Territory, while we will be restricted from supplying the Products into the Territory, except through the Licensees. In addition, we agreed to assist the Licensees (and/or any affiliate of CMS) with their applications for marketing approvals for the Products in the Territory, which approvals, if granted, will be exercised by CMS Bridging or CMS Medical HK, unless it is being transferred to us when we are entitled to terminate the CMS License Agreement for material breach by CMS Bridging or CMS Medical HK. We will manufacture the Products for the Licensees and their sub-licensees, which Products will be subject to exclusive purchase and supply arrangements with the Licensees for the Territory.

Further, we agreed to permit the Licensees to identify their own product and line extension targets in respect of which, if we agree, we will carry out initial development and then will, for a technology transfer fee, the amount of which will be dependent on the circumstances, transfer the specific program know-how and data to enable the Licensees to continue to develop using our platform technologies and then to commercialize in the Territory. We will receive a low single digit royalty on the Net Sales (as such term is defined in the CMS License Agreement) in the Territory. The Licensees will own any intellectual property rights it creates and any data they collect during the development process and will license such rights and data to us for the purposes of manufacturing the products in question and also to commercialize the products outside the Territory, for which we will pay the Licensees a low double digit royalty.

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The Licensees shall pay us lump sum payments on a Product-by-Product basis (in U.S. dollars) upon the achievement of certain regulatory approvals (in six, or potentially seven, figure amounts) and sales performance milestones (in seven, or potentially, eight figure amounts), as well as royalties upon Net Sales (as a low double digit percentage for the Products other than MTX110, for which the royalty will be a single digit percentage) in the Territory.

The CMS License Agreement may be terminated by either party for specific material breaches or insolvency. In particular, our rights to terminate are limited to breaches of certain non-compete restrictions, failure to pay milestones or royalties, insolvency, or a failure to develop and/or commercialize particular Products in particular countries after the grant of an FDA or EMA regulatory approval. In addition, we have the right to terminate the agreement if the Licensee directly or indirectly infringes upon our intellectual property rights or challenges their validity or, in relation to a particular Product and a particular Territory at any time, because the Licensee has made a determination that it no longer wishes to develop and/or commercialize the Product in that country in the Territory. The CMS License Agreement also includes customary indemnification for a transaction of this type.

Secura License Agreement. On or about June 6, 2017, our subsidiary, Midatech Limited, entered into the Secura License Agreement with Novartis, pursuant to which Novartis granted it a non-exclusive worldwide, sublicenseable license to research, develop and commercialize, under Novartis patents, the Novartis oncology compound panobinostat, used for the treatment of brain cancer in humans, administered by CED. Subsequently, Novartis transferred the license and related agreement to Secura Bio.

Under the terms of the Secura License Agreement, Midatech Limited was required to make an upfront flat fee payment in the low seven figures in United States dollars, and will be required to make certain milestone payments to Secura Bio of up to an aggregate of \$48 million if certain regulatory and commercial events are achieved. Midatech Limited must also make royalty payments based on expected sales of the licensed product, with rates ranging from the mid-teens to mid-twenties based on net sales of the licensed products. Pursuant to the terms of the agreement, the license will continue until the expiration of the royalty term (as defined in the agreement) for the last licensed product, unless earlier terminated pursuant to its terms.

On June 8, 2020, we received a letter sent on behalf of Secura Bio purporting to terminate the Secura License Agreement. We plan to continue to pursue development of MTX110. For more information, see “-Recent Developments-Secura License Agreement.”

Consejo Superior De Investigaciones Cientificas. In June 2002, CSIC and Midatech Limited, the Company's predecessor entity, entered into a patent and know-how agreement, whereby CSIC granted Midatech Limited an exclusive license to exploit its patent and know-how rights in any field and anywhere in the world where those patents are registered, and to make applications to register such patents throughout the world in CSIC and Midatech Limited's joint names, provided that CSIC may use the patents and know-how for the purpose of performing a research agreement between CSIC and Midatech Limited, to deal in products supplied to it by Midatech Limited and to perform research for its own non-commercial purposes. CSIC also assigned to Midatech Limited PCT Application Number PCT/GB01/04633. The agreement between the parties was amended on October 14, 2004 so as to specifically include magnetic nanoparticles in the scope of the license and rights granted to Midatech Limited. The patents and know-how are considered by Midatech to be core to its business.

Pursuant to the terms of the agreement, CSIC is obliged to reassign the patents into Midatech Limited's sole name within 14 days of Midatech accomplishing one of the following:

- concluding a license agreement with a third party in respect of any of the intellectual property rights comprising the subject matter of the agreement;
- demonstrating therapeutic and/or diagnostic efficacy in an animal model derived from research sponsored by Midatech (or its affiliated companies);
- demonstration of a diagnostic product in Phase I clinical trials arising from intellectual property rights; or
- selling products made by Midatech, affiliated companies or licensees exploiting the intellectual property rights comprising the subject matter of the agreement which generate net sales royalties or net revenue royalties for CSIC.

As of the December 31, 2020, Midatech had accomplished all of the above milestones other than milestone related to the sale of products, and may therefore request that the relevant patents are assigned to it.

Midatech Limited is under an obligation to pay the following royalties to CSIC in prescribed circumstances following the commercialization of the relevant intellectual property:

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Cumulative Sales Amount	Royalty
Net Sales to €1 million	6%
Net Sales between €1 million and €9,999,999	5%
Net Sales between €10 million and €99,999,999	4%
Net Sales €100 million and above	3%

As of December 31, 2020, no royalties have been due or payable to CSIC.

Either party may terminate the agreement upon the insolvency of the other party or a material breach that is not remedied within 30 days' notice.

Sales and Marketing.

We do not currently have any internal sales and marketing organization or distribution capabilities.

Research and Development

We have a polymer micro-sphere laboratory in Cardiff, Wales used for development purposes only of our sustained release technology. We also have pilot scale manufacturing facilities for Q-Sphera and MidaCore products in Cardiff, Wales.

As of December 31, 2020, the research and development staff comprised approximately five Ph.D. scientists, six MSc scientists and four BSc scientists.

Intellectual Property

Our success depends in large part on our ability to obtain and maintain proprietary protection for our product candidates (and products derived therefrom), technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We strive to protect the proprietary technology that we believe is important to our business by, among other methods, seeking and maintaining patents, where available, that are intended to cover our product candidates (and products derived therefrom), compositions and formulations, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary and competitive position.

We have developed a strong intellectual property base globally, comprising patents, know-how, and trade secrets. Currently, we have 108 granted patents, 57 applications in process, in each case covering all major world markets, and 35 separate patent families covering all major regions. We continue to strengthen our patent portfolio by strategically submitting new patents and divisional patent applications based on our active research and development activities. Central to our business are our three intellectual property technologies that are designed to enable the targeted delivery, i.e. right place, and controlled sustained release, i.e. right time, of existing therapeutic drugs. These technologies have broad applications in multiple therapeutic areas and offer the potential to create multiple revenue opportunities.

Patent rights have been granted in all the major world markets, including Europe, the United States and Japan, or the Key Markets. They confer a broad position of exclusivity for metal-core glycosylated-nanoparticles, including our GNPs. Our granted patents in our patent family 1 (expiring 2021) provide the foundation to the portfolio with product, process and use claims that encompass the GNPs used in all of our major programs and technology platforms, including oncology, nanoparticle technology and sustained release technology. The granted patents and pending patent applications in our patent families are owned solely by us, co-owned with other parties or in-licensed to us. These include:

- *Sustained release technology.* 12 patent families which protect devices, methods and formulations for sustained release drug delivery.
- *Oncology including Nano-inclusion technology.* Nine patent families, which have predicted expiration dates ranging from 2025 to 2040. These patent rights include 15 granted patents and 24 pending applications in Key Markets relating to products and methods for treating and imaging cancers. In addition to the radiative and immune-based therapies contemplated by many of these patent families, our pipeline of GNP-drug conjugates for oncology benefits from protection by the foundation GNP patents of patent family 1.
- *Nanoparticle technology.* 14 patent families, with expiration dates ranging from 2021 to 2040. These patent families include 59 granted patents and nine pending patent applications in Key Markets protecting products in our pipeline.

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We also have in our portfolio several vaccine and infectious disease related patent families. These relate to GNPs for immune-based therapy and antibiotic-GNP conjugates. We acquired through the Q Chip transaction patent applications directed to the apparatus and methods of "Q-Sphera" technology, which employs a piezoelectric droplet generator to form polymeric microparticles that encapsulate a drug for sustained release. The combination of our GNP technology with Midatech Wales' sustained release technology has provided possibilities for new formulations of GNP-drug conjugates. Our GNPs, when encapsulated in Midatech Wales' microparticles, enjoy patent protection conferred by the existing granted patents.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the filing date of a non-provisional patent application. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent.

The term of a United States patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for patent term extension when FDA approval is granted, provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug, provided that statutory and regulatory requirements are met. Thus, in the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates of our patents and patent applications referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology and maintain our competitive position. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, corporate and scientific collaborators, consultants, scientific advisors, contractors and other third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Government Regulations

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union and the United Kingdom, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. As we have disclosed herein, we are seeking to license our products candidates and other formulations to licensing partners. While many of the rules and regulations set forth herein do and will apply to us, some are more applicable to any licensing partner who seeks to conduct clinical trials, obtain regulatory approval and commercialize any of formulations or product candidates, which could

have an impact on any licensing revenue received by us.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, exclusion from participation in government sponsored insurance programs such as Medicare, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or the DOJ, or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, which must take effect before human clinical trials may begin;

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- approval of clinical protocols by an independent institutional review board, or IRB, representing each clinical site before each site may enroll subjects;
- potential initiation and completion of successive clinical trials that establish safety dose ranges;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA, or a biologics license application, or BLA;
- review of the submission by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- agree to comply with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or API and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the clinical trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, Phase I, Phase II and Phase III, which may overlap or be combined.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

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Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently \$2,942,965, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently \$325,424. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses. The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of

the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for “priority review” products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients, or API), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product’s NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA’s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

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In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as “breakthrough therapies.” A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA’s goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of

therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

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Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health

insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

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The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Patent Term Restoration and Extension

The term of a United States patent that covers a drug, biological product or medical device approved pursuant to a PMA may also be eligible for patent term extension when FDA approval is granted, provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a

patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug may be extended. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug, provided that statutory and regulatory requirements are met. The United States Patent and Trade Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

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Regulation and Marketing Authorization in the European Union

The process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable European Union Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced current cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant European Union regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice, or GCP, and the related national implementing provisions of the individual European Union Member States govern the system for the approval of clinical trials in the E.U. Under this system, an applicant must obtain prior approval from the competent national authority of the European Union Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual European Union Member States and further detailed in applicable guidance documents.

In April 2014, a new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation), or Clinical Trials Regulation, was adopted which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new European Union clinical trials legislation was passed as a “regulation” that is directly applicable in all European Union member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation becomes applicable. Although the new Clinical Trials Regulation entered into force on June 16, 2014 the timing of its application depends on the development of a fully functional Clinical Trial Information System (CTIS), which will be confirmed by an independent audit. It is currently envisaged for the CTIS to go live in December 2021, but given the delays experienced in the past, there is some uncertainty to this date. The new Clinical Trial Regulation becomes applicable six months after the European Commission publishes a notice of this confirmation. Despite not yet being in force, the Clinical Trial Regulation is being treated as the template with respect to the emphasis it places on the need for transparency, accuracy and fairness in reporting clinical data.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the “E.U. Portal and Database”; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the appointed reporting Member State, whose assessment report is submitted for review by the sponsor and all other competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States). Part II is assessed separately by each Concerned Member State. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the Concerned Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

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As in the United States, similar requirements for posting clinical trial information are present in the European Union (EudraCT) website: <https://eudract.ema.europa.eu/> and other countries.

PRIME Designation in the European Union

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRiOritY Medicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies, or CAT, are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Marketing Authorization

To obtain a marketing authorization for a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the European Union Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across the European Economic Area (i.e. the European Union as well as Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. The centralized procedure may at the request of the applicant also be used in certain other cases.

Under the centralized procedure, the CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of European Union law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product the European Commission must consult the Standing Committee on Medicinal Products for Human Use. The Standing Committee is composed of representatives of the European Union Member States and chaired by a non-voting European Commission representative. The European Parliament also has a related "droit de regard." The European Parliament's role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

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- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radiopharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of a marketing authorization of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" marketing authorization. Thus, a marketing authorization under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products), if (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. The European Union medicines rules expressly permit the European Union Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain

European Union Member States may prohibit or restrict us from commercializing our products, even if they have been granted a European Union marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each European Union Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference European Union Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned European Union Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned European Union Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all European Union Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the European Union Member States of the marketing authorization of a medicinal product by the competent authorities of other European Union Member States. The holder of a national marketing authorization may submit an application to the competent authority of a European Union Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union Member State.

Regulatory Data Protection in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance to the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator's data to assess a generic (abridged) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

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Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the E.U. Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the E.U. Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the E.U. market (in case of centralized procedure) or on the market of the authorizing E.U. Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Paediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Regulatory Requirements after a Marketing Authorization has been Obtained

In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83/EC, as amended, and European Union Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

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Orphan Drug Designation and Exclusivity

The European Commission, following an evaluation by the EMA's Committee for Orphan Medicinal Products, has designed MTX110 as an orphan medicinal product. Pursuant to Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000, the European Commission can grant orphan

medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the European Union, or a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that sales of the drug in the European Union would generate a sufficient return to justify the necessary investment. In addition, the sponsor must establish that there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

Orphan drug designation is not a marketing authorization. It is a designation that provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization, as well as ten years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, the European Commission nor the member states can accept an application or grant a marketing authorization for a "similar medicinal product". A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as those contained in an authorized orphan medicinal product and that is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may in limited circumstances be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan drug. Furthermore, a product can lose orphan designation, and the related benefits, prior to us obtaining a marketing authorization if it is demonstrated that the orphan designation criteria are no longer met.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union's General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

Pricing Decisions for Approved Products

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each European Union member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

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A six month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

United Kingdom Regulation

From January 1, 2021, European Union law no longer directly applies in the United Kingdom. The United Kingdom has adopted existing European Union medicines regulation as standalone United Kingdom legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions.

In order to market medicines in the United Kingdom, manufacturers must hold a United Kingdom authorization. On January 1, 2021, all European Union marketing authorizations were converted to United Kingdom marketing authorizations subject to a manufacturer opt-out. For a transitional period, Great Britain will adopt decisions taken by the European Commission on the approval of new marketing authorizations in the community marketing authorization procedure. Such applications must include all information provided to the EMA during the relevant licensing procedure including the final CHMP opinion. The MHRA's guidance states that the United Kingdom will have the power to take into account marketing authorizations made under the European Union decentralized and mutual recognition procedures. In addition, the MHRA's guidance has been updated to refer to new national licensing procedures including new routes of evaluation for novel and biotechnological products.

United Kingdom medicines legislation is subject to future regulatory change under the Medicines and Medical Devices Act 2021. This act sets out a new framework for the adoption of medicines regulation.

Different rules will apply in Northern Ireland following implementation of the Northern Ireland Protocol. In Northern Ireland, European Union central marketing applications will continue to apply.

The Trade and Cooperation Agreement contains an Annex in relation to medicinal products with the objective of facilitating availability of medicines, promotion of public health and consumer protection in respect of medicinal products between the United Kingdom and the European Union. The Annex provides for mutual recognition of Good Manufacturing Practice (GMP) inspections and certificates, meaning that manufacturing facilities do not need to undergo duplicate inspections for the two markets. The Annex establishes a Working Group on Medicinal Products to deal with matters under the Trade and Cooperation Agreement, facilitate co-operation and for the carrying out of technical discussions. It is expected that further bilateral discussions will continue with respect to regulatory areas not the subject of the Trade and Cooperation Agreement, including pharmacovigilance. The Trade and Cooperation Agreement also does not include reciprocal arrangements for the recognition of batch testing certification. However, the United Kingdom has listed approved countries, including the EEA which will enable United Kingdom importers and wholesales to recognize certain certification and regulatory standards. The European Commission has not adopted such recognition procedures.

It is expected that the establishment of a separate United Kingdom authorization system, albeit with transitional recognition procedures in the United Kingdom, will lead to additional regulatory costs. In addition, additional regulatory costs will be incurred with respect to the lack of mutual recognition of batch testing and related regulatory measures.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

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- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the ACA requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Additionally, similar healthcare laws and regulations in the European Union, United Kingdom and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as GDPR and UK GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data).

Finally, the majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. Some states and local jurisdictions require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

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Coverage and Reimbursement

The future commercial success of our product candidate or any of our collaborators' ability to commercialize any approved product candidate successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidate. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government, through the Medicare or Medicaid programs, provides reimbursement for such treatments. In the United States, the United Kingdom, the European Union, and other potentially significant markets for our product candidate, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the United Kingdom and European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidate may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidate or exclusion of our product candidate from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidate in whole or in part.

Healthcare Reform

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidate. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidate, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product on a profitable basis.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expanded eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the Public Health Service pharmaceutical pricing program. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect such challenges and amendments to continue. Since January 2017, President Trump has signed Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA.

While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. The U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made.

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Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year

2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Trump administration previously released a blueprint for action, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration’s proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, the Centers for Medicare and Medicaid Services issued an interim final rule implementing President Trump’s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives, we expect the Biden administration will overturn several of the last minute regulations and waivers approved by the Trump administration, including Medicaid work requirements. In fact, the administration on his first day issued a regulatory freeze to all federal agencies and requested agencies delay the effective date of new regulations until the new appointed agency head has reviewed those regulations.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

As a result of the ACA, Medicare payments are increasingly tied to quality of care and value measures, and reporting of related data by providers such as physicians and hospitals. So called “value based reimbursement” measures may present challenges as well as potential opportunities for biopharmaceutical manufacturers. Medicare incentives for providers meeting certain quality measures may ultimately prove beneficial for manufacturers that are able to establish that their products may help providers to meet such measures. However, manufacturers' ability to market their drug products based on quality or value is highly regulated and not always permissible. In addition, potentially decreased Medicare reimbursement to those providers that fail to adequately comply with quality reporting requirements could translate to decreased resources available to purchase products and may negatively impact marketing or utilization of our product candidate if it is approved for marketing. We cannot predict at this time what impact, if any, the longer-term shift towards value based reimbursement will have on our product candidate in either the Medicare program, or in any other third-party payor programs that may similarly tie payment to provider quality.

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In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011 was enacted, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted and, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding. For example, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. There have been, and likely will continue to be, additional legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Competition

Our drug conjugate platform is among the latest generation of nanomedicine technology. Liposomes, an artificially prepared spherical vehicle composed of a lipid bilayer that can be used as vehicle for the administration of nutrients and drugs, followed by various polymeric nanoparticles, were the first nanotechnologies, and now inorganic nanoparticles like our GNPs are emerging as the fastest growing sector within the nanomedicine market. The speed and nature of technological change means that physical science is always evolving and new competition and alternatives are always a possibility, however we believe that we have established competitive advantage over our peers. As a result of the combination of our platform technology, intellectual property and proprietary know-how, we have a protected position in the nanoparticle space which allows the potential for highly differentiated drugs serving high unmet needs like orphan oncology to be rapidly and independently manufactured and scaled.

Competitive Dynamics

Barriers to entry for competitors are high. The significant level of capital, scientific capabilities, and infrastructure required to achieve what we have achieved to date may deter new entrants. A high degree of specialization and expertise in equivalent drug conjugate and sustained release technologies and relevant therapeutic areas is essential for any competitor to succeed, which we have built up over many years since inception. While the power of suppliers has been relatively low given our development manufacturing capabilities, with the reduction in these capabilities the power of suppliers will likely increase. The power of buyers, i.e. pharmaceutical companies, is important insofar as they may be partners for the commercialization and distribution of our product candidates. Even for large pharmaceutical companies, the know-how, manufacturing, and effort involved in developing alternative products to us would potentially see them engage as partners rather than as competitors. Competitive pressures or substitutes for our compounds come from conventional small molecules or biologics (such as antibody drug conjugates). There is a growing trend for drugs to be produced using biotechnologies and it is likely that the main threat in the future will come from this class, albeit the costs of production and development are much higher, and the regulatory pathways more complex.

Competitive Technology

The main competing nanotechnologies are liposomes, polymers, carbon assemblies and other inorganic/metallic platforms. Carbon assemblies are not widely used in healthcare applications. Most nano activity has traditionally involved liposomes and polymers. More recently, the focus has moved to include inorganic nanoparticles using solid cores whereas ours is one of a few companies using gold. To the best of our knowledge, we

are the only company using non-colloidal gold (colloidal gold is defined as larger GNPs 10-15nm and more, whereas our core GNP construct is less than 2nm) and are sufficiently progressed with the technology to have undertaken Phase II clinical trials. We believe we are therefore well positioned versus the other technologies and companies providing a differentiated platform that imparts favorable characteristics in drug delivery, including targeting and mobility, solubility (for otherwise non soluble compounds), stability (of peptides), compatibility (inert and biocompatible) and highly controlled delivery and release in the cell.

Competitive Therapeutic Areas

Much of the historical and current focus and activity of the nanomedicine market is oncology. Within this domain, we believe we are well positioned given our focus on selected orphan oncology applications where unmet needs persist, an accelerated regulatory process is possible and fewer companies compete (reflecting the challenges that need to be addressed). With our sustained release technology, the ability to address shortcomings of other controlled technologies such as burst, lag, release profile and consistency enables us to pursue unmet opportunities such as sustained release octreotide, which to date has no generic competition despite being off patent for many years. Our nano inclusion technology conjugates solubilize cancer drugs that could otherwise not be administered directly into tumors.

Competitive Companies

Our Q-Sphera technology for biodegradable sustained-release formulation takes a microsphere-based approach that is based on printing individual microspheres. It enables next-generation formulation and engineering. We believe other companies in the sustained release space include MedinCell S.A., GP Pharm, S.A., Peptron, Inc., Graybug, Inc. and Nanomi B.V.

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From a technology perspective, we believe other companies using GNP technologies include CytImmune Sciences, Inc., and Nanospectra Biosciences, Inc. Some companies use larger colloidal GNPs of 10 to 15nm or bigger, whereas we typically use non-colloidal gold cores smaller than 5nm.

Manufacturing

Following the closing of our Bilbao, Spain operating facilities, we no longer have our own manufacturing facilities.

To establish proof-of-concept for potential licensees, we are able to manufacture non-GMP material at pilot scale at our facility in Cardiff, Wales. We would expect a licensee to assume responsibility for manufacturing GMP material and commercial scale-up pursuant to a technology transfer agreement.

Environmental Matters

We may from time to time be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on it. The operation of our manufacturing facility, however, entails risks in these areas. Significant expenditures could be required in the future if these facilities are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

Our current business does not generally reflect any significant degree of seasonality.

Legal Proceedings

From time to time, we may be subject to various claims or legal proceedings that arise in the ordinary course of our business. Other than as disclosed in this Annual Report on Form 20-F, we currently are not a party to, and are not aware of any threat of, any legal proceedings, which, in the opinion of management, is likely to have or could reasonably possibly have a material adverse effect on our business, financial condition or results of operations.

Property, Plant and Equipment

Our current headquarters, which houses our corporate offices, is located in Cardiff, Wales. We lease approximately 265 square meters (approximately 2,854 square feet), which also includes a sustained release research laboratory.

We have entered into a new lease to house our corporate offices, laboratories and pilot scale manufacturing in Cardiff, Wales. The new premises comprise 754 square meters (approximately 8,118 square feet) and, subject to any delays related to COVID-19, we expect the lease to become effective within six months of April 23, 2021. The lease expires in 2026.

We believe that our new Cardiff, Wales facility will be sufficient to meet our current needs.

In connection with the termination of the MTD201 program, we closed our two leased Bilbao manufacturing facilities and provided the requisite one month notice to the landlords in respect of our leases.

ITEM 4A. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto appearing at the end of this Annual Report on Form 20-F. We present our consolidated financial statements in British pounds sterling and in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The following discussion and analysis contains forward-looking statements. Statements that are not statements of historical fact, including expression of management's beliefs and expectations, may be forward-looking in nature and based on current plans, estimates, projections and beliefs. Forward-looking statements are applicable only as of the date made, and we undertake no obligation to update any of them in light of new information or future events. Forward-looking statements involve inherent risks and uncertainties. A number of important factors could cause actual results or outcomes to differ materially from those expressed in any forward-looking statement. These factors include those identified under the headings "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

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Information pertaining to fiscal year 2018 was included in our Annual Report on Form 20-F for the year ended December 31, 2019 beginning on page 69 under "Item 5. Operating and Financial Review and Prospects" which was filed with the SEC on June 15, 2020, as amended on June 17, 2020.

Recent Developments

For information regarding our recent developments, please see "Item 4. Information on the Group-B. Business Overview-Recent Developments," which is incorporated herein by reference.

A. Operating Results.

This section begins with an overview of the principal factors and trends affecting our results of operations. The overview is followed by a discussion of the components of our income statement and our critical accounting policies and estimates that we believe are important to understanding the assumptions and judgments reflected in our reported financial results. We then present an analysis of our results of operations for the last two fiscal years. Following the sale of Midatech US, we contain one reportable segment, referred to as Pipeline Research and Development.

The following discussion should be read in conjunction with our consolidated financial statements included in Item 18 of this Annual Report on Form 20-F and “Item 3.D-Key Information-Risk Factors.” Our financial statements and the financial information discussed below have been prepared in accordance with IFRS.

Principal Factors Affecting Results of Operations

We consider the currency exchange rate between the British pound sterling, Euros and the United States dollar and certain other factors affecting the comparability of results of operations between periods as those most likely to influence our financial condition and results of operations.

Currency Exchange Rate

We report our financial results in British pound sterling and our cash reserves are also largely denominated in British pound sterling. Costs from our Spanish operation are denominated in Euros and revenues and costs from our former United States operations are denominated in United States dollars, which subjects us to currency exchange risks. A strong Euro or United States dollar against the British pound sterling would result in these Euros or United States dollars denominated costs needing a greater amount of cash to settle the cost.

During the periods set forth in our financial statements, incorporated herein by reference, and in particular during 2019 and 2020, there has been considerable volatility in the British pound sterling against the Euro and the United States dollar. During 2019 and 2020, volatility in the British pound sterling was significant as currency markets fluctuated over the prospect of the United Kingdom and European Union reaching a deal over Brexit. At this time, we do not consider the exposure sufficient to utilize derivatives to manage the forward exchange risk. Certain other costs are denominated in other currencies; however, these are not considered material.

Disposal Transactions

Effective November 1, 2018, we sold Midatech US. In accordance with IFRS 5, the sale of Midatech US has been accounted for as a discontinued operation. Under IFRS 5, the results of the discontinued operation are removed from each line in the statement of comprehensive income and the overall losses attributable to the continuing and discontinued operations are reported separately on the face of the statement of comprehensive income. Consequently, the results set out in the statement of comprehensive income and described below refer to the continuing operations only; the loss from discontinued operations is shown in aggregate as a single line entry on the face of our consolidated statement of comprehensive income. Comparative figures in the statement of comprehensive income were restated to show continuing operations on a consistent basis.

Components of Consolidated Statement of Comprehensive Income Items

Revenue

Our income streams comprise revenue derived from licensing agreements, supply of goods and services, milestone income from research and development contracts and grant revenue. Revenue is recognised in-line with that set out in Note 1 to our consolidated financial statements for the year ended December 31, 2020.

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Operating Expenses

We classify our operating expenses into three categories: (i) research and development, (ii) administrative costs and (iii) distribution costs, sales and marketing. These categories correspond to different functional areas within the Company.

Our operating expenses primarily consist of personnel costs, contract research and development costs, professional service fees and depreciation. Personnel costs for each category of operating expenses include salaries, bonuses, social security, health insurance, other employee benefits and share-based compensation for personnel in that category. We allocate share-based compensation expense resulting from the amortization of the fair value of options. Central overheads, such as rent, computer and other technology costs, are not allocated out to departments.

Research and Development Cost. Research and development costs consist of costs that are directly attributable to our research and development programs associated with the products described herein, including the cost of operating our Spanish manufacturing facility, which produces material exclusively for preclinical and clinical studies. This includes costs of third party contract research organizations, research specialist professional services providers, chemicals and other consumables used in the research and manufacturing process, depreciation of assets related to the research and development function, and payroll costs of staff directly assigned to the research and manufacturing operations.

Administrative Costs. These primarily consist of personnel costs for our executive, finance, corporate development and administrative personnel, as well as legal, accounting and other professional service fees, other corporate expenses, merger and acquisition costs and initial public offering costs that are charged to the consolidated statement of comprehensive income. Administrative costs also include depreciation of administrative assets.

Impairment of Intangible Assets. As of December 31, 2020, in connection with our decision to terminate further in-house development of MTD201, our Q-Sphera formulation of octreotide, we recognized an impairment loss for in-process research and development of £9.3 million. In addition, because no other Q-Sphera products were advanced beyond the formulation stage as of December 31, 2020, we recognized an impairment of goodwill arising from our acquisition of Q Chip Limited in December 2014 of £2.3 million. Further, in connection with the purported termination of our license to panobinostat, the active ingredient for our MTX110 product, by Secura Bio, Inc. in June 2020, we recognized an impairment of an intangible asset of £0.8 million as of December 31, 2020.

There was no impairment charge in 2019.

Finance Income

Finance income includes all interest receivable on cash deposits. In 2020, finance income comprised bank interest received.

In 2019, finance income also included a gain on an equity settled derivative financial liability. In October 2019 we issued 3,150,000 warrants in connection with a registered direct offering. In 2015, we assumed fully vested warrants and share options on the acquisition of DARA. The number of Ordinary Shares to be issued when the warrants and options are exercised is fixed, however the exercise prices are denominated in United States dollars, which is different from the functional currency of the Company. Therefore, the warrants and share options are classified as equity settled derivative financial liabilities in the consolidated statement of financial position with any gains or losses being recognized through finance income or finance expense in the consolidated statement of comprehensive income.

Finance Expense

Finance expenses include all interest payable on borrowings and loan instruments. In 2020 and 2019, finance expenses were comprised primarily of interest payable on lease liabilities and other loans.

In 2020, finance expenses also included a loss on equity settled derivative financial liability. We issued warrants in 2020 and 2019 in connection with our registered direct offerings. In 2015, we assumed fully vested warrants and share options on the acquisition of DARA. The number of Ordinary

Shares to be issued when the warrants and options are exercised is fixed, however the exercise prices are denominated in United States dollars, which is different from the functional currency of the Company. Therefore, the warrants and share options are classified as equity settled derivative financial liabilities in the consolidated statement of financial position with any gains or losses being recognized through finance income or finance expense in the consolidated statement of comprehensive income.

Taxation

Taxation represents tax credits receivable by Group companies in respect of qualifying research and development costs incurred.

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Critical Accounting Estimates and Judgments

The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that can have a significant impact on the reported amounts of assets and liabilities, revenue and expenses and related disclosure of contingent assets and liabilities, at the respective dates of our financial statements. We base our estimates, assumptions and judgments on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. Management evaluates estimates, assumptions and judgments on a regular basis and makes changes accordingly, and discusses critical accounting estimates with the Board of Directors.

The following are considered to be critical accounting policies because they are important to the portrayal of our financial condition or results of operations and they require critical management estimates and judgments about matters that are uncertain.

Revenue

There are significant management judgments and estimates involved in the recognition of revenue from the supply of services. Revenue on services is recognized over the contract term, proportionate to the progress in overall satisfaction of the performance obligations (the services performed by the Group), measured by cost incurred to date out of total estimate of costs.

Impairment of Goodwill and Intangible Assets Not Yet Ready for Use

Goodwill and intangibles not yet ready for use are tested for impairment at the cash generating unit level on an annual basis at the year end and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a cash generating unit below its carrying value. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of a significant portion of a reporting unit.

Application of the goodwill impairment test requires judgment, including the identification of cash generating units, assignment of assets and liabilities to such units, assignment of goodwill to such units and determination of the fair value of a unit and for intangible assets not yet ready for use the fair value of the asset. The fair value of each cash generating unit or asset is estimated using the income approach, on a discounted cash flow methodology. This analysis requires significant judgments, including estimation of future cash flows, which is dependent on internal forecasts, estimation of the long-term rate of growth for the business, estimation of the useful life over which cash flows will occur and determination of our weighted-average cost of capital. The carrying value of our goodwill was £0 and £2.3 million as of December 31, 2020 and 2019, respectively, and intangible assets not yet ready for use was £0 and £10.1 million as of December 31, 2020 and 2019, respectively.

The estimates used to calculate the fair value of a cash generating unit change from year to year based on operating results and market conditions. Changes in these estimates and assumptions could materially affect the determination of fair value and goodwill impairment for each such unit.

As a result of our strategic review, an impairment charge of £2.3m has been recognized against goodwill in the year ended December 31, 2020 (2019:£Nil; 2018:£Nil) and an impairment charge against the IPRD of the Midatech Wales cash generating unit of £9.3m (2019:£Nil; 2018: £Nil). As a result of the purported termination of our license to panobinostat by Secura Bio in June 2020, there is an impairment charge of £0.8m against the acquired IPRD in relation to MTX110.

Share-Based Payments

We account for share-based payment transactions for employees in accordance with IFRS 2, *Share- Based Payment*, which requires it to measure the cost of employee services received in exchange for the options on our ordinary shares, based on the fair value of the award on the grant date. We selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of its share-based awards without market conditions. For performance-based options that include vesting conditions relating to the market performance of our ordinary shares, a Monte Carlo pricing model was used in order to reflect the valuation impact of price hurdles that have to be met as conditions to vesting.

The resulting cost of an equity incentive award is recognized as expense over the requisite service period of the award, which is usually the vesting period. Compensation expense is recognized over the vesting period using the straight-line method and classified in the consolidated statements of comprehensive income.

The assumptions used for estimating fair value for share-based payment transactions are disclosed in Note 27 to our consolidated financial statements for the year ended December 31, 2020 and are estimated as follows:

- volatility is estimated based on the average annualized volatility of a number of publicly traded peer companies in the biotech sector;

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- the estimated life of the option is estimated to be until the first exercise period, which is typically the month after the option vests; and
- the dividend return is estimated by reference to our historical dividend payments. Currently, this is estimated to be zero as no dividend has been paid in the prior periods.

Financial Liabilities

Fair Value Through Profit and Loss (FVTPL). We have outstanding warrants in the Ordinary Share capital of the company. The number of Ordinary Shares to be issued when exercised is fixed, however the exercise price is denominated in U.S. dollars, being different to the our functional currency. Therefore, the warrants are classified as equity settled derivative financial liabilities recognised at fair value through the profit and loss account.

The financial liability is valued using either the Monte Carlo model or the Black-Scholes option pricing model. Financial liabilities at FVTPL are stated at fair value, with any gains or losses arising on re-measurement recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest paid on the financial liability and is included in the 'finance income' or 'finance expense' lines item in the income statement. Fair value is determined in the manner described in Note 22 to our consolidated financial statements.

Income Taxes

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized based upon the likely timing and the level of future taxable profits together with future tax planning strategies.

In 2020 and 2019, there were £63.2 million and £49.6 million of gross unutilized tax losses carried forward, respectively. No deferred tax asset has

been provided in respect of losses, as there was insufficient evidence to support their recoverability in future periods.

Research and Development Cost

Research and development costs are charged to expense as incurred and are typically made up of salaries and benefits, clinical and preclinical activities, drug development and manufacturing costs, and third-party service fees, including for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are periodically recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued expenses.

Leases

IFRS 16, *Leases*, defines the lease term as the non-cancellable period of a lease together with the options to extend or terminate a lease, if the lessee were reasonably certain to exercise that option. Where the lease includes the option for us to extend the lease term, we make a judgement as to whether it is reasonably certain that the option will be taken. This will take into account the length of time remaining before the option is exercisable, current trading, future trading forecasts as to the ongoing profitability of the organisation and the level and type of planned future capital investment. The judgement is reassessed at each reporting period. A reassessment of the remaining life of the lease could result in a recalculation of the lease liability and a material adjustment to the associated balances.

The discount rate used in the calculation of the lease liability involves estimation. The discount rate used is the incremental borrowing rate. This rate represents the rate we would have had to pay to borrow, over a similar term and with similar security, the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment.

During 2020, following the closure of Midatech Spain and the termination of a property lease we occupied, a profit on disposal has been recognised in the accounts of £109,000. During 2019, we considered the appropriate life of a new property lease entered into in Spain. The lease was for an initial period of five years, however the lease allowed us to break the lease at any-time with one-month notice, provided we returned the property to its original condition. At December 31, 2019, we assessed we were reasonably certain the expected life of the lease would be five years.

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Discontinued Operations

Under the terms of the Purchase Agreement for the sale of Midatech US, we agreed to indemnify the Purchaser against, among other things, any liability related to any prescription drug user fee amounts owed to the FDA under the Prescription Drug Fee User Act by Midatech US for the United States government's fiscal year ended September 30, 2018.

Midatech US had successfully obtained waivers for user fees for all prior fiscal periods in which it was liable under PDUFA and entered into the Purchase Agreement with the Purchaser believing that a further waiver would be obtained. However, during 2019 Midatech US sought approval from the FDA for a filing relating to one of its commercial products and was informed by the FDA that the approval would not be forthcoming while the PDUFA fee remained unpaid. Consequently, Midatech US paid the PDUFA fee of £0.95m and then, in accordance with the terms of the Purchase Agreement, we deposited the same amount with Midatech US, pending completion of the waiver application process. As of December 31, 2019, we considered the requirement to provide for a claim under the indemnity provisions in the Purchase Agreement, and concluded no provision was required.

As of June 30, 2019, we considered the deposit amount recoverable from Midatech US, based on the waiver application process being on-going and the historical success Midatech US had had in obtaining the waiver.

As of December 31, 2019, we reconsidered the recoverability of the deposit sum paid under the indemnity, and although the waiver process was still on-going, we concluded, based on third party advice, that the probability of successfully achieving the waiver had diminished and therefore have taken the decision to expense the cost of the indemnity claim in 2019. In 2020, we were notified by the FDA that our appeal had been denied.

Going Concern

We are subject to a number of risks similar to those of other development and early-commercial stage pharmaceutical companies. These risks include, amongst others, generation of revenue from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of our pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include obtaining adequate financing to fulfill our commercial and development activities and generating a level of revenue adequate to support our cost structure.

We have experienced net losses and significant cash outflows from cash used in operating activities over the past years as we develop our portfolio. For the year ended December 31, 2020, the Company incurred a consolidated loss from operations of £22.2 million and negative cash flows from operations of £9.3 million. As of December 31, 2020, we had an accumulated deficit of £122.4 million.

Our future viability is dependent on our ability to generate cash from operating activities, to raise additional capital to finance our operations and to successfully obtain regulatory approval to allow marketing of our development products. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies.

Our consolidated financial statements have been presented on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As of December 31, 2020, we had cash and cash equivalents of £7.5 million. We believe we currently have enough cash to fund our planned operations into the fourth quarter of 2021.

We have prepared cash flow forecasts and considered the cash flow requirement for our next three years, including the period twelve months from the date of the approval of the financial statements. These forecasts show that further financing will be required during the course of the next 12 months, assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2020 with respect to this uncertainty.

In addition, the global spread of pandemic novel coronavirus, COVID-19, places increased uncertainty over our forecasts. The restrictions placed and being placed on the movement of people have caused, and may in the future cause, delays to some of our plans. We have established a COVID-19 task force internally to monitor the impact of COVID-19 on our business and prioritize activities to minimize its effect. It is not currently possible to quantify the impact of COVID-19 and resultant delays on the Company until it becomes clear that the global crisis has abated and a normalization of the business environment can be foreseen with confidence.

In addition to utilizing the existing cash reserves, as part of our strategic review, we and our advisors are evaluating a number of near-term funding options potentially available to us, including fundraising, the partnering of assets or technologies or the sale of the Company. After considering the uncertainties, we considered it appropriate to continue to adopt the going concern basis in preparing the financial information.

Our ability to continue as a going concern is dependent upon our ability to obtain additional capital and/or dispose of assets, for which there can be no assurance we will be able to do on a timely basis, on favorable terms or at all.

Recently Issued and Adopted Accounting Pronouncements

IFRS 16 Leases. IFRS 16 was issued in January 2016 and it replaces IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17. The standard includes two recognition exemptions for lessees - leases of 'low-value' assets (e.g., personal computers) and short-term leases (i.e., leases with a lease term of 12 months or less). At the commencement date of a lease, a lessee will recognize a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees will be required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Adoption of IFRS 16 results in us recognizing right-of-use assets and lease liabilities for all contracts that are, or contain, a lease. For leases previously classified as operating leases, we did not recognize related assets or liabilities, and instead spread the lease payments on a straight-line basis over the lease term, disclosing in our annual financial statements the total commitment.

We have implemented the new standard effective January 1, 2019, applying the modified retrospective adoption method in IFRS 16, and, therefore, we only recognize leases on the balance sheet as at January 1, 2019. In addition, we have determined to measure right-of-use assets by reference to the measurement of the lease liability on that date. This will ensure there is no immediate impact to net assets on that date. At January 1, 2019 and December 31, 2019, we recorded a lease liability of £546,000 and £907,000, respectively in our accounts, reflecting a 3.0% and 4.8%, respectively, discount rate on the lease commitment. At January 1, 2019 and December 31, 2019, we recognized a corresponding right-of-use asset of £395,000 in respect of two of our leases, based upon the present value of future payments under these leases. As of December 31, 2019, we recognized a corresponding right-of-use asset of £828,000 in respect of three of our leases, based upon the present value of future payments under these leases. During 2020, we terminated two leases on our Spanish properties as a result of our strategic review. As of December 31, 2020 we recorded a lease liability of £76,000 reflecting a 3% discount rate on the lease commitment. We recognized a corresponding right-of-use asset of £76,000 in respect of our one remaining lease, based on the present value of future payments under the lease.

The balance of the lease liability of £152,000 relates to a sublease agreement entered into by the Company to mitigate the impact of an otherwise onerous lease on the closure of our Abingdon, United Kingdom headquarters. This has been recognized as a lease receivable as we have determined that the sublease meets the definition of a finance lease under the transitional provisions of IFRS16 and therefore, no right-of-use asset is recognized. This lease expired in 2020.

Instead of recognizing an operating expense for our operating lease payments, we instead recognize interest on our lease liabilities and amortization on our right-of-use assets. Given the nature of the leases involved and assuming the current low interest rate environment continues, we do not currently expect the effect on loss from operations to be significant.

IFRIC 23 Uncertainty over Income Tax Treatments. IFRIC 23 provides guidance on the accounting for current and deferred tax liabilities and assets in circumstances in which there is uncertainty over income tax treatments. IFRIC 23 requires us:

- to contemplate whether uncertain tax treatments should be considered separately, or together as a group, based on which approach provides better predictions of the resolution;
- to determine if it is probable that the tax authorities will accept the uncertain tax treatment; and
- to measure, if it is not probable that the uncertain tax treatment will be accepted, the tax uncertainty based on the most likely amount or expected value, depending on whichever method better predicts the resolution of the uncertainty.

We elected to apply IFRIC 23 retrospectively with any cumulative effect to be recorded in retained earnings as at the date of initial application, January 1, 2019. The adoption of IFRIC 23 did not result in a change in corporate tax liabilities or assets.

In addition to the above standards previously adopted, we adopted the following standards, amendments and interpretations for the year ended December 31, 2020:

- IFRS 3, *Business Combinations (Amendment - Definition of Business)*;

- *Interest Rate Benchmark Reform - IBOR "Phase 2"* (amendments to IFRS 9, IAS 39 and IFRS 7); and
- *COVID-19 Related Rent Concessions* (Amendments to IFRS 16).

The adoption of these new standards has not had a material impact on our financial statements during the year ended December 31, 2020.

There are a number of standards, amendments to standards, and interpretations which have been issued by the IASB that are effective in future accounting periods that we have decided not to adopt early. The following amendments are effective for the period beginning January 1, 2022:

- *Contracts-Cost of Fulfilling a Contract* (Amendments to IAS 37);
- *Property, Plant and Equipment: Proceeds before Intended Use* (Amendments to IAS 16);
- *Annual Improvements to IFRS Standards 2018-2020* (Amendments to IFRS 1, IFRS 9, IFRS 16 and IAS 41; and
- *References to Conceptual Framework* (Amendments to IFRS 3).

We do not expect any other standards issued by the IASB, but not yet effective, to have a material impact on us.

In January 2020, the IASB issued amendments to IAS 1, which clarifies the criteria used to determine whether liabilities are classified as current or non-current. These amendments clarify that current or non-current classification is based on whether an entity has a right at the end of the reporting period to defer settlement of the liability for at least twelve months after the reporting period. The amendments also clarify that 'settlement' includes the transfer of cash, goods, services, or equity instruments unless the obligation to transfer equity instruments arises from a conversion feature classified as an equity instrument separately from the liability component of a compound financial instrument. The amendments were originally effective for annual reporting periods beginning on or after January 1, 2022, however this was deferred to annual reporting periods beginning on or after January 1, 2023.

We are currently assessing the impact of this new accounting standard and amendment.

Results of Operations

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

The following table summarizes our consolidated results of operations for the years ended December 31, 2020 and 2019.

Year Ended December 31,	
2020	2019*
(£ in thousands)	

Revenue	180	312
Grant revenue	163	362
Total revenue	343	674
Other income	12	15
Research and development costs	(6,068)	(7,843)
Distribution costs, sales and marketing	(6)	(323)
Administrative costs	(4,952)	(3,841)
Impairment of intangible assets	(12,369)	--
Loss from operations	(23,040)	(11,318)
Finance income	1	492
Finance expense	(431)	(97)
Loss before taxation	(23,470)	(10,923)
Taxation	1,281	1,785
Loss from continuing operations	(22,189)	(9,138)
Loss from discontinued operations	--	(947)
Loss for the year attributable to the owners of the parent	(22,189)	(10,085)

* During 2018, we made the decision to sell our commercial business based in the United States, Midatech US. The sale was completed on November 1, 2018, to Barings LLC, an affiliate of the MassMutual Financial Group, for total consideration of up to \$19 million. During 2019, an indemnification claim was made by Midatech US against us, which was accounted for as a loss from discontinued operations in 2019.

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Revenue. For the year ended December 31, 2020, we generated consolidated Revenues from continuing operations of £0.18 million, compared to £0.31 million in 2019, comprising formulation services for customers in each year.

Research and Development Costs. We incurred research and development costs of £6.07 million in 2020, compared to £7.84 million in 2019, a decrease of 23%, primarily due to lower aggregate clinical development costs of £3.38 million, including reduced expenditure on MTD201 of £2.33 million. Lower clinical development expenses were offset by £0.89 million of redundancy costs and £0.85 million of accelerated depreciation in connection with the closure of our operations in Bilbao, Spain.

Distribution costs, sales and marketing. For the year ended December 31, 2020, these costs were £6,000, as opposed to £0.32 million for the same period in 2019, due to a reduction in market and payor research expenses associated with our pipeline R&D products.

Administrative costs. For the year ended December 31, 2020, our administrative costs were £4.95 million, as opposed to £3.84 million in 2019, an increase of 29% and included increases in professional fees and insurance of £0.48 million and £0.36 million, respectively, offset by a reduction in personnel costs of £0.40 million. In addition, administrative costs in 2020 included £0.72 million in connection with the closure of our operations in Bilbao, Spain, of which £0.55 million related to interest on repaid Spanish soft loans and £0.17 million related to the settlement of a lawsuit.

Impairment of Intangible Assets. In connection with our decision to terminate further in-house development of MTD201, we recognized an impairment loss for in-process research and development of £9.30m. In addition, because no other Q-Sphera products were advanced beyond the formulation stage as of December 31, 2020, we recognized an impairment of goodwill arising from our acquisition of Q Chip Limited in December 2014 of £2.30 million. In connection with the purported termination of our license to panobinostat by Secura Bio in June 2020, we recognized an impairment of an intangible asset of £0.78 million as of December 31, 2020.

Finance Income. Finance income generally represents interest earned on cash balances. However, in 2019, finance income of £0.49 million was credited to the income statement and included a gain in respect of an equity settled financial liability of £0.48 million.

Finance Expense. Finance expenses of £0.43 million were charged in 2020, as compared to £0.10 million in 2019, an increase of £0.33 million. The increase is due primarily to a loss in respect of an equity settled financial liability of £0.40 million.

Loss from discontinued operations. This comprises the aggregate income statement loss from the Midatech US business. The loss in the year ended December 31, 2019 was £0.95 million. The 2019 loss relates to a claim made under the indemnification provisions pursuant to the Purchase Agreement for Midatech US, which we paid a deposit on in April 2019, pending the final determination of the PDUFA waiver by the FDA.

B. Liquidity and Capital Resources.

Overview

We have incurred significant net losses and have had negative cash flows from operations during each period from inception through December 31, 2020, and had an accumulated deficit of £122.4 million as of December 31, 2020. We have yet to generate a profit and, excluding share issues, cash flows have been consistently negative from the date of incorporation. Management expects operating losses and negative cash flows to continue for the foreseeable future. We believe our existing balances of cash and cash equivalents will be insufficient to satisfy our working capital needs and other liquidity requirements associated with our existing operations over the next 12 months. Additional funding will have to be obtained, which may include public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of our product candidates and formulations, as well as consider other strategic alternatives.

If we raise additional funds through the issuance of debt securities or additional equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our ordinary shares (including the Depositary Shares) and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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As of December 31, 2020, we had cash and cash equivalents of £7.5 million. Historically, we have financed our operations primarily from the net proceeds of public and private share placings. In December 2014, we received net proceeds of £30.6 million from the issuance and sale of 599,250 of our Ordinary Shares in our initial public offering and associated listing on AIM. In October 2016, we received net proceeds of £15.6 million from the issuance and sale of 757,852 of our Ordinary Shares in a placing and open offer outside of the United States. In September 2017, we received net proceeds of £5.7 million from the issuance and sale of 615,733 Ordinary Shares in a placing outside of the United States. In February 2019, we

received net proceeds of £12.3 million from the issuance and sale of 17,410,773 Ordinary Shares in a subscription, placing and open offer outside of the United States. In October 2019, we received net proceeds of £1.8 million from the issuance and sale of 600,000 Depositary Shares (representing 3,000,000 Ordinary Shares) and warrants to purchase 600,000 Depositary Shares (representing 3,000,000 Ordinary Shares) in registered direct offering and concurrent private placement in the United States.

In May 2020, we received net proceeds of \$2.6 million from the issuance and sale of 1,818,182 Depositary Shares (representing 9,090,910 Ordinary Shares) and warrants to purchase 600,000 Depositary Shares (representing 9,090,910 Ordinary Shares) in a registered direct offering and concurrent private placement in the United States. In addition, in May 2020, we received net proceeds of £1.6 million from the issuance and sale of 6,666,666 Units in the May Placing. In July 2020, we received net proceeds of £5.3 million from the issuance and sale of 21,296,295 Ordinary Shares in a placing to investors in the United Kingdom. Further, in August 2020 and February 2021, we received net proceeds of \$1.0 million and \$0.1 million, respectively, upon the exercise of warrants issued in the May 2020 private placement.

In addition to the potential issuance of any debt securities or additional equity securities, we continue to assess the market value of certain of our assets so that non-dilutive funding could be available, if required, to drive long term value for the Company without a reliance on equity funding.

On September 1, 2018, we were awarded a €1.5 million unsecured loan from the regional government of the Basque region of Spain as part of their Gauzatu Industry program, which is a government funded program to support local small and medium-sized enterprises in establishing infrastructure and capability for global industries. The Basque Loan was intended to be used as part of our commercial scale up for our MTD201 program and Q-Sphera technology platform. The Basque Loan was never drawn by the Company. Due to the termination of the MTD201 program and shut down of our Bilbao, Spain manufacturing facilities, we have terminated this loan agreement.

On September 11, 2019, we were awarded a €6.6 million loan from the Spanish Ministry of Industry, Commerce and Tourism, under its Re-industrialisation Programme, or the REINDUS Loan. The REINDUS Loan was intended to partially fund activities to scale-up the manufacturing capability of our MTD201 program, however, in connection with our decision to terminate the MTD201 program and shut down of our Bilbao, Spain manufacturing facilities, we repaid this loan and the corresponding cash bond was released.

Our current strategy is based on advancing our proprietary technology platforms and programs with a view to partnering these assets during the course of their development, thereby earning royalty income, or working with third party pharmaceutical companies to re-formulate their proprietary medicine on a fee-for-service basis. We are subject to risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the timing of clinical trials. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. If we lack sufficient capital to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2020 and 2019:

	Year ended December 31,	
	2020	2019
	(£ in thousands)	
Cash used in operating activities	(9,301)	(6,489)
Cash provided by (used in) investing activities	2,574	(3,807)
Cash provided by financing activities	3,084	18,733
Net (decrease) increase in cash and equivalents	(3,643)	8,437

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The following table presents a summary of our cash flows from discontinued operating activities arising from the discontinued Midatech US business:

	Year ended December 31,	
	2020	2019
	(£ in thousands)	
Cash used in operating activities	--	--
Cash provided by (used in) investing activities	--	(947)
Cash provided by financing activities	--	--
Net (decrease) increase in cash and equivalents	--	(947)

Operating Activities

The following table presents a summary of the cash used in operations as of the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(£'s in thousands)	
Cash flows from operating activities before changes in working capital	(9,697)	(10,207)
Changes in working capital	(1,558)	1,798
Cash used in operations	(11,255)	(8,409)

Cash flows from Operating Activities before Changes in Working Capital. Net cash outflow from operating activities before changes in working capital was £9.70 million in the year ended December 31, 2020, as opposed to £10.21 million during the same period in 2019. This decreased cash outflow of £0.51 million, or 5%, driven by increased losses attributable to the owners of the Company of £12.10 million and increases in depreciation and amortization, share based payments and losses on disposals of fixed assets of £0.07 million, £0.37 million and £0.23 million, respectively offset by impairment of intangible assets of £12.37 million, an increase in net finance expense of £0.83 million, a lower tax charge of £0.50 million and an increase in foreign exchange gains of £0.53 million. Included in 2019 was a £0.95 million loss in respect of discontinued operations.

Cash Used in Operations. Working capital increased in cash flow terms by £1.56 million for the year ended December 31, 2020, compared to a decrease of £1.80 million for 2019. The increase in 2020 primarily comprised a decrease in trade and other payables of £2.00 million offset by an increase in trade and other receivables of £0.49 million.

Taxes Paid. Research and development tax credits of £1.95 million were received in 2020, as opposed to £1.92 million in 2019. This related to claims submitted in the prior financial year.

Investing Activities

Purchase of property, plant and equipment of £0.20 million occurred in the year ended December 31, 2020, compared to £0.31 million for the same period in 2019. In 2020, capital expenditure was largely related to the purchase of laboratory equipment for our laboratories and pilot scale manufacturing facilities in Cardiff, Wales. The £2.55 million cash-backed guarantee for a Spanish government loan that was put in place in 2019 was repaid in the amount of £2.64 million in 2020.

Financing Activities

Government loans, grants and subsidies. In connection with the closure of our Bilbao, Spain operations, in 2020, we repaid Spanish government loans and grants of £6.18 million and £0.22 million respectively. In 2019, we received combined proceeds from government loans and a subsidy of £5.58 million.

Amounts paid on lease liabilities. In 2020 we paid £0.26 million in respect of lease liabilities compared with £0.45 million in 2019. We surrendered both our property leases in Bilbao, Spain during 2020.

Shares Issues Including Warrants, Net of Costs. We raised £9.74 million in net proceeds for the year ended December 31, 2020 in cash, in a registered direct offering and private placement in May 2020, a private placement in July 2020 and from the exercise of warrants.

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On May 20, 2020, we completed the closing of the Registered Direct Offering with certain Investors for the sale of 1,818,182 Depositary Shares (representing 9,090,910 Ordinary Shares) at a price per Depositary Share of \$1.65, for aggregate gross proceeds of \$3.0 million. In a concurrent private placement, we sold to the Investors Private Placement Warrants to purchase a total of 1,818,182 Depositary Shares (representing 9,090,910 Ordinary Shares) at an exercise price of \$2.05 per Depositary Share. The Private Placement Warrants, which were immediately exercisable, will expire five and one-half years from the issuance date. The closing of the private placement occurred on May 20, 2020. As of December 31, 2020, Private Placement Warrants to purchase 500,000 Depositary Shares had been exercised for an aggregate exercise price of approximately \$1.0 million. Wainwright served as the sole placement agent for the transaction. In connection therewith, we also issued to certain designees of Wainwright the Wainwright Warrants for the purchase of a total of 90,909 Depositary Shares (representing 454,546 Ordinary Shares) at an exercise price of \$2.0625 per Depositary Share pursuant to the terms of our engagement letter agreement with Wainwright. The Wainwright Warrants became exercisable on May 18, 2020 and expire May 18, 2025.

Concurrently with the Registered Direct Offering, on May 22, 2020, we, through TPI completed a placing with certain investors in the United Kingdom of 6,666,666 Units, with each Unit comprising one new Ordinary Share and one UK Warrant, at an issue price of £0.27 per Unit. The exercise price of the UK Warrants is £0.34 per share, for aggregate gross proceed of £1.8 million. The UK Warrants expire five years and six months from the issuance date. In connection with TPI acting as the placement agent for the May Placing, we issued to TPI UK Warrants to purchase an aggregate of 333,333 Ordinary Shares, or 5.0% of the aggregate UK Warrants issued in the May Placing.

In July 2020, we, through TPI, completed a placing with certain investors in the United Kingdom of 18,518,518 Placing Shares. A further 2,777,777 Broker Option Shares were placed by TPI pursuant to a broker option. Each of the Placing Shares and the Broker Option Shares were sold at an issue price of £0.27 per share.

For the years ended December 31, 2020 and 2019, we issued 25,000 Ordinary Shares in each year to be purchased by the Midatech Pharma Share Incentive Plan, an employee share incentive trust.

Cash and Cash Equivalents

Cash decreased for the year ended December 31, 2020 by £3.64 million, before the impact of foreign exchange movements, compared to an increase of £8.44 million in the corresponding period in 2019. This decrease was due to continuing trading losses offset by the net proceeds from share issuances and warrant exercises during the year of £9.74 million. As of December 31, 2020, we had cash and cash equivalents of £7.55 million compared to £10.93 million as at December 31, 2019.

C. Research and Development, Patents and Licenses, Etc.

For more information regarding our research and development program, see “*Item 4. Information on the Company-B. Business Overview-Research and Development.*”

D. Trend Information.

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenues, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Off-Balance Sheet Arrangements.

We have elected to voluntarily comply with the amendments to Item 5.E of Form 20-F, effective February 10, 2021, contained in SEC Release No. 33-10890.

F. Tabular Disclosure of Contractual Obligations.

We have elected to voluntarily comply with the amendments to Item 5.F of Form 20-F, effective February 10, 2021, contained in SEC Release No. 33-10890.

G. Safe Harbor

Certain of the statements included in this annual report and the documents incorporated herein by reference may be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For our cautionary statement on the forward-looking statements in this Annual Report on Form 20-F, see “*Cautionary Note Regarding Forward-Looking Statements.*”

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ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES.

A. Directors and Senior Management

The following table sets forth certain information about our current directors and senior management. The professional address of each of the directors is care of Midatech Pharma PLC, Oddfellows House, 19 Newport Road, Cardiff, CF24 0AA, United Kingdom.

Name	Age at 12/31/2020	Position/Title
Directors:		
Stephen Stamp (1) (2)	59	Chief Executive Officer and Chief Financial Officer, Director
Rolf Stahel (1) (2) (3) (4)	76	Non-Executive Chairman of the Board of Directors
Simon Turton, Ph.D. (1) (2) (3) (4)	53	Senior Independent Non-Executive Director
Sijmen de Vries, M.D. (1) (2) (3) (4)	61	Non-Executive Director

Senior Management (5):

Steve Damment, Ph.D.

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Executive Vice President, Research & Development

- (1) Nominations Committee member
- (2) Disclosure Committee member
- (3) Remuneration Committee member
- (4) Audit Committee member
- (5) Other than directors who are also members of senior management.

Directors

Stephen Stamp has served as our Chief Executive Officer since March 31, 2020, and our Chief Financial Officer and a member of our Board of Directors since September 2019. Prior to joining the Company, Mr. Stamp served as Chief Executive Officer of Ergomed plc (AIM: ERGO) from December 2017 until January 2019 and Chief Financial Officer from January 2016 to July 2018. From March 2013 until July 2015, Mr. Stamp served as the Chief Financial Officer of Assurex Health, Inc. Mr. Stamp served as Chief Financial Officer of EZCORP Inc. (NASDAQ: EZPW) and KV Pharmaceuticals Co. from November 2010 to October 2012 and March 2010 to June 2010. Mr. Stamp has also previously served as Chief Operating Officer of Xanodyne Pharmaceuticals, Inc., and Group Finance Director of Regus PLC (now IWG plc) (LON: IWG) and Shire plc (subsequently acquired by Takeda Pharmaceuticals Company Limited). Mr. Stamp is a Chartered Accountant and qualified with KPMG LLP. Mr. Stamp has a Bachelor's degree in economics from the University of Manchester.

Rolf Stahel has served as our non-executive Chairman of the Board and director (including his service to our predecessor entity) since March 1, 2014. Since December 2016, Mr. Stahel served as the non-executive Chairman and a director of Ampha Limited. Between 2009 and 2016, Mr. Stahel served as the Non-Executive Chairman and a director of Connexios Sciences Pvt. Ltd., and between April 2014 and March 2017 he served as Non-Executive Chairman and a director of Ergomed plc (LON: ERGO). Mr. Stahel is also the sole shareholder and founder of Chesyl Pharma Ltd. From March 1994 to March 2003, Mr. Stahel served as the Chief Executive Officer and a director of Shire plc (subsequently acquired by Takeda Pharmaceuticals Company Limited). Prior to that time, Mr. Stahel worked in various positions with Wellcome plc, the predecessor to GlaxoSmithKline plc (NYSE: GSK), for 27 years. Mr. Stahel has previously served as the Non-Executive Chairman of EUSA, Cosmos Pharmaceuticals SpA (SIX: COPN), PowderMed Ltd. and Newron Pharmaceuticals SpA (SWX: NWRN).

Simon Turton, Ph.D. has served as a non-executive member of our Board of Directors since December 2014. Dr. Turton served as Chairman of Q Chip and OpsiRx Pharmaceuticals from March 2014 until their acquisition by us in December 2014. Since January 2015, he has served as the Managing Director of Gensmile Limited. In 2002, Dr. Turton joined Warburg Pincus', most recently as head of healthcare investing activities in Europe, until June 2011. Dr. Turton has previously served on the board of Archimedes Pharma, Eurand, ProStrakan Group plc and Tornier, Inc. Dr. Turton has a Master's of Business Administration from INSEAD and a Ph.D. in pharmacy from the University of London.

Sijmen de Vries, M.D. has served as a non-executive member of our Board of Directors since October 2004 (including his service to our predecessor entity). Since November 2008, Dr. de Vries has served as of the Chief Executive Officer of Pharming Group NV (Euronext: PHARM). Prior to that, Dr. de Vries served as Chief Executive Officer of 4-Antibody and Morphochem AG. Prior to this he worked at Novartis Pharma, Novartis Ophthalmics and at SmithKline Beecham Pharmaceuticals Plc, where he held senior business and commercial positions. Dr. de Vries holds an M.D. degree from the University of Amsterdam and a Masters of Business Administration in General Management from Ashridge Management College (United Kingdom).

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[Table of Contents](#)**Senior Management**

Steve Damment has served as our Executive Vice President, Research and Development since March 2018. Prior to that time, Dr. Damment served our Senior Vice President of Translational Medicine from May 2015 to March 2018. Dr. Damment is also the founder and, since January 2014, the Chief Science Officer of Aluztura Bio Ltd., a start-up oncology company. From January 2000 to December 2013, Dr. Damment served as Senior Vice President, Biosciences for Shire Pharmaceutical Development Ltd., a subsidiary of Shire plc. Dr. Damment also served in various roles with Glaxo-Wellcome R&D Ltd., most recently as Head of Toxicology. Dr. Damment has a Bachelor of Science in zoology and marine biology from the University of Liverpool, a Master's of Science and a diploma in toxicology from the University of Birmingham and Royal College of Pathologists, respectively, and a Ph.D. in toxicology/physiology from the University of Manchester.

For the biographical information of Stephen Stamp, our Chief Executive Officer and Chief Financial Officer, see “-A. Directors and Senior Management-Directors.”

B. Compensation

The following section reports the remuneration of our Board of Directors and senior management and describes our compensation policies and actual compensation for its executive officers as well as our use of equity incentives.

Compensation of Non-Executive Directors

Our non-executive directors receive a fee for their services as a director, which is approved by our Board of Directors, giving due consideration to the time commitment and responsibilities of their roles and of current market rates for comparable organizations and appointments. Non-executive directors are reimbursed for travelling and other incidental expenses incurred on our business in accordance with our expenses policy.

The following table summarizes the compensation paid to our non-employee directors during 2020.

Name	Fees Earned or Paid in Cash (£)(1)	All Other Compensation (£)(2)	Total £
Sijmen de Vries	30,400	-	30,400
Frédéric Duchesne (3)	7,600	-	7,600
Dr. Huaizheng Peng (4)	7,600	-	7,600
Rolf Stahel	40,000	50,000	90,000
Simon Turton (5)	30,400	-	30,400

- (1) Includes annual fees, committee chairpersonship fees and meeting fees.
- (2) Includes fees paid to Mr. Stahel in connection with a consultancy agreement with Chesyl Pharma Limited, a company wholly owned by Mr. Stahel.
- (3) Mr. Duchesne resigned from the Board of Directors effective March 31, 2020.
- (4) Dr. Peng resigned from the Board of Directors effective March 31, 2020.
- (5) A portion of the compensation paid to each of Mr. Turton for his services on the Board of Directors are paid to a consulting firm owned by Mr. Turton; however, we do not receive any consulting services from Mr. Turton or their respective consulting firms.

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The following table sets forth, as of December 31, 2020, the aggregate number of option awards held by those individuals who served as non-executive directors during 2020:

Name	Number of Options	Grant Date	Exercise Price per Share (£)	Expiration Date
Sijmen de Vries	200 (1)	4/20/2012	83.80	4/20/2022
	500 (2)	6/30/2014	1.50	6/30/2024

(1) The stock options are fully vested.

(2) The stock options vest in the following installments: (i) 50% of the stock options vest when our share price is £106.20 a share, (ii) a further 25% of the stock options vest when our share price is £274.40 a share and (iii) the remaining 25% of the stock options vest when our share price is £377.20 a share.

All stock options were granted with an exercise price at or above market value on the date of grant.

Deed of Indemnity

Under a deed poll declared by the Company on August 5, 2015, or a Deed of Indemnity, the Board of Directors and our Company Secretary are indemnified against costs and liabilities incurred in connection with their office, other than any liability owed by such person to the Company itself (or any of its associated entities) and other than indemnification for liabilities in certain circumstances, which are prohibited by virtue of the Companies Act. The Deed of Indemnity provides that a director may also be lent sums to finance any relevant defense costs, provided that, in the event such proceedings involve criminal or civil matters in which the person is convicted or has a judgment made against him or her, then such loan must be repaid.

Letters of Appointment

Each non-executive director (other than Mr. Stahel) has been appointed to serve on our Board of Directors pursuant to a letter of appointment. The initial term of appointment for each director is three years, unless terminated earlier by either party upon one month's prior notice or in accordance with the terms of the letters of appointment. The appointment is subject to our articles of association, and is subject to confirmation at any annual general meeting of the Company.

Each non-executive director (other than Mr. Stahel) is paid an annual fee of £30,400, which covers all duties, including committee service or service on the board of a Midatech subsidiary, with the exception of committee chairmanships and certain additional responsibilities, such as taking on the role of senior independent director. In addition, we reimburse each director for reasonable and properly documented expenses incurred in performing their duties. As noted above, we also grant each director a deed of indemnity against certain liabilities that may be incurred as a result of their service, to the extent permitted by the Companies Act.

In addition, without our prior written consent, for a period of six months following a director's termination from service, such director will not, whether as a principal or agent and whether alone or jointly with, or as a director, manager, partner, shareholder, employee consultant of, any other person, carry on or be engaged, concerned or interested in any business which is similar to or which is (or intends to be) in competition with any business being carried on by Midatech or any subsidiary, as applicable.

Rolf Stahel Letter of Appointment

Pursuant to a term of appointment dated April 15, 2014, as amended on December 2, 2014, or the Stahel Appointment Agreement, Rolf Stahel was appointed non-executive Chairman of the Board of Directors, with effect from March 1, 2014. The initial term of appointment for Mr. Stahel expired on February 28, 2015 but Mr. Stahel was subsequently re-elected by the directors of Midatech with the current term expiring in April 2022. In addition, his appointment may be terminated:

- by either party giving at least three months prior written notice;
- by the Board of Directors reasonably determining that Mr. Stahel's acceptance of any other employment, engagement, appointment, interest or involvement with any business or person competes or conflicts with his appointment and would result in a serious conflict of interest or Mr. Stahel reasonably determines such interest would result in a serious conflict of interest, and Mr. Stahel accepts such employment, engagement, appointment, interest or involvement; or
- in accordance with our articles of association or applicable law.

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Pursuant to the terms of the Stahel Appointment Agreement, Mr. Stahel is paid an annual fee of £40,000 (reduced from £50,000 with effect from October 1, 2017). Mr. Stahel is also paid an additional fee of £40,000 under a consultancy agreement (reduced from £50,000 with effect from October 1, 2017). Mr. Stahel is entitled to additional payments depending upon the amount of time he devotes to the Company under the consultancy agreement. See "Item 7. Major Shareholders and Related Party Transactions-B. Related Party Transactions-Agreement with Chesyl Pharma Limited." In addition, in connection with the execution of the Stahel Appointment Agreement, we granted to Mr. Stahel options to acquire Ordinary Shares at a price of £1.50 per share, which he subsequently exercised. Mr. Stahel, in accepting the options, agreed to certain restrictions on any disposal and voting rights of such shares. As to 6,122 of such shares held by Mr. Stahel, Mr. Stahel is prohibited from disposing of such shares unless and until the Company reaches certain milestones set forth in the Stahel Appointment Letter. Such shares that are subject to disposal restrictions are unable to be voted upon by Mr. Stahel during the periods described above in respect of the amount of such shares which remain under restriction.

We also are obligated to take out a reasonable directors and officers liability insurance policy, which applies to Mr. Stahel. We also agreed to reimburse Mr. Stahel for reasonable and documented expenses accrued in the course of performing his duties and provide him with up to £7,500 in professional advice in connection with performing his duties. The Stahel Appointment Agreement includes provisions related to the non-disclosure of information and assignment of inventions. Among other things, these provisions obligate Mr. Stahel from disclosing any of our proprietary and confidential information received during the course of employment and to assign to us any inventions conceived or developed during the course of their employment.

In the event we terminate the agreement with Mr. Stahel at any time in accordance with the provisions of the articles of association or applicable laws, Mr. Stahel will have no right to damages or compensation if he:

- is found guilty of any misconduct, gross negligence or dishonesty or acts in a manner which is materially adverse to our interests;
- commits any serious or repeated breach or non-observance of his obligations to the Company;
- becomes bankrupt, has an interim order made against him under the United Kingdom Insolvency Act 1986 or makes any composition

or enters into any deed of arrangement with his creditors or the equivalent of any of these under any other jurisdictions;

- becomes of unsound mind, becomes a patient under any statute relating to mental health or is unable, due to any accident, illness or injury, to undertake his duties for the Company for a period of more than six consecutive months;
- is convicted of a criminal offense (other than a motoring offense for which a non-custodial penalty is imposed);
- is disqualified by law or an order of a court of competent jurisdiction from holding office; or
- has failed to submit his resignation as Chairman and as a director of the Company when required to so pursuant to the terms of the Stahel Appointment Agreement.

In the event we terminate the agreement at any time with immediate effect (other than pursuant to the preceding paragraph), we will pay to Mr.

Stahel all fees which are due to him for the following 12 months.

Mr. Stahel may resign from his positions at any time if the Company (i) is guilty of any gross negligence which affects him or any dishonesty towards or concerning him or (ii) becomes insolvent, makes any composition or enters into any deed of arrangement with its creditors or the equivalent. If Mr. Stahel resigns due to these reasons, we will pay to Mr. Stahel all fees which are due to him for the following 12 months. Further, in the event that Mr. Stahel is unable, due to an accident, illness or injury, to undertake his duties for the Company in accordance with the terms of the Stahel Appointment Agreement for a period of more than six consecutive months, he may resign at any time without any rights to damages or compensation. Mr. Stahel is also required to resign in connection with the Board of Directors determination that his acceptance of any other employment, engagement, appointment, interest or involvement with any business or person competes or conflicts with his appointment and would result in a serious conflict of interest or Mr. Stahel reasonably determines such interest would result in a serious conflict of interest, and Mr. Stahel accepts such employment, engagement, appointment, interest or involvement, without any rights to damages or compensation. If Mr. Stahel resigns for any other reason, he must provide 12 months written notice.

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Compensation of Executive Officers

The following table summarizes the compensation earned by our senior management during 2020 (including for any service on any our subsidiaries), including one former executive officer.

Name	Salary (£)	Bonus (1)(£)	Option Awards (2) (£)	All Other Compensation (3)(£)	Total (£)
Stephen Stamp <i>Chief Executive Officer & Chief Financial Officer (4)</i>	175,000	--	45,000	18,169	238,169
Steve Damment, Ph.D. <i>Executive Vice President, Research and Development</i>	137,582	30,617	30,000	9,640	207,839
Craig Cook, MB, BCH <i>Former Chief Executive Officer (5)</i>	100,530	--	16,000	36,950	153,480
All current and former senior management as a group (3 persons)	443,112	30,617	91,000	74,759	599,488

- (1) Mr. Stamp, Dr. Damment and Dr. Cook have or had a bonus target of 33%, 30%, and 50% respectively, of their annual base salary, which bonus is or was payable upon attainment of objectives as determined in the subjective judgment of the Board of Directors or a committee thereof, taking into account various factors without any preassigned weighting. The Dr. Damment's bonus achieved for fiscal 2020 was paid in March 2021. Dr. Cook was not eligible to receive a bonus due to his resignation from the Company in March 2020.
- (2) The amounts reported in this column represent the aggregate grant date fair value of option awards computed in accordance with IFRS as of the grant date. The grant date fair value of the stock option awards to Mr. Stamp and Dr. Damment was £0.202 per share. Dr. Cook forfeited his outstanding stock options upon his resignation from the Company in March 2020, however, in connection with his resignation he was awarded 100,000 stock options. The grant date fair value of the stock option award granted to Dr. Cook in connection with his resignation was £0.16 per share.
- (3) The amounts reflect the value of benefits payable for medical benefits (£1,069, £1,385 and £177 for Mr. Stamp, Dr. Damment and Dr. Cook, respectively) and pursuant to pension plans (£17,100, £8,255 and £6,773 for Mr. Stamp, Dr. Damment and Dr. Cook, respectively). In addition, in connection with his resignation from the Company in March 2020, Dr. Cook received a one-time payment of £40,000, £10,000 of which was paid for work during his transition period and £30,000 of which was paid as a severance payment.
- (4) Mr. Stamp was appointed as our Chief Executive Officer effective March 31, 2020. He also continues to serve as our Chief Financial Officer.
- (5) Dr. Cook resigned as a director and Chief Executive Officer of the Company (including all positions held with our subsidiaries) effective March 31, 2020.

The following table sets forth, as of December 31, 2020, the aggregate number of option awards held by our senior management. Dr. Cook forfeited all of his outstanding option awards upon his resignation from the Company effective March 31, 2020. In connection with his resignation, Dr. Cook was subsequently granted an award for 100,000 stock options, as further detailed herein.

Name	Number of Options	Grant Date	Exercise Price per Share (£)	Expiration Date
Stephen Stamp	30,000 (1)	9/9/2019	1.05	9/9/2029
	300,000(2)	6/17/2020	0.202	1/17/2030
Steve Damment, Ph.D.	890(2)	10/31/2016	53.60	10/31/2026
	1,000(2)	12/19/2016	24.20	12/19/2026
	1,000(2)	12/15/2017	9.20	12/15/2027
	20,000(2)	4/24/2019	1.46	4/24/2029
	200,000(2)	6/17/2020	0.202	6/17/2030
Craig Cook, MB, BCH	100,000 (3)	4/17/2020	0.24	4/17/2030
All senior management as a group (3 persons)	652,890 (4)	(5)	(6)	(7)

- (1) 40% of the options were to vest upon a successful fundraise of at least \$20 million during the 12 months of Mr. Stamp's employment. These options did not vest and were subsequently cancelled. Of the remaining 60% of the options, 7,500 vested on September 9, 2020, and the remaining 22,500 options vest subsequently in 12 equal quarterly tranches, over a three-year period.
- (2) 25% of the options vest 12 months after the grant date, followed by vesting of 12 equal quarterly tranches, over a subsequent three-year period.
- (3) All of Dr. Cook's stock options are fully vested.
- (4) 118,890 stock options are fully vested.
- (5) The grant dates range from October 31, 2016 to June 17, 2020.
- (6) The exercise price of the options range from £0.202 to £53.60.
- (7) The stock options expire between October 31, 2026 and June 17, 2030.

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Agreements with Senior Management

Stephen Stamp. On September 9, 2019, we entered into a service agreement, or the Service Agreement, with Mr. Stamp. The Service Agreement provides for a base salary, incentive compensation benefits, and, in certain circumstances, severance benefits. The Service Agreement may be terminated, subject to certain exceptions, upon six months' prior notice.

The Service Agreement provides for an initial base salary of £160,000. Mr. Stamp's base salary is subject to increase each April 1 by the percentage increase, if any, in the "All Items Index of Retail Prices" published by the United Kingdom Office for National Statistics over the previous year. The base salary of Mr. Stamp is to be reviewed annually to consider any increase in salary. In connection with his promotion to Chief Executive Officer, Mr. Stamp's base salary was increased to £180,000 with effect from April 1, 2020.

The Service Agreements also include a bonus target for Mr. Stamp of 33% of his annual base salary, which bonus is payable upon attainment of objectives as determined in the subjective judgment of the Board of Directors or a committee thereof, taking into account various factors without any preassigned weighting. For the year ended December 31, 2020, the Remuneration Committee determined that, although 74% of the 2020 bonus objective had been achieved, the bonus award for Mr. Stamp would be deferred pending further evaluation of the Company's performance. In addition to base salary and bonus, the Service Agreement provides for additional benefits, such as a 10% pension contribution, life insurance, medical insurance, vacation benefits and any other additional benefits as determined by the Board of Directors from time to time.

Pursuant to the terms of the Service Agreement, Mr. Stamp has also agreed that, for a period of six months following his termination, he will not directly or indirectly compete with the Company. The Service Agreement includes provisions related to the non-disclosure of information and assignment of inventions. Among other things, these provisions prohibit Mr. Stamp from disclosing any of our proprietary and confidential information received during the course of employment and obligates him to assign to the Company any inventions conceived or developed during the course of his employment. The Service Agreement also includes customary confidentiality, non-solicitation, non-poaching and non-disparagement provisions.

The Service Agreement also provides Mr. Stamp with certain payments and/or benefits upon certain terminations of employment. If he is terminated due to his inability to perform his duties due to illness or other incapacity for a continuous period of three months, or an aggregate period exceeding 100 working days in any period of 12-months, we may, notwithstanding any other provision of the Service Agreement, terminate Mr. Stamp's employment upon six months' written notice. During that period, Mr. Stamp will not be entitled to receive his salary or any bonus payment, but will be entitled to any benefits owed under the Service Agreement. Further, notwithstanding any notice requirements for termination set forth in the Service Agreements, we may, at any time and in our absolute discretion, terminate the Service Agreement and provide Mr. Stamp with a payment in lieu of any required notice. The payment will comprise of his base salary, but will not include any bonus or other benefits, and shall be subject to any tax or insurance deductions. Notwithstanding the foregoing, we may terminate the Service Agreement without notice or payment in lieu thereof if Mr. Stamp:

- is guilty of serious misconduct or any other misconduct which affects, or is likely to affect, prejudicially our interests;
- fails or neglects to efficiently and diligently discharge his duties or commits any serious or repeated breach or non-observance of any of the provisions of the Service Agreement or any share dealing code we have adopted;
- has an interim receiving order made against him, becomes bankrupt or makes any composition or enters into any deed of arrangement with his creditors;
- is charged with an arrestable criminal offense (other than a road traffic offense in the United Kingdom or elsewhere for which a fine or non-custodial penalty is imposed);
- is disqualified from holding office in any company by reason of an order of a court of competent jurisdiction;
- becomes of unsound mind or becomes a patient under any statute relating to mental health;

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- is convicted of an offense under the United Kingdom's Criminal Justice Act 1993 in relation to insider dealings or under any other present or future statutory enactment or regulations relating to insider dealings;
- is in breach of the Model Code on directors' dealings in listed securities, including securities trading on AIM, published by the London Stock Exchange (the Model Code has subsequently been replaced by provisions under the MAR, however the employment agreements have not been updated to reflect this); or
- commits any other act warranting summary termination at common law including, but not limited to, any act justifying dismissal without notice in the terms of our generally applicable disciplinary rules.

Dr. Steve Damment. We have entered into a contract of employment, or the Contract of Employment, with Dr. Damment. The Contract of Employment was effective as of May 11, 2015 and provides for Dr. Damment's base salary, incentive compensation benefits, and compensation surrounding a termination of his employment. The Contract of Employment may be terminated by either Dr. Damment or the Company with three months prior notice.

The Contract of Employment provides for an initial base salary, which is subject to adjustment and which is currently £139,917, and also includes an initial bonus target of 20% (since updated to 30%) of Dr. Damment's annual base salary. In addition to base salary and bonus, the Contract of Employment provides for additional benefits, such as a 6% pension contribution, medical insurance, vacation benefits and any other additional benefits as determined by the Board of Directors from time to time.

Dr. Damment has also agreed that, for a period of six months following his termination (as reduced by any "garden leave" period), he will not compete with the Company, directly or indirectly, or solicit any customer, prospective customer or key employee. The Contract of Employment includes provisions related to confidentiality and the non-disclosure of information and assignment of inventions. Among other things, these

provisions prohibit Dr. Damment from disclosing any of our proprietary and confidential information received during the course of employment and require Dr. Damment to assign to us any inventions conceived or developed during the course of his employment.

The Contract of Employment provides that we will pay Dr. Damment his normal salary during any notice period prior to termination. We are also permitted to terminate Dr. Damment's employment effective immediately, without notice or payment, if Dr. Damment is found guilty of any fundamental or repudiatory breach of contract or any breach of the disciplinary rules applicable to Dr. Damment.

Settlement Agreement. In connection with Dr. Cook's resignation as our Chief Executive Officer and a member of the Board of Directors, on April 17, 2020, we entered into a settlement agreement, or the Settlement Agreement, with him. In consideration for Dr. Cook's resignation as Chief Executive Officer and from all other positions held with the Company or any of its subsidiaries, as well as his agreement to assist in the transition to Mr. Stamp as our Chief Executive Officer until April 30, 2020, we agreed to pay Dr. Cook a one-time payment of £40,000, £10,000 of which was paid for work during the transition period and £30,000 of which was paid as a severance payment, and unreimbursed expenses and accrued vacation time. The Settlement Agreement contains (or incorporates by reference) customary confidentiality, non-disparagement and restrictive covenants.

In addition, Dr. Cook was awarded 100,000 stock options at an exercise price of £0.24 per share. These options vested upon grant. Any additional options held lapsed upon his departure. Dr. Cook was also eligible to participate in the management incentive scheme, as discussed further herein.

Management Incentive Scheme

In connection with our implementation of a strategic review of our operations, the Board of Directors approved a management incentive plan, or the Management Incentive Scheme, that was designed to provide for a payment of a bonus, or a Retention Bonus, to members of our senior management, including Mr. Stamp, Dr. Damment and our former Chief Executive Officer, Dr. Cook, (i) upon the closing of a change of control or, (ii) if in the event one or a series of sales of our assets occurs, but such sale or sales do not constitute a change of control, then upon the determination of the Remuneration Committee, in its sole discretion.

We expect the Management Incentive Scheme will terminate in accordance with its terms on April 30, 2021, with no payments made under such scheme.

C. Board Practices

Board of Directors

Our Board of Directors is currently comprised of four directors, one of whom is an executive director and three non-executive directors, reflecting a blend of different experience and backgrounds. The roles of Chairman of the Board of Directors (which is a non-executive position) and Chief Executive Officer have been split and there is a clear division of responsibility between the two. With a view towards maintaining the independence of the Board of Directors, no remuneration is paid to either the Chairman or non-executive directors in the form of shares.

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With effect from September 28, 2018, all AIM listed companies were required to formally apply a recognized corporate governance code. We have chosen to adopt the principles of the Quoted Companies Alliance Corporate Governance Code for Small and Mid-Sized Quoted Companies, or the QCA Code. The QCA Code identifies ten principles to be followed in order for companies to deliver growth in long term shareholder value, encompassing and efficient, effective and dynamic management framework, accompanied by good communication, to promote confidence and trust.

The Board of Directors is responsible for *inter alia*, approving interim and annual financial statements, formulating and monitoring our strategy, approving financial plans and reviewing performance, as well as complying with legal, regulatory and corporate governance matters. There is a schedule of matters reserved for the Board of Directors.

The Board of Directors meets regularly to consider strategy, performance and the framework of internal controls. To enable the Board of Directors to discharge its duties, all directors receive appropriate and timely information. Briefing papers are distributed to all directors in advance of board meetings.

Board Committees

We have established audit, nomination, remuneration and disclosure committees of the Board of Directors with formally delegated duties and responsibilities. From time to time separate committees may be set up by the Board of Directors to consider specific issues when the need arises.

Audit Committee

The Audit Committee consists of three members: Simon Turton (Chairman), Sijmen de Vries and Rolf Stahel. The Board of Directors has determined that Messrs. de Vries, Turton and Stahel are independent under Rule 10A-3 of the Exchange Act and the applicable rules of NASDAQ and that Mr. Turton qualifies as an "audit committee financial expert" as defined under Item 16A of Form 20-F.

The Audit Committee of the Board of Directors assists the Board of Directors in discharging its responsibilities with regard to financial reporting, external and internal audits and controls, including reviewing and monitoring the integrity of the Company's annual and interim financial statements, advising on the appointment of external auditors, reviewing and monitoring the extent of the non-audit work undertaken by external auditors, overseeing our relationship with our external auditors, reviewing the effectiveness of the external audit process and reviewing the effectiveness of our internal control review function. The ultimate responsibility for reviewing and approving the annual report and accounts and the half-yearly reports remains with the Board of Directors.

The Audit Committee meets not less than twice a year and otherwise as required.

Nomination Committee

The Nomination Committee is chaired by Rolf Stahel and is currently comprised of all other members of the Board of Directors. The Nomination Committee assists the Board of Directors in discharging its responsibilities relating to the composition and make-up of the Board of Directors and any committees of the Board of Directors. It is responsible for periodically reviewing the Board of Directors' structure and identifying potential candidates to be appointed as directors or committee members as the need may arise. The Nomination Committee is responsible for evaluating the balance of skills, knowledge and experience and the size, structure and composition of the Board of Directors and committees of the Board of Directors, retirements and appointments of additional and replacement directors and committee members and will make appropriate recommendations to the Board of Directors on such matters.

The Nomination Committee meets not less than once a year and otherwise as required.

Remuneration Committee

The Remuneration Committee consists of three members: Sijmen de Vries (Chairman), Simon Turton and Rolf Stahel. The Board of Directors has determined that Messrs. de Vries, Turton and Stahel are independent under applicable rules of NASDAQ.

The Remuneration Committee of the Board of Directors is responsible, within agreed terms of reference, for establishing a formal and transparent procedure for developing policy on executive remuneration and setting the remuneration packages of individual directors. This includes agreeing with the Board of Directors on the framework for remuneration of the executive directors, the company secretary and such other members of our executive management as it is designated to consider. It is also responsible for determining the total individual remuneration packages of each director including, where appropriate, bonuses, incentive payments and share options. No director may be involved in any decision as to his/her own remuneration. The Remuneration Committee ensures compliance with the QCA Code in relation to remuneration wherever possible.

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The Remuneration Committee meets not less than twice a year and otherwise as required.

Disclosure Committee

The Disclosure Committee is chaired by Rolf Stahel and is currently comprised of all other members of the Board of Directors. The Disclosure Committee is considered to have a quorum with at least one executive and one non-executive director in attendance. The Disclosure Committee is responsible, within agreed terms of reference, for ensuring compliance with the AIM Rules, rules and regulations promulgated by the U.S. Securities and Exchange Commission and the rules of NASDAQ, and disclosure of information. The Disclosure Committee works closely with the Board of Directors to ensure that our nominated adviser is provided with any information it reasonably requests or requires in order for it to carry out its responsibilities under the AIM Rules and the AIM Rules for Nominated Advisers.

The Disclosure Committee meets at least four times a year and otherwise as required.

Service Contracts

Except as described herein, we do not have service contracts with any member of our Board of Directors or our senior management.

D. Employees

The number of our employees by geographic location and function as of the end of the period for the fiscal years ended December 31, 2020, 2019 and 2018 were as follows:

	As of December 31,		
	2020	2019	2018
Business functional area:			
Research and development	13	52	62
General and administration	5	13	11
Total	<u>18</u>	<u>65</u>	<u>73</u>
	As of December 31,		
	2020	2019	2018
Geography:			
United Kingdom	18	24	35
Spain	—	41	38
Total	<u>18</u>	<u>65</u>	<u>73</u>

To our knowledge, none of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Following our strategic review, our facilities in Bilbao, Spain were closed and all employee made redundant. The redundancy process was implemented under a process under Spanish mediation process that entailed extensive consultation with a worker's council.

E. Share Ownership

Information with respect to share ownership of members of our Board of Directors and our senior management is included in "Item 7. Major Shareholders and Related Party Transactions-A. Major Shareholders."

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Equity Benefit Plans

Midatech Pharma PLC 2014 Enterprise Management Incentive Scheme

The Board of Directors has established the Midatech Pharma PLC 2014 Enterprise Management Incentive Scheme, or 2014 Plan, to allow us to grant options to purchase Ordinary Shares to qualifying employees and directors of the Group, or Plan Participants, for the purpose of attracting, rewarding and retaining such persons.

Administration. The overall responsibility for the operation and administration of the 2014 Plan is vested in the Board of Directors.

Eligibility. In order to be eligible to participate as a Plan Participant in the 2014 Plan, a person must be an employee or director of the Company or any of its subsidiaries whose "committed time" amounts to at least 25 hours a week or, if less, 75% of his or her "working time," as each of those terms are defined under the Her Majesty's Revenue and Customs rules set out in Schedule 5 to the Income Tax (Earnings and Pensions) Act 2003 of the United Kingdom, or Schedule 5. The Board of Directors may exercise its discretion in selecting the Plan Participants to whom stock options will be granted under the 2014 EMI Scheme.

Grant of Options. Options may be granted from time to time by the Board of Directors, other than when grants are not permitted under the applicable law or there are other restrictions with regards to the Ordinary Shares. No payment will be made for the grant of a stock option.

Form of Options. Stock options granted under the 2014 Plan may be granted either with an exercise price greater than or equal to the market value of Ordinary Share at the date of grant, but not in any event at a price less than the nominal value of such share. The stock options may be stock options to subscribe for new Ordinary Shares.

The participant will have no stockholder rights until such time as he is able to exercise the stock option and acquire Ordinary Shares.

Size of Option Grants and Plan Limits. Stock options shall be granted under, and comply with, Schedule 5. This confers tax benefits on stock options up to a certain threshold. That threshold is currently such that when an employee has received and holds stock options with a value at grant of £250,000 or more, he or she may not have any further granted options for three years. In the event that this threshold is exceeded or the Company ceases to satisfy the qualifying conditions, unapproved options may instead be granted under the terms of the 2014 Plan. The total value of shares subject to unexercised options at any time may not exceed £3.0 million. All options must be exercised within 10 years from the grant date as set out in the rules of the 2014 Plan, or as set forth in the applicable option agreement.

The Board of Directors may from time to time specify the maximum number of Ordinary Shares in respect of which options may be granted.

Vesting of Options. In the normal course, stock options will become eligible for vesting subject to the satisfaction of time and financial performance targets.

If a Plan Participant leaves the employment of the Company or its subsidiaries for any reason, his or her stock option will generally lapse unless the Board of Directors exercises its discretion to allow the exercise of the stock option.

Performance Targets. All stock options granted under the 2014 Plan will be subject to appropriate performance targets determined by the Board of Directors, which may include share price targets, with stock options vesting in part on the attainment of each performance target.

Rights Attaching to Ordinary Shares. Ordinary Shares issued in connection with the exercise of stock options will rank equally with all other Ordinary Shares then in issue (save as regards any rights attaching to Ordinary Shares by reference to a record date prior to entry of the shares on

the register of stockholders). Application will be made for admission to trading on AIM of new Ordinary Shares issued under the 2014 Plan. *Adjustments.* If there is any adjustment of our issued share capital, the Ordinary Shares subject to a stock option will be subject to appropriate adjustment. The Board of Directors may adjust stock options in such manner as it determines to be appropriate.

Midatech Pharma PLC Employee Share Incentive Plan

In 2017, we set up the Midatech Pharma Share Incentive Plan, or the MPSIP. Under the MPSIP, our employees and directors can acquire Ordinary Shares in the Company via a salary sacrifice arrangement. We grant matching shares for every share bought. In order to retain these shares, scheme participants must remain employed by the Group for three years from the date of acquisition. All shares purchased by the MPSIP are held by an Employee Benefit Trust that is not under our control. Shares must be left in the plan for five years to qualify for full income tax relief. As of December 31, 2020, we had available 4,807,407 of our Ordinary Shares for issuance under the MPSIP.

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ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS.

A. Major Shareholders

The following table sets forth information, to our knowledge, as of April 15, 2021, regarding the beneficial ownership of Ordinary Shares, including:

- each person that is known by us to be a beneficial owner of 3% or more of Ordinary Shares (based on information in our share register and information provided by such persons);
- each member of our Board of Directors;
- each member of our senior management; and
- all members of our Board of Directors and our senior management, taken as a group.

Beneficial ownership of shares is determined under rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Except as noted by footnote, and subject to community property laws where applicable, we believe, based upon the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all Ordinary Shares shown as beneficially owned by them. The percentage of beneficial ownership is based upon 63,380,667 Ordinary Shares outstanding as of April 15, 2021. Ordinary Shares subject to options or warrants currently exercisable or exercisable within 60 days of April 15, 2021 are deemed to be outstanding and beneficially owned by the person holding the options for the purposes of computing the percentage of beneficial ownership of that person and any group of which that person is a member, but are not deemed outstanding for the purpose of computing the percentage of beneficial ownership for any other person. Unless otherwise indicated, the address for each holder listed below is Midatech Pharma PLC, Oddfellows House, 19 Newport Road, Cardiff, CF24 0AA, United Kingdom. All holders of Ordinary Shares, including those shareholders listed below, have the same voting rights with respect to such shares.

Name of Beneficial Owner	Amount and Nature Of Ownership	Percent of Class
Major Stockholders:		
Entities affiliated with Dr. Lam Kong (1)	20,779,220	28.3%
Armistice Capital LLC (2)	3,310,000**	4.9%
Directors and Senior Management:		
Steve Damment, Ph.D. (3)	9,266	*
Sijmen de Vries, M.D. (4)	47,785	*
Rolf Stahel (5)	77,709	*
Stephen Stamp (6)	63,125	*
Simon Turton, Ph.D. (7)	97,179	*
Directors and senior management as a group (5 persons) (8)	295,064	*

* Less than one percent of the outstanding Ordinary Shares.

** Subject to 4.99% blocker. See Footnote (2) below.

- (1) Information in the table and this footnote is based upon information contained in a Schedule 13D filed with the SEC on April 4, 2019 by A&B (HK) Company Limited, A&B Brother Limited, China Medical System Holdings Limited, CMS Medical Venture Investment (HK) Limited, and Dr. Lam Kong. Includes (i) for A&B (HK) Company Limited, 5,194,805 Ordinary Shares held of record and 5,194,805 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at April 15, 2021, and (ii) for CMS Medical Venture Investment (HK) Limited, 5,194,805 Ordinary Shares held of record and 5,194,805 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at April 15, 2021. A&B (HK) Company Limited is a wholly owned subsidiary of A&B Brother Limited, which is wholly owned by Dr. Lam Kong. CMS Medical Venture Investment (HK) Limited is a wholly owned subsidiary of China Medical System Holdings Limited, of which Dr. Lam Kong is the President, Chief Executive Officer and Chairman of the Board and maintains a 43.96% indirect ownership interest. Each of A&B (HK) Company Limited and A&B Brother Limited is deemed to be the beneficial owner with shared dispositive and voting power with respect to 5,194,805 Ordinary Shares and 5,194,805 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at April 15, 2021. Each of China Medical System Holdings Limited and CMS Medical Venture Investment (HK) Limited is deemed to be the beneficial owner with shared dispositive and voting power with respect to 5,194,805 Ordinary Shares and 5,194,805 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at May 22, 2020. Dr. Lam Kong is deemed to be the beneficial owner with shared dispositive and voting power with respect to 10,389,610 Ordinary Shares and 10,389,610 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at May 22, 2020. The principal business address of China Medical System Holdings Limited and CMS Medical Venture Investment (HK) Limited is Unit 2106, 21/F, Island Place Tower, 510 King's Road, North Point, Hong Kong, China. The principal place of business for A&B (HK) Company Limited is Unit A, 11/F, Chung Pont Commercial Building, 300 Hennessy Road, Wanchai, Hong Kong, China. The principal business address for A&B Brother Limited is Trident Chambers, P.O. Box 146, Road Town, Tortola, British Virgin Island. The principal business address of Dr. Lam Kong is Unit 2106, 21/F, Island Place Tower, 510 King's Road, North Point, Hong Kong, China.

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- (2) Information in the table and this footnote is based upon information contained in a Schedule 13G/A filed with the SEC on February 14, 2020 by Armistice Capital, LLC (though amounts included in such Schedule 13G/A have been adjusted in this annual

report to give effect to the reverse stock split and Depositary Share ratio change), information provided to us by the direct stockholder, Armistice Capital Master Fund Ltd., or Armistice, and our information and belief. The amounts and percentages in the table give effect to the 4.99% beneficial ownership limitation set forth in warrants held by Armistice. Armistice Capital, LLC, the investment manager of Armistice, and Steven Boyd, the managing member of Armistice Capital, LLC, hold shared voting and dispositive power over the shares held by Armistice. The principal business address of Armistice is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, New York, 10022.

- (3) Shares owned by Dr. Damment include 7,266 Ordinary Shares subject to outstanding stock options which are exercisable at April 15, 2021 or will become exercisable within 60 days after such date.
- (4) Shares owned by Dr. de Vries include 200 Ordinary Shares subject to outstanding stock options and 21,344 Ordinary Shares issuable upon the exercise of warrants, each of which are exercisable at April 15, 2021 or will become exercisable within 60 days after such date. Includes 2,957 Ordinary Shares held by Promida Holdings, in which Dr. de Vries has a minority interest.
- (5) Shares owned by Mr. Stahel include 23,856 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at April 15, 2021.
- (6) Shares owned by Mr. Stamp include 13,125 Ordinary Shares subject to outstanding stock options which are exercisable at April 15, 2021 or will become exercisable within 60 days after such date.
- (7) Shares owned by Dr. Turton include 41,854 Ordinary Shares issuable upon the exercise of warrants, which are exercisable at April 15, 2021.
- (8) Shares owed by all directors and senior management as a group include 20,591 Ordinary Shares subject to outstanding stock options and 87,054 Ordinary Shares issuable upon the exercise of warrants, each of which are exercisable at April 15, 2021 or will become exercisable within 60 days after such date.

As of April 15, 2021, 21% of our outstanding Ordinary Shares was held by registered shareholders with addresses in the United Kingdom, and we had 305 individual holders of record. The Bank of New York Mellon is the holder of record for our Depositary Share program, pursuant to which each Depositary Share represents five Ordinary Shares. As of April 15, 2021, The Bank of New York Mellon, as depositary for the Depositary Shares, held 39,227,410 Ordinary Shares, representing 62% of the issued share capital held at that date. As of April 15, 2021, we had 24 holders of record with an address in the United States, and such holders held less than one percent of our outstanding Ordinary Shares. The number of holders of record or registered holders in the United States or United Kingdom is not representative of the number of beneficial holders or of the residence of beneficial holders.

Based on our share register, and the limitations set forth in the Relationship Agreement with the CMS Parties or their affiliates, we believe that we are not directly or indirectly controlled by another corporation or government, or by any other natural or legal persons. There are no arrangement that may result in a change of control. Our major shareholders do not have different voting rights than other holders of our Ordinary Shares.

To our knowledge, other than as disclosed elsewhere in this Annual Report on Form 20-F, there has been no significant change in the percentage ownership of our Ordinary Shares held by the principal shareholders listed above in the last three years.

B. Related Party Transactions

Agreement with Chesyl Pharma Limited

In April 2014, Midatech Limited entered into a consultancy agreement, or the Consultancy Agreement, with Chesyl Pharma Limited, or Chesyl. Chesyl is wholly owned by Mr. Rolf Stahel, our non-executive Chairman of the Board and director. The term of the Consultancy Agreement commenced on March 1, 2014, with an initial term of 12 months and continuing thereafter until terminated in accordance with its terms. Chesyl was engaged to provide management consultancy services, including support and assistance to the board of directors of Midatech Limited in relation to operational issues and the provision of advice in relation to corporate strategy, corporate activities, fund raising and mergers and acquisition opportunities, collectively the Services.

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Pursuant to the terms of the Consultancy Agreement, Mr. Stahel (or a similarly qualified substitute party, approved by the Midatech Limited) is obliged to procure the Services at such times and at such locations as may be reasonably necessary for 10 full working days per year. Mr. Stahel may not sub-contract these obligations. Midatech Limited will pay Chesyl £40,000 per annum for Mr. Stahel's services (reduced from £50,000 with effect from October 1, 2017), and if engaged for any additional days, a rate of £2,000 will be paid per full working day.

Agreements with the CMS Parties

CMS License Agreement

For information regarding the CMS License Agreement, see "Item 4. Information on the Group-B. Business Overview-Commercial Agreements, Strategic Partnerships and Collaborations-CMS License Agreement."

Relationship Agreement

On January 29, 2019, the Company, Panmure Gordon (UK) Limited (our nominated advisor), the CMS Stockholders and certain affiliates of the CMS Stockholders, entered a Relationship Agreement, or the Relationship Agreement, in order to regulate our relationships with the CMS and its affiliated entities, collectively the CMS Parties, and to limit their influence over our corporate actions and activities and the outcome of general matters pertaining to the Group. The Relationship Agreement was effective from February 26, 2019. The Relationship Agreement was subsequently amended on May 12, 2020.

Pursuant to the terms of the Relationship Agreement, the CMS Parties have agreed to (amongst other things):

- conduct all transactions with us on an arm's length terms and on a normal commercial basis, including in accordance with the related party rules set out in the AIM Rules and any other applicable laws, regulations and stock exchange rules, and only with the prior approval of a majority of independent directors;
- exercise their voting rights or other rights and powers so as to ensure that each member of their respective Groups is capable of carrying on its business and making decisions independently of each of the CMS Parties (and any of their group companies and associates);
- abstain from voting in respect of any resolution concerning any contract, arrangement or transaction with a related party of each of the CMS Parties (or any of their associates); and
- vote, at a general meeting or when an election is required, their shares in the same manner and proportion as all other Ordinary Shares are voted by shareholders other than the CMS Parties.

We further agreed to conduct all transactions, agreements and relationships (whether contractual or otherwise) with the CMS Parties (and any of their group companies and associates) on arm's length terms and on a normal commercial basis and in accordance with the related party rules set out in the AIM Rules.

The Relationship Agreement provides that any respective dispute between the Company and the CMS Parties and/or any of their respective associates relating to any existing or proposed transaction, arrangement or agreement between each of CMS Parties (or any of their associates) and

the Company shall be resolved by a decision of the majority of independent directors.

The obligations of the parties under the Relationship Agreement shall automatically terminate upon:

- the CMS Parties (or any of their associates) ceasing to beneficially hold 10%, in aggregate, of our issued Ordinary Shares; or
- the Ordinary Shares ceasing to be admitted to AIM.

Warrant Instrument

The CMS Stockholders were issued the CMS Warrants pursuant to a warrant instrument entered into by way of deed poll, or the Warrant Instrument, by the Company dated January 29, 2019, under which we agreed to issue up to an aggregate of 17,410,773 warrants to purchase our Ordinary Shares. Of this amount, and in connection with the Subscription Agreement, we issued an aggregate of 10,389,610 warrants to the CMS Stockholders.

Each warrant confers the right to subscribe for one Ordinary Share. The warrants are freely transferable. Each warrant is exercisable for cash at a price of £10.00 per share, subject to the terms and conditions described in the Warrant Instrument, or the Warrant Exercise Price, during the period commencing on August 26, 2019 and until August 26, 2022, or the Subscription Period.

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The Warrant Instrument contains customary provisions for adjustments to the Warrant Exercise Price in certain circumstances, including if, prior to the end of the Subscription Period, there shall occur any reorganization, recapitalization, consolidation or subdivision, involving the Company.

Deed of Indemnity

We have entered into a Deed of Indemnity for the benefit of our Board of Directors and Company Secretary. For more information, see “*Item 6. Directors, Senior Management and Employees-B. Compensation-Deed of Indemnity.*”

Agreements with Directors and Senior Management

We have entered into certain agreements with directors and our senior management related to their service on our Board of Directors or employment with the Company. For more information, see “*Item 6. Directors, Senior Management and Employees.*”

Share Acquisitions by Related Parties

Since January 1, 2020, we have not engaged in transactions with our directors, senior management or holders of 10% or more of our Ordinary Shares, or affiliates of our directors, senior management or holders of more than 10% of our Ordinary Shares that are the type required to be described in this Annual Report on Form 20-F pursuant to Item 7.B. of Form 20-F.

C. Interests of Experts and Counsel

Not Applicable

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information

See “*Item 18. Financial Statements.*”

Legal Proceedings

For more information, see “*Information on the Group-B. Business Overview-Legal Proceedings.*”

Dividend Policy

We have never declared or paid any cash dividends on our shares, and have no present intention of declaring or paying any dividends in the foreseeable future. We may, by ordinary resolution, declare a dividend to be paid to the share owners according to their respective rights and interests in profits, and may fix the time for payment of such dividend. No dividend may be declared in excess of the amount recommended by the directors. The directors may from time to time declare and pay to our share owners such interim dividends as appear to the directors to be justified by our profits available for distribution. There are no fixed dates on which entitlement to dividends arises on our Ordinary Shares.

The share owners may pass, on the recommendation of the directors, an ordinary resolution to direct that all or any part of a dividend to be paid by distributing specific assets, in particular paid up shares or debentures of any other body corporate. The articles also permit, with the prior authority of an ordinary resolution of shareholders, a scrip dividend scheme under which share owners may be given the opportunity to elect to receive fully paid Ordinary Shares instead of cash, or a combination of shares and cash, with respect to future dividends.

By the way of the exercise of a lien, if a share owner owes any money to the Company relating in any way to shares, the Board of Directors may deduct any of this money from any dividend on any shares held by the share owner, or from other money payable by the Company in respect of the shares. Money deducted in this way may be used to pay the amount owed to the Company.

Unclaimed dividends and other money payable in respect of a share can be invested or otherwise used by directors for the benefit of the Company until they are claimed. A dividend or other money remaining unclaimed 12 years after it first became due for payment will be forfeited and shall revert to the Company.

All of the shares represented by the Depositary Shares have the same dividend rights as all of our other outstanding shares.

B. Significant Changes

Other than the information set forth herein, there have been no significant changes since December 31, 2020.

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ITEM 9. THE OFFER AND LISTING.

A. Offer and Listing Details.

Our Ordinary Shares are listed on AIM under the symbol “MTPH” and the Depositary Shares are listed on the NASDAQ Capital Market under the symbol “MTP.”

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed on AIM under the symbol “MTPH” and the Depositary Shares are listed on the NASDAQ Capital Market under the symbol “MTP.”

D. Seller Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We incorporate by reference into this Annual Report on Form 20-F the description of our articles of association contained in Exhibit 2.1 to this Annual Report on Form 20-F.

C. Material Contracts

Except as otherwise disclosed in this annual report, we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

Other than certain economic sanctions which may in place from time to time, there are currently no United Kingdom laws, decrees or regulations restricting the import or export of capital or affecting the remittance of dividends or other payment to holders of Ordinary Shares who are non-residents of the United Kingdom. Similarly, other than certain economic sanctions which may be in force from time to time, there are no limitations relating only to non-residents of the United Kingdom under English law or our articles of association on the right to be a holder of, and to vote in respect of, the Ordinary Shares.

E. Taxation

Certain United Kingdom Taxation Considerations

The following is a general summary of certain United Kingdom tax considerations relating to the ownership and disposal of our Ordinary Shares or Depositary Shares and does not address all possible tax consequences relating to an investment in our Ordinary Shares or Depositary Shares. It is based on United Kingdom tax law and generally published Her Majesty's Revenue & Customs, or HMRC, practice as of the date of this Annual Report, both of which are subject to change, possibly with retrospective effect. A United Kingdom tax year runs from April 6th in any year to April 5th in the following year.

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Save as provided otherwise, this summary applies only to a person who is the absolute beneficial owner of our Ordinary Shares or Depositary Shares and who is resident (and, in the case of an individual, domiciled) in the United Kingdom for tax purposes and who is not resident for tax purposes in any other jurisdiction and does not have a permanent establishment or fixed base in any other jurisdiction with which the holding of our Ordinary Shares or Depositary Shares is connected, or a U.K. Holder. A person who is not a U.K. Holder, including a person (a) who is not resident (or, if resident, is not domiciled) in the United Kingdom for tax purposes, including an individual and company who trades in the United Kingdom through a branch, agency or permanent establishment in the United Kingdom to which an Ordinary Share or Depositary Share is attributable, or (b) who is resident or otherwise subject to tax in a jurisdiction outside the United Kingdom, is recommended to seek the advice of professional advisors in relation to their taxation obligations.

This summary is for general information only and is not intended to be, nor should it be considered to be, legal or tax advice to any particular investor. It does not address all of the tax considerations that may be relevant to specific investors in light of their particular circumstances or to investors subject to special treatment under United Kingdom tax law. In particular this summary:

- only applies to an absolute beneficial owner of Ordinary Shares or Depositary Shares and any dividend paid in respect of that Ordinary Share where the dividend is regarded for United Kingdom tax purposes as that person's own income (and not the income of some other person); and
- (a) only addresses the principal United Kingdom tax consequences for an investor who holds Ordinary Shares or Depositary Shares as a capital asset, (b) does not address the tax consequences that may be relevant to certain special classes of investor such as a dealer, broker or trader in shares or securities and any other person who holds Ordinary Shares or Depositary Shares otherwise than as an investment, (c) does not address the tax consequences for a holder that is a financial institution, insurance company, collective investment scheme, pension scheme, charity or tax-exempt organization, (d) assumes that a holder is not an officer or employee of the company (nor of any related company) and has not (and is not deemed to have) acquired the Ordinary Shares or Depositary Shares by virtue of an office or employment, and (e) assumes that a holder does not control or hold (and is not deemed to control or hold), either alone or together with one or more associated or connected persons, directly or indirectly (including through the holding of Depositary Shares), an interest of 10% or more in the issued share capital (or in any class thereof), voting power, rights to profits or capital of the company, and is not otherwise connected with the company.

This summary further assumes that a holder of Depositary Shares is the beneficial owner of the underlying Ordinary Shares for United Kingdom direct tax purposes.

POTENTIAL INVESTORS IN THE DEPOSITARY SHARES SHOULD SATISFY THEMSELVES PRIOR TO INVESTING AS TO THE OVERALL TAX CONSEQUENCES, INCLUDING, SPECIFICALLY, THE CONSEQUENCES UNDER UNITED KINGDOM TAX LAW AND HMRC PRACTICE OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ORDINARY SHARES OR DEPOSITARY SHARES, IN THEIR OWN PARTICULAR CIRCUMSTANCES BY CONSULTING THEIR OWN TAX ADVISERS.

Taxation of Dividends

Withholding Tax. A dividend payment in respect of an Ordinary Share may be made without withholding or deduction for or on account of United Kingdom tax.

Income Tax. An individual holder of Ordinary Shares or Depositary Shares who is not a U.K. Holder will not be chargeable to United Kingdom income tax on a dividend paid by the Company, unless such holder carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency in the United Kingdom to which the Ordinary Shares or Depositary Shares are attributable. In these circumstances, such holder may, depending on his or her individual circumstances, be chargeable to United Kingdom income tax on a dividend received from the Company.

A dividend received by individual U.K. Holders will be subject to United Kingdom income tax. The rate of United Kingdom income tax that is chargeable on dividends received in the tax year 2021/2022 by an individual U.K. Holder who is (i) an additional rate taxpayer is 38.1%, (ii) a higher rate taxpayer is 32.5%, and (iii) a basic rate taxpayer is 7.5%. An individual U.K. Holder may be entitled to a tax-free dividend allowance (in addition to their personal allowance) of £2,000 for the tax year 2021/2022. This means that the relevant individual does not need to pay United Kingdom income tax on their first £2,000 of dividend income received. Dividends within the dividend allowance will still count towards the relevant individual's basic, higher or additional rate bands however. An individual's dividend income is treated as the top slice of their total income that is chargeable to United Kingdom income tax. Dividends which are covered by an individual's personal income tax allowance do not count towards and are ignored for the dividend allowance.

Corporation Tax. A U.K. Holder within the charge to United Kingdom corporation tax may be entitled to exemption from United Kingdom corporation tax in respect of dividend payments in respect of an Ordinary Share. If the conditions for the exemption are not satisfied or such U.K. Holder elects for an otherwise exempt dividend to be taxable, United Kingdom corporation tax will be chargeable on the dividend. The rate of United Kingdom corporation tax is currently 19%. If potential investors are in any doubt as to their position, they should consult their own professional advisers.

A corporate holder of Ordinary Shares or Depositary Shares that is not a U.K. Holder will not be subject to United Kingdom corporation tax on a dividend received from the company, unless it carries on a trade in the United Kingdom through a permanent establishment to which the Ordinary Shares or Depositary Shares are attributable. In these circumstances, such holder may, depending on its individual circumstances and if the exemption from United Kingdom corporation tax discussed above does not apply, be chargeable to United Kingdom corporation tax on dividends received from the Company.

Taxation of Disposals

U.K. Holders. A disposal or deemed disposal of Ordinary Shares or Depositary Shares by an individual U.K. Holder may, depending on his or her individual circumstances, give rise to a chargeable gain or to an allowable loss for the purpose of United Kingdom capital gains tax. The principal factors that will determine the capital gains tax position on a disposal of Ordinary Shares or Depositary Shares are the extent to which the holder realizes any other capital gains in the tax year in which the disposal is made, the extent to which the holder has incurred capital losses in that or any earlier tax year and the level at which the annual exempt amount for United Kingdom capital gains tax (the “annual exempt amount”) is set by the United Kingdom government for that tax year. The annual exempt amount for the 2021/2022 tax year is £12,300. If, after all allowable deductions, an individual U.K. Holder’s total taxable income for the relevant tax year exceeds the basic rate income tax limit, a taxable capital gain accruing on a disposal of an Ordinary Share or a Depositary Shares is taxed at the rate of 20%. In other cases, a taxable capital gain accruing on a disposal of our Ordinary Shares or Depositary Shares may be taxed at the rate of 10% or the rate of 20% or at a combination of both rates.

An individual U.K. Holder who ceases to be resident in the United Kingdom (or who fails to be regarded as resident in a territory outside the United Kingdom for the purposes of double taxation relief) for a period of less than five calendar years and who disposes of Ordinary Shares or Depositary Shares during that period of temporary non-United Kingdom residence may be liable to United Kingdom capital gains tax on a chargeable gain accruing on such disposal on his or her return to the United Kingdom (or upon ceasing to be regarded as resident outside the United Kingdom for the purposes of double taxation relief) (subject to available exemptions or reliefs).

A disposal (or deemed disposal) of Ordinary Shares or Depositary Shares by a corporate U.K. Holder may give rise to a chargeable gain or an allowable loss for such holder for the purpose of United Kingdom corporation tax. Such a holder should be entitled to an indexation allowance, which applies to reduce a capital gain to the extent that such a gain arises due to inflation. The allowance may reduce a chargeable gain but will not create or increase an allowable loss. The indexation allowance was frozen with effect from December 31, 2017, such that for disposals on or after January 1, 2018, the indexation allowance figure only covers the movement in the “retail price index” to December 31, 2017.

Any gain or loss in respect of currency fluctuations over the period of holding Ordinary Shares or Depositary Shares is also brought into account on a disposal.

Non-U.K. Holders. An individual holder who is not a U.K. Holder will not be liable to United Kingdom capital gains tax on capital gains realized on the disposal of Ordinary Shares or Depositary Shares unless such holder carries on (whether solely or in partnership) a trade, profession or vocation in the U.K. through a branch or agency in the United Kingdom to which the Ordinary Shares or Depositary Shares are attributable. In these circumstances, such holder may, depending on his or her individual circumstances, be chargeable to United Kingdom capital gains tax on chargeable gains arising from a disposal of his or her Ordinary Shares or Depositary Shares.

A corporate holder of Ordinary Shares or Depositary Shares that is not a U.K. Holder will not be liable for United Kingdom corporation tax on chargeable gains realized on the disposal of Ordinary Shares or Depositary Shares unless it carries on a trade in the United Kingdom through a permanent establishment to which the Ordinary Shares or Depositary Shares are attributable. In these circumstances, a disposal (or deemed disposal) of Ordinary Shares or Depositary Shares by such holder may give rise to a chargeable gain or an allowable loss for the purposes of United Kingdom corporation tax.

Inheritance Tax

If for the purposes of the Double Taxation Relief (Taxes on Estates of Deceased Persons and on Gifts) Treaty United States of America Order 1979 (SI 1979/1454) between the United States and the United Kingdom an individual holder is at the time of their death or a transfer made during their lifetime, domiciled in the United States and is not a national of the United Kingdom, any Ordinary Shares or Depositary Shares beneficially owned by that holder should not generally be subject to United Kingdom inheritance tax, provided that any applicable United States federal gift or estate tax liability is paid, except where (i) the Ordinary Shares or Depositary Shares are part of the business property of a United Kingdom permanent establishment or pertains to a United Kingdom fixed base used for the performance of independent personal services; or (ii) the Ordinary Shares or Depositary Shares are comprised in a settlement unless, at the time the settlement was made, the settlor was domiciled in the United States and not a national of the United Kingdom (in which case no charge to United Kingdom inheritance tax should apply).

Stamp Duty and Stamp Duty Reserve Tax

The United Kingdom stamp duty, or stamp duty, and United Kingdom stamp duty reserve tax, or SDRT, treatment of the issue and transfer of, and the agreement to transfer, an ordinary share outside a depositary receipt system or a clearance service is discussed in the paragraphs under “General” below. The stamp duty and SDRT treatment of such transactions in relation to such systems is discussed in the paragraphs under “Depositary Receipt Systems and Clearance Services” below.

General

An agreement to transfer an ordinary share would normally give rise to a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer. SDRT is, in general, payable by the purchaser. However, since April 28, 2014, no SDRT or stamp duty is chargeable in respect of shares that are admitted to trading on a ‘recognized growth market’ and not listed on any ‘recognized stock exchange’, or the AIM Exemption. As our Ordinary Shares are admitted to trading on AIM (which qualifies as a ‘recognized growth market’) and not listed on any market that would qualify as a ‘recognized stock exchange,’ a transfer of an ordinary share is presently exempt from the charge to SDRT.

Subject to the above noted AIM Exemption, a transfer of an Ordinary Share would be subject to stamp duty at the rate of 0.5% of the consideration given for the transfer (rounded up to the next £5). The purchaser is liable to HMRC for the payment of the stamp duty (if any). Under current HMRC guidance, no stamp duty should be payable on a written instrument transferring a Depositary Share or on a written agreement to transfer a Depositary Share, on the basis that the Depositary Share is not regarded as either “stock” or a “marketable security” for United Kingdom stamp duty purposes.

If a duly stamped transfer completing an agreement to transfer is produced within six years of the date on which the agreement is made (or, if the

agreement is conditional, the date on which the agreement becomes unconditional) any SDRT already paid is generally repayable, normally with interest, and any SDRT charge yet to be paid is canceled to avoid a double charge as the stamp duty has been paid.

Depository Receipt Systems and Clearance Services

The Court of Justice of the European Union in *C-569/07 HSBC Holdings Plc, Vidacos Nominees Limited v The Commissioners of Her Majesty's Revenue & Customs* and the First-tier Tax Tribunal decision in *HSBC Holdings Plc and the Bank of New York Mellon Corporation v The Commissioners of Her Majesty's Revenue & Customs*, have considered the provisions of the European Union Council Directive 69/335/EEC, which was subsequently substituted by the European Union Council Directive 2008/7/EEC, or the E.U. Directives. Following these decisions HMRC has publicly confirmed that issues or transfers of shares of United Kingdom incorporated companies, such as us, to a clearance service (such as, in our understanding, DTC) or a depository receipt system will not be charged to United Kingdom SDRT at 1.5% where that issue or transfer is an integral part of a raising of new capital.

It was announced as part of the United Kingdom Budget 2017 by the United Kingdom government that the 1.5% stamp duty and SDRT charge will not be enforced on the issue of shares by United Kingdom incorporated companies (and transfers of such shares where the transfer is integral to new capital raising) into clearance services and depository receipt systems following Brexit. However, the United Kingdom government could potentially introduce new United Kingdom legislation with the effect that a future issue or transfer of our Ordinary Shares into a clearance service or depository receipt system (even where such an issue or transfer is an integral part of the raising of new capital by the company) may potentially become chargeable to 1.5% stamp duty or SDRT. However, as long as our Ordinary Shares continue to be admitted to trading on AIM and not to be listed on any market that would qualify as a 'recognized stock exchange,' it is our understanding that the AIM Exemption should continue to exempt future issues and transfers of our Ordinary Shares into clearance services or depository receipt systems from any 1.5% stamp duty and SDRT charge.

Subject to the AIM exemption, where an ordinary share is transferred (i) to, or to a nominee for, a person whose business is or includes the provision of clearance services or (ii) to, or to a nominee for a person whose business is or includes issuing depository receipts and that transfer is not integral to the raising of new capital by the company, stamp duty or SDRT would generally be chargeable at the rate of 1.5% of the amount or value of the consideration given or, in certain circumstances, the value of the shares.

There is an exception from the 1.5% charge on the transfer to, or to a nominee, a clearance service where the clearance service has made and maintained an election under section 97A(1) of the Finance Act 1986, which has been approved by HMRC. If such an election were made by a clearance service, subject to the AIM exemption, SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer would arise on any transfer of an ordinary share into such a clearance service and on subsequent agreements to transfer such share within such clearance service. It is our understanding that DTC has not to date made an election under section 97A(1) of the Finance Act of 1986.

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Any liability for stamp duty or SDRT in respect of a transfer into a clearance service or depository receipt system, or in respect of a transfer within such a service, which does arise, will strictly be accountable to HMRC by the clearance service or depository receipt system operator or their nominee, as the case may be, but will, in practice, be payable by the participants in the clearance service or depository receipt system.

Certain United States Taxation Considerations

The following is a summary of material United States federal income tax consequences of the ownership and disposition of Depository Shares by United States holders (as defined below). This summary is for general information only and is not tax advice. Each investor should consult its tax advisor with respect to the tax consequences of the ownership and disposition of our securities, including the impact of the recently enacted Tax Cut Act.

This summary is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, United States Treasury regulations promulgated thereunder (whether final, temporary, or proposed), administrative rulings, and judicial interpretations thereof, and the Convention Between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and on Capital Gains of 2001, as amended, or the United States-U.K. Treaty, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect.

For purposes of this discussion, the term "United States holder" means a holder of our Ordinary Shares or Depository Shares that is, for United States federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation that is created or organized in the United States or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
- any trust if (a) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons have the authority to control all substantial decisions of the trust, or (b) such trust has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person.

This summary addresses only the United States federal income tax considerations for United States holders that acquire and hold the Depository Shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of United States federal income taxation that may be relevant to a holder in light of its particular circumstances, or that may apply to holders that are subject to special treatment under the United States federal income tax laws (including, for example, banks, financial institutions, underwriters, insurance companies, dealers in securities or foreign currencies, traders in securities who elect the mark-to-market method of accounting for their securities, persons subject to the alternative minimum tax, persons that have a functional currency other than the United States dollar, tax-exempt organizations (including private foundations), mutual funds, subchapter S corporations, partnerships or other pass-through entities for United States federal income tax purposes, certain expatriates, corporations that accumulate earnings to avoid United States federal income tax, persons who hold Depository Shares as part of a hedge, straddle, constructive sale, conversion or other integrated transaction, persons who acquire Depository Shares through the exercise of options or other compensation arrangements, persons who own (or are treated as owning) 10% or more of our outstanding voting stock, or persons who are not United States holders). In addition, this discussion does not address any aspect of state, local, foreign, estate, gift or other tax law that may apply to holders of Depository Shares.

The United States federal income tax treatment of a partner in a partnership (including any entity or arrangement treated as a partnership for United States federal income tax purposes) generally will depend on the status of the partner and the activities of the partnership. A partner in such a partnership should consult its tax advisor regarding the associated tax consequences.

Consequences Relating to Ownership and Disposition of Depository Shares

Ownership of Depository Shares. For United States federal income tax purposes, a holder of Depository Shares will generally be treated as if such holder directly owned the ordinary shares represented by such Depository Shares.

Distributions on Depository Shares. Subject to the discussion below under "*-Passive Foreign Investment Company Rules*," the gross amount of any distribution on Depository Shares (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined

for United States federal income tax purposes) will generally be taxable to a United States holder as dividend income on the date such distribution is actually or constructively received. Any such dividends paid to corporate United States holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. Distributions in excess of our current and accumulated earnings and profits would generally be treated first as a non-taxable return of capital to the extent of the United States holder's basis in the Depositary Shares, and thereafter as capital gain. However, since we do not calculate our earnings and profits under United States federal income tax principles, it is expected that any distribution on Depositary Shares will be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

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Dividends paid in currencies other than the United States dollar, if any, will generally be taxable to a United States holder as ordinary dividend income in an amount equal to the United States dollar value of the currency received on the date such distribution is actually or constructively received. Such United States dollar value must be determined using the spot rate of exchange on such date, regardless of whether the non-United States currency is actually converted into United States dollars on such date. The United States holder may realize exchange gain or loss if the currency received is converted into United States dollars after the date on which it is actually or constructively received. In general, any such gain or loss will be ordinary and will be treated as from sources within the United States for United States foreign tax credit purposes.

Subject to the discussion below under “*3.8% Medicare Tax on Net Investment Income*,” dividends received by certain non-corporate United States holders (including individuals) from a “qualified foreign corporation” may be eligible for reduced rates of taxation, currently at a maximum rate of 20%, provided that certain holding period requirements and other conditions are satisfied. For these purposes, a foreign corporation will generally be treated as a qualified foreign corporation with respect to dividends paid by that corporation on shares that are readily tradable on an established securities market in the United States. United States Treasury Department guidance indicates that the Depositary Shares, which are listed on the NASDAQ Capital Market, would be considered readily tradable on an established securities market in the United States. However, there can be no assurance that the Depositary Shares will be considered readily tradable on an established securities market in future years. A foreign corporation is also treated as a qualified foreign corporation if it is eligible for the benefits of a comprehensive income tax treaty with the United States which is determined by the United States Treasury Department to be satisfactory for purposes of these rules and which includes an exchange of information provision. The United States Treasury Department has determined that the United States-U.K. Treaty meets these requirements. We would not constitute a qualified foreign corporation for purposes of these rules if we are a passive foreign investment company for the taxable year in which we pay a dividend or for the preceding taxable year, as discussed below under “*Passive Foreign Investment Company Rules*.”

Subject to certain conditions and limitations, non-United States taxes, if any, withheld on dividends paid by the Company may be treated as foreign taxes eligible for a credit against a United States holder's United States federal income tax liability under the United States foreign tax credit rules. The rules governing the United States foreign tax credit are complex, and United States holders should consult their tax advisors regarding the availability of the United States foreign tax credit under their particular circumstances.

Sale of Depositary Shares

A United States holder will generally recognize gain or loss on any sale, exchange, redemption, or other taxable disposition of Depositary Shares in an amount equal to the difference between the amount realized on the disposition and such holder's tax basis in such securities. Subject to the discussion below under “*Passive Foreign Investment Company Rules*,” any gain or loss recognized by a United States holder on a taxable disposition of Depositary Shares will generally be capital gain or loss and will be long-term capital gain or loss if the holder's holding period in such share exceeds one year at the time of the disposition. The deductibility of capital losses is subject to limitations.

For a cash basis taxpayer, units of foreign currency received will generally be translated into United States dollars at the spot rate on the settlement date of the sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such sale. An accrual basis taxpayer may elect to apply the same rules applicable to cash basis taxpayers with respect to the sale of Depositary Receipts that are traded on an established securities market, provided that the election must be applied consistently from year to year and cannot be changed without the consent of the IRS. For an accrual method taxpayer who does not make such an election, units of foreign currency received will generally be translated into United States dollars at the spot rate on the trade date of the sale. Such an accrual basis taxpayer may recognize foreign currency exchange gain or loss based on currency fluctuations between the trade date and the settlement date of such sale. In general, any such gain or loss will be ordinary and will be treated as from sources within the United States for United States foreign tax credit purposes.

Passive Foreign Investment Company Rules

A foreign corporation is a PFIC if either (1) 75% or more of its gross income for the taxable year is passive income or (2) the average percentage of assets held by such corporation during the taxable year that produce passive income or that are held for the production of passive income is at least 50%. For purposes of applying the tests in the preceding sentence, the foreign corporation is deemed to own its proportionate share of the assets, and to receive directly its proportionate share of the income, of any other corporation of which the foreign corporation owns, directly or indirectly, at least 25% by value of the stock.

Based upon estimates with respect to its income, assets, and operations, it is expected that we will not be a PFIC for the current taxable year. However, because the determination of PFIC status must be made on an annual basis after the end of the taxable year and will depend on the composition of the income and assets, as well as the nature of the activities, of our activities and those of our subsidiaries from time to time, there can be no assurance that we will not be considered a PFIC for any taxable year.

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If we were to be classified as a PFIC for any taxable year in which a United States holder held the Depositary Shares, various adverse United States tax consequences could result to such United States holders, including taxation of gain on a sale or other disposition of the shares of the corporation, Depositary Shares at ordinary income rates and imposition of an interest charge on gain or on distributions with respect to the shares, Depositary Shares. Unless a United States holder of PFIC shares elects, in either case if eligible, to be taxed annually on a mark-to-market basis or makes a QEF election and certain other requirements are met, gain realized on the sale or other disposition of PFIC shares would generally not be treated as capital gain. Instead, the United States holder would be treated as if the United States holder had realized such gain ratably over the holder's holding period for such securities. The amounts allocated to the taxable year of sale or other disposition and to any year before the foreign corporation became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for such year, together with an interest charge in respect of the tax attributable to each such year. Similar rules apply to the extent any distribution in respect of PFIC shares exceeds 125% of the average annual distribution on such PFIC securities received by the shareholder during the preceding three years or holding period, whichever is shorter. With certain exceptions, a foreign corporation is treated as a

PFIC with respect to a shareholder (or warrant holder, as applicable) if the corporation was a PFIC with respect to such holder at any time during the holder's holding period of the foreign corporation's stock or warrants. Dividends paid to with respect to shares of a PFIC are not eligible for the special tax rates applicable to qualified dividend income of certain non-corporate holders. Instead, such dividend income is taxable at rates applicable to ordinary income.

If we were to be treated as a PFIC, the tax consequences described above could be avoided by a "mark-to-market" election with respect to the Depositary Shares. A United States holder making a "mark-to-market" election (assuming the requirements for such an election are satisfied) generally would (i) be required to include as ordinary income the excess of the fair market value of the Depositary Shares on the last day of the United States holder's taxable year over the United States holder's adjusted tax basis in such Depositary Shares and (ii) be allowed a deduction in an amount equal to the lesser of (A) the excess, if any, of the United States holder's adjusted tax basis in the Depositary Shares over the fair market value of such Depositary Shares on the last day of the United States holder's taxable year or (B) the excess, if any, of the amount included in income because of the election for prior taxable years over the amount allowed as a deduction because of the election for prior taxable years. In addition, upon a sale or other taxable disposition of Depositary Shares, a United States holder would recognize ordinary income or loss (which loss could not be in excess of the amount included in income because of the election for prior taxable years over the amount allowed as a deduction because of the election for prior taxable years). If we were to be treated as a PFIC, different rules would apply to a United States holder making a QEF election with respect to Depositary Shares. However, we do not intend to prepare or provide the information necessary for United States shareholders to make a QEF election.

United States holders are urged to consult their own tax advisors about the PFIC rules, including the availability of the "mark-to-market" election.

3.8% Medicare Tax on "Net Investment Income"

A 3.8% tax, or "Medicare Tax," is imposed on all or a portion of "net investment income," which may include any gain realized or amounts received with respect to Depositary Shares received by (i) United States holders that are individuals with modified adjusted gross income in excess of certain thresholds, and (ii) certain estates and trusts. United States holders should consult their own tax advisors with respect to the applicability of the Medicare Tax resulting from ownership or disposition of Depositary Shares.

Information Reporting and Backup Withholding

United States holders may be subject to information reporting requirements and may be subject to backup withholding with respect to dividends on Depositary Shares and on the proceeds from the sale, exchange, or disposition of Depositary Shares unless the United States holder provides an accurate taxpayer identification number and complies with certain certification procedures or otherwise establishes an exemption from backup withholding. Backup withholding is not an additional tax and amounts withheld may be allowed as a credit against the United States holder's United States federal income tax liability and may entitle the United States holder to a refund, provided that certain required information is timely furnished to the IRS.

Foreign Asset Reporting

United States holders who are individuals and who own "specified foreign financial assets" with an aggregate value in excess of \$50,000 are generally required to file an information statement along with their tax returns, currently on IRS Form 8938, with respect to such assets. "Specified foreign financial assets" include securities issued by a non-United States issuer (which would include an investment in our securities) that are not held in accounts maintained by financial institutions. Higher reporting thresholds apply to certain individuals living abroad and to certain married individuals. Individuals who fail to report the required information could be subject to substantial penalties, and such individuals should consult their own tax advisors concerning the application of these rules to their investment in Depositary Shares.

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F. Dividends and Payment Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also make available on our website, free of charge, our annual report and the text of its reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is "www.midatechpharma.com." The information contained on our website is not incorporated by reference in this annual report.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to a variety of financial risks, including, but not limited to, market risk (including foreign exchange and interest rate risks), credit risks, and liquidity risks. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on its financial performance.

Credit Risk

Credit risk is the risk of financial loss to the Group if a development partner or counterparty to a financial instrument fails to meet its contractual obligations. We are mainly exposed to credit risk from amounts due from collaborative partners which are deemed to be low.

Credit risk also arises from cash and cash equivalents and deposits with banks and financial institutions. For banks and financial institutions, only independently rated parties with high credit status are accepted.

We do not enter into derivatives to manage credit risk.

The total exposure to credit risk of the Group is equal to the total value of the financial assets held at year end. The consolidated entity recognizes a loss allowance for expected credit losses on financial assets which are either measured at amortized cost or fair value through other comprehensive income. The measurement of the loss allowance depends upon the consolidated entity's assessment at the end of each reporting period as to whether the financial instrument's credit risk has increased significantly since initial recognition, based on reasonable and supportable information that is available, without undue cost or effort to obtain.

Where there has not been a significant increase in exposure to credit risk since initial recognition, a 12-month expected credit loss allowance is estimated. This represents a portion of the asset's lifetime expected credit losses that is attributable to a default event that is possible within the next 12 months. Where a financial asset has become credit impaired or where it is determined that credit risk has increased significantly, the loss allowance is based on the asset's lifetime expected credit losses. The amount of expected credit loss recognized is measured on the basis of the probability weighted present value of anticipated cash shortfalls over the life of the instrument discounted at the original effective interest rate. For

financial assets measured at fair value through other comprehensive income, the loss allowance is recognized within other comprehensive income. In all other cases, the loss allowance is recognized in profit or loss.

Cash in Bank

We are continually reviewing the credit risk associated with holding money on deposit in banks and seek to mitigate this risk by holding deposits with banks with high credit status.

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Foreign Exchange Risk

Foreign exchange risk arose in 2020 and prior years because we had a material operation located in Bilbao, Spain, whose functional currency was not the same as our functional currency. Due to significant currency fluctuations during the years ended December 31, 2020, 2019 and 2018, particularly in respect of British pounds sterling against the Euro, our foreign exchange risk was significant. Our net assets arising from such overseas operations were exposed to currency risk resulting in gains or losses on retranslation into British pounds sterling. Given the closure of our Spanish operations and the levels of materiality, and despite this historical volatility, we do not hedge our net investments in overseas operations as the cost of doing so is disproportionate to the exposure.

Foreign exchange risk also arises when our individual entities enter into transactions denominated in a currency other than our functional currency. Our transactions outside the United Kingdom to Europe drive foreign exchange movements where suppliers invoice in currency other than British pounds sterling. These transactions are not hedged because the cost of doing so is disproportionate to the risk.

Interest Rate Risk

We do not hold any derivative instruments, or other financial instruments, that expose us to material interest rate risk

Liquidity Risk

Liquidity risk arises from our management of working capital. It is the risk that we will encounter difficulty in meeting our financial obligations as they fall due.

It is our aim to settle balances as they become due.

In May 2020, we completed a Registered Direct Offering and concurrent private placement in the United States which raised gross proceeds of \$3.0 million and a placing in the United Kingdom which raised gross proceeds of £1.8 million. In July 2020, we completed a placing in the United Kingdom which raised gross proceeds of £5.3 million. Further, in August 2020 and February 2021, warrants were exercised for our Depositary Shares that raised gross proceeds of approximately £1.1 million. We have prepared cash flow forecasts and considered the cash flow requirement for our next five years, including the period twelve months from the date of the approval of the financial statements. These forecasts show that further financing will be required during the course of the next 12 months, assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2020 with respect to this uncertainty.

In addition, the global spread of pandemic novel coronavirus, COVID-19, places increased uncertainty over our forecasts. The restrictions placed and being placed on the movement of people will likely cause delays to some of our plans. The scale of the impact of COVID-19 is evolving and it is difficult to assess to what extent, and for how long, it will cause delays to our operations. We have established a COVID-19 task force internally to monitor the impact of COVID-19 on our business and prioritize activities to minimize its effect.

In addition to utilizing the existing cash reserves, we are evaluating a number of near-term funding options potentially available to us, including fundraising, and the partnering of assets or technologies. After considering the uncertainties, we considered it appropriate to continue to adopt the going concern basis in preparing the financial information.

Our ability to continue as a going concern is dependent upon our ability to obtain additional capital and/or dispose of assets, for which there can be no assurance we will be able to do on a timely basis, on favorable terms or at all.

For more information, see “Item 5. Operating and Financial Review and Prospects-A. Operating Results-Critical Accounting Estimates and Judgments-Going Concern.”

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

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C. Other Securities

Not applicable.

D. American Depositary Shares

The Bank of New York Mellon, or the Depositary, has acted as depositary in relation to our Depositary Shares program since February 8, 2021. The principal executive office of the Depositary is located at 240 Greenwich Street, New York, New York 10286. Each Depositary Share will also represent any other securities, cash or other property which may be held by the Depositary from time to time. The deposited Ordinary Shares, together with any other securities, cash or other property held by the depositary are referred to as the “deposited securities.”

Fees and Expenses

Persons depositing or withdrawing our Ordinary

Shares or Depositary Share holders must pay:

For:

5.00 USD (or less) per 100 Depositary Shares (or portion of 100 Depositary Shares)	Issue of Depositary Shares, including issues resulting from a distribution of our Ordinary Shares or rights or other property
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	Cancellation of Depositary Shares for the purpose of withdrawal, including if the deposit agreement terminates
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0.05 USD (or less) per Depositary Share	Any cash distribution to Depositary Share holders
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A fee equivalent to the fee that would be payable if securities distributed to Depositary Share holders had been our Ordinary Shares and the Ordinary Shares had been deposited for issuance of Depositary Shares	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to Depositary Share holders
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0.05 USD (or less) per Depositary Share per calendar	
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year	Depository services
Registration or transfer fees	Transfer and registration of shares of our Ordinary Shares on our share register to or from the name of the depository or its agent when persons deposit or withdraw our Ordinary Shares
Expenses of the Depository	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depository or the custodian has to pay on any Depository Shares or our Ordinary Shares underlying Depository Shares, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the Depository or its agents for servicing the deposited securities	As necessary

The Depository collects its fees for delivery and surrender of Depository Shares directly from investors depositing our Ordinary Shares or surrendering Depository Shares for the purpose of withdrawal or from intermediaries acting for them. The Depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The Depository may collect its annual fee for depository services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depository may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to Depository Share holders that are obligated to pay those fees. The Depository may generally refuse to provide fee-attracting services until its fees for those services are paid.

In performing its duties under the deposit agreement, the Depository may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depository and that may earn or share fees, spreads or commissions.

The Depository may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depository or its affiliate receives when buying or selling foreign currency for its own account. The Depository makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to Depository Share holders, subject to the Depository's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

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The Depository has agreed to reimburse us for a portion of certain expenses it incurs that are related to establishment and maintenance of the American Depositary Receipt program. There are limits on the amount of expenses for which the Depository will reimburse us, but the amount of reimbursement available to us is not related to the amounts of fees the Depository collects from investors. Further, the Depository has agreed to reimburse us certain fees payable to the Depository by holders of Depository Shares. Neither we nor the Depository can determine the exact amount to be made available to us because (i) the number of Depository Shares that will be issued and outstanding, (ii) the level of service fees to be charged to holders of Depository Shares and (iii) its reimbursable expenses related to the program are not known at this time.

Payment of Taxes

Depository Share holders will be responsible for any taxes or other governmental charges payable on their Depository Shares or on the deposited securities represented by any of their Depository Shares. The Depository may refuse to register any transfer of Depository Shares or allow a Depository Share holder to withdraw the deposited securities represented by his or her Depository Shares until those taxes or other charges are paid. It may apply payments owed to such Depository Share holder or sell deposited securities represented by such Depository Share holder's Depository Shares to pay any taxes owed and such Depository Share holder will remain liable for any deficiency. If the Depository sells deposited securities, it will, if appropriate, reduce the number of Depository Shares to reflect the sale and pay to Depository Share holders any proceeds, or send to Depository Share holders any property, remaining after it has paid the taxes.

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PART II**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES.**

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS.

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES.**A. Disclosure Controls and Procedures**

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the Group's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Group's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

During 2020 we have taken a number of corrective measures to address the material weaknesses identified by our previous firm of external auditors. The measures introduced were as follows:

- Regarding IT general controls environment, we introduced a new vendor approval process, carried out reorganization of administration access accounts and introduced regular users access reviews;
- Regarding previous deficiencies identified in the consolidation and financial reporting close process, robust processes and greater oversight have been introduced to provide greater assurance. External technical accounting advice has also been sought during the year where necessary; and
- Regarding the revenue recognition process, we carried out a review and introduced additional steps within the process to ensure revenue is recognized appropriately.

Based upon our evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

B. Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed, under the supervision of the Chief Executive Officer and the Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with International Financial Reporting Standards.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Moreover, projections of any evaluation of the effectiveness of internal control to future periods are subject to a risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2020 based on the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 2013.

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Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 20-F does not include an attestation report of our registered public accounting firm we are a non-accelerated filer.

D. Changes in Internal Control Over Financial Reporting

We regularly review our system of internal control over financial reporting to ensure we maintain an effective internal control environment. Other than the changes discussed herein, there were no changes in our internal control over financial reporting that occurred during the fiscal year ended December 31, 2020 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT.

The Audit Committee consists of three members: Simon Turton (Chairman), Sijmen de Vries and Rolf Stahel. The Board of Directors has determined that Messrs. de Vries, Turton and Stahel are independent under Rule 10A-3 of the Exchange Act and the applicable rules of NASDAQ and that Dr. Turton qualifies as an "audit committee financial expert" as defined under in Item 16A of Form 20-F.

ITEM 16B. CODE OF ETHICS.

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at <http://www.midatechpharma.com>. The Code of Business Conduct and Ethics provides that our directors and officers are expected to avoid any action, position or interest that conflicts with the interests of the Group or gives the appearance of a conflict. Our directors and officers have an obligation under the Code of Business Conduct and Ethics to advance the Group's interests when the opportunity to do so arises. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on the website to be part of this document.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table sets forth by category of service the total fees for services provided to us by our independent registered public accounting firm during the fiscal years ended December 31, 2020 and 2019.

	2020	2019 (1)
	(£ in thousands)	
Audit Fees (2)	323	368
Audit-Related Fees(3)	-	-
Tax Fees(4)	-	-
All Other Fees(5)	-	-
Total	323	368

- (1) All fees for the year ended December 31, 2019 were paid to BDO LLP.
- (2) Audit fees consist of the aggregate fees billed in connection with the audit and United Kingdom statutory audit of our annual consolidated financial statements included in this annual report, the issuance of comfort letters, interim reviews of our half-yearly financial information and other services related to SEC filings. For the fiscal year ended December 31, 2020, audit fees include £186,000 in respect of fees paid to BDO LLP, and the balance relates to Mazars LLP.
- (2) Audit-related fees are fees for services that are traditionally performed by the independent accountants, including consultations concerning financial accounting and reporting, and employee benefit plan audits, and due diligence on mergers or acquisitions.
- (3) Represents the aggregate fees billed for tax compliance, tax advice and tax consulting services.
- (4) Represents the aggregate fees billed for all products and services provided that are not included under "audit fees", "audit related fees" or "tax fees," including, but not limited to, fees billed for services relating to mergers and acquisitions.

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Audit Committee Pre-Approval Policies and Procedures

The pre-approval of the Audit Committee or member thereof, to whom pre-approval authority has been delegated, is required for the engagement of our independent auditors to render audit or non-audit services. Audit Committee pre-approval of audit and non-audit services will not be required if the engagement for the services is entered into pursuant to pre-approval policies and procedures established by the Audit Committee regarding our engagement of the independent auditor, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to management. Audit Committee pre-approval of non-audit services (other than review and attest services) also will not be required

if such services fall within available exceptions established by the SEC.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES.

Not applicable.

ITEM 16E. PURCHASE OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS.

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANTS.

On November 5, 2020, we terminated the appointment of BDO LLP as our independent registered public accounting firm and appointed Mazars LLP in its stead. The Audit Committee and the Board of Directors participated in and approved the decision to change our independent registered public accounting firm. The change in auditors was made following a tender process. Both the commercial terms and expertise of the tender participants were assessed during the tender process.

The reports of BDO LLP on our consolidated financial statements for the fiscal years ended December 31, 2019 and 2018 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle, except that the opinion for the year ended December 31, 2019 contained a modification regarding the Company's ability to continue as a going concern.

During the two fiscal years ended December 31, 2019 and 2018 and the subsequent interim period through November 5, 2020, there were no disagreements, as that term is defined in Item 16F(a)(1)(iv) of Form 20-F, with BDO LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of BDO LLP, would have caused BDO LLP to make reference thereto in their reports on our consolidated financial statements for such fiscal years.

During the two fiscal years ended December 31, 2019 and 2018 and the subsequent interim period through November 5, 2020, there were no "reportable events" as that term is defined in Item 16F(a)(1)(v) of Form 20-F.

We requested BDO LLP to furnish us with a copy of a letter addressed to the SEC stating whether or not it agrees with the above statements. A copy of such letter, dated April 30 2021, is filed as Exhibit 16.1 to this Form 20-F.

ITEM 16G. CORPORATE GOVERNANCE.

Companies with securities listed on NASDAQ are required to comply with United States federal securities laws, including the Sarbanes-Oxley Act of 2002, as well as certain NASDAQ rules and corporate governance requirements. As a foreign private issuer, however, we are entitled to follow our home country practice in lieu of the NASDAQ corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to United States federal securities laws. The United Kingdom laws and practices followed by the Company in lieu of NASDAQ rules are described below:

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- We do not follow NASDAQ's requirement that the Board of Directors be comprised of a majority of Independent Directors, as defined under Rule 5605(a)(2). In accordance with United Kingdom law and practice, we do not require a majority of our Board of Directors to be considered independent.
- We do not follow NASDAQ's requirements applicable to independent director oversight of director nominations, which require that director nominees either be selected or recommended by independent directors. In accordance with United Kingdom law and practice, our directors are nominated by the Nominations Committee, which is comprised of all of the directors of the Company.
- We do not follow NASDAQ's requirement that the compensation committee be comprised of Independent Directors, as defined under Rule 5605(a)(2). One of the members of our compensation committee, Mr. Stahel, is not considered independent under the applicable NASDAQ rule. He is, however, considered to be independent under United Kingdom law and practice.
- We do not require that the compensation committee consider the specific factors affecting consultant independence that are set forth in NASDAQ Rule 5605(d)(3)(D). Our compensation committee may engage independent compensation consultants at its discretion.
- We do not follow NASDAQ's requirements that non-executive directors meet on a regular basis without management present. Our Board of Directors may choose to meet in executive session at their discretion.
- We do not follow NASDAQ's quorum requirements for stockholder meetings. In accordance with United Kingdom law and practice, our Articles of Association provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not follow NASDAQ's requirements to seek shareholder approval for the implementation of certain equity compensation plans and issuances of Ordinary Shares. In accordance with the AIM Rules, we are not required to seek shareholder approval in such circumstances.

ITEM 16H. MINE SAFETY DISCLOSURE.

Not applicable.

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PART III

ITEM 17. FINANCIAL STATEMENTS.

We have elected to provide financial statements pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS.

The financial statements are filed as part of this Annual Report on Form 20-F beginning on page F-1.

The financial statements of the Company included in this Annual Report on Form 20-F do not constitute statutory financial statements within the meaning of the United Kingdom Companies Act 2006. The Company's statutory financial statements for the year ended December 31, 2020 have been reported on by Mazars LLP, independent auditors, under applicable law and the International Standards on Auditing (United Kingdom), and for the years ended December 31, 2019 and 2018 have been reported on by BDO LLP independent auditors, under applicable law and the International Standards on Auditing (United Kingdom). The Independent Auditors' Report of Mazars LLP on the statutory financial statements for the year ended December 31, 2020 was unqualified. The Independent Auditors' Report of BDO LLP on the statutory financial statements for the years ended December 31, 2019 and 2018 was unqualified. The Independent Auditors' Report of Mazars LLP on the statutory financial statements for the year ended December 31, 2020 included an emphasis of matter regarding material uncertainty over going concern. The Independent Auditors' Report of BDO LLP on the statutory financial statements for the year ended December 31, 2019 included an emphasis of matter regarding material uncertainty over going concern.

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ITEM 19. EXHIBITS.

Exhibit Number	Title
1.1	Articles of Association of Midatech Pharma PLC (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
2.1*	Description of Securities Registered Under Section 12 of the Exchange Act.
2.2	Specimen certificate representing ordinary shares of Midatech Pharma PLC (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
2.3	Form of Amended and Restated Deposit Agreement by and among Midatech Pharma PLC, The Bank of New York Mellon, as depositary, and all owners and holders from time to time of American Depositary Shares thereunder (incorporated by reference to Exhibit A to the Company's Registration Statement on Form F-6 (File No. 333-252507), filed with the SEC on January 28, 2021).
2.4	Form of American Depositary Receipt (included in Exhibit 2.3 as Exhibit A thereto).
2.5	Form of Warrant Assumption Agreement by and between Midatech Pharma PLC and DARA BioSciences, Inc. (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
2.6	Form of "Phase 2b" Common Stock Purchase Warrant issued to General Hospital Corporation d/b/a Massachusetts General Hospital (incorporated by reference to Exhibit 4.1 to DARA BioSciences, Inc.'s Current Report on Form 8-K filed with the SEC on December 15, 2014).
2.7	Form of "FDA Approval" Common Stock Purchase Warrant issued to General Hospital Corporation d/b/a Massachusetts General Hospital (incorporated by reference to Exhibit 4.2 to DARA BioSciences, Inc.'s Current Report on Form 8-K filed with the SEC on December 15, 2014).
2.8	Warrant Instrument, dated as of February 24, 2017 (incorporated by reference to Exhibit 4.1 of the Company's Annual Report on Form 20-F for the year ended December 31, 2017, filed with the SEC on April 24, 2018).
2.9	Form of Warrant Instrument, dated as of January 29, 2019, constituting warrants to subscribe for ordinary shares in Midatech Pharma PLC (incorporated by reference to Exhibit 2.11 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 30, 2019).
2.10	Form of Warrant issued on October 25, 2019 (incorporated by reference to Exhibit 4.1 of the Company's Report on Form 6-K, filed with the SEC on October 24, 2019).
2.11	Form of Placement Agent Warrant issued on October 25, 2019 (incorporated by reference to Exhibit 4.2 of the Company's Report on Form 6-K, filed with the SEC on October 24, 2019).
2.12	Form of Warrant issued on May 20, 2020 (incorporated by reference to Exhibit 4.1 of the Company's Report on Form 6-K, filed with the SEC on May 19, 2020).
2.13	Form of Placement Agent Warrant issued on May 20, 2020 (incorporated by reference to Exhibit 4.2 of the Company's Report on Form 6-K, filed with the SEC on May 19, 2020).
2.14	Form of Warrant Instrument issued on May 22, 2020 (incorporated by reference to Exhibit 4.3 of the Company's Report on Form 6-K, filed with the SEC on May 19, 2020).

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4.1#	Midatech Pharma PLC 2014 Enterprise Management Incentive Scheme (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.2#	Form of Option Agreement (included in Exhibit 4.1).
4.3	Nominated Advisor and Broker Agreement, dated as of December 2, 2014, by and between Midatech Pharma PLC and Panmure Gordon (UK) Limited (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.4	Patent and Know-How Agreement, dated June 21, 2002, as amended on October 14, 2004, by and between Consejo Superior de Investigaciones Cientificas and Midatech Limited (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.5#	Consultancy Agreement, dated as of April 15, 2014, by and between Midatech Limited and Chesyl Pharma Limited (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.6#	Service Agreement dated as of June 1, 2018, by and between Midatech Pharma PLC and Craig Cook (incorporated by reference to Exhibit 4.9 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 30, 2019).
4.7#	Appointment Agreement, dated as of April 15, 2014, by and between Midatech Limited and Rolf Stahel (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.8#	Revised Appointment Agreement, dated as of December 2, 2014, by and between Midatech Pharma PLC and Rolf Stahel (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.9#	Form of Appointment Letter between Midatech Pharma PLC and certain directors of Midatech Pharma PLC (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.10#	Deed of Indemnity dated August 5, 2015 (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form F-4 (File No. 333-206305), originally filed with the SEC on August 11, 2015, as amended).
4.11†	License Agreement, executed on or about June 6, 2017, by and between Novartis Pharma AG and Midatech Limited (incorporated by reference to Exhibit 99.1 to the Company's Report of Foreign Private Issuer on Form 6-K filed with the SEC on July 19, 2017).
4.12*	Novation Agreement, dated February 18, 2019, by and among Novartis Pharma AG, Midatech Limited, and Secura Bio, Inc.
4.13††	License, Collaboration and Distribution Agreement, dated as of January 29, 2019, by and between Midatech Pharma PLC, CMS Bridging Limited, CMS Medical Hong Kong Limited and China Medical System Holdings Limited (incorporated by reference to Exhibit 4.17 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, as amended, filed with the SEC on May 28, 2019).
4.14	Relationship Agreement, dated January 29, 2019, by and among the Company, certain CMS Concert Party Members and Panmure

[Gordon \(UK\) Limited \(incorporated by reference to Exhibit 4.18 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 30, 2019\).](#)

4.15*	Deed of Variation of Relationship Agreement, dated May 12, 2020, between Midatech Pharma PLC, Certain CMS Concert Party Members and Panmure Gordon (UK) Limited.
4.16	Subscription Letter, dated January 29, 2019, between the Company and A&B (HK) Company Limited (incorporated by reference to Exhibit 4.19 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 30, 2019).
4.17	Subscription Letter, dated January 29, 2019, between the Company and CMS Medical Venture Investment (HK) Limited (incorporated by reference to Exhibit 4.20 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 30, 2019).
4.18#	The Midatech Pharma Share Incentive Plan (incorporated by reference to Exhibit 4.27 of the Company's Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 24, 2018).

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4.19††#	Service Agreement date as of September 9, 2019, by and between Midatech Pharma PLC and Stephen Stamp (incorporated by reference to Exhibit 10.1 of the Company's Report on Form 6-K, filed with the SEC on September 19, 2019).
4.20††#	Service Agreement dated as of April 23, 2015, by and between Midatech Limited and Stephen Damment (incorporated by reference to Exhibit 4.24 of the Company's Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on June 15, 2020).
4.21	Form of Securities Purchase Agreement, dated as of October 22, 2019, by and between Midatech Pharma PLC and the purchaser identified on the signature page thereto (incorporated by reference to the Company's Report on Form 6-K, filed with the SEC on October 24, 2019).
4.22#	Settlement Agreement, dated as of April 17, 2020, by and between Midatech Pharma PLC and Dr. Craig Cook (incorporated by reference to Exhibit 4.24 of the Company's Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on June 15, 2020).
4.23	Form of Securities Purchase Agreement, dated as of May 18, 2020, by and between Midatech Pharma PLC and the purchasers identified on the signature page thereto (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 6-K, filed with the SEC on May 20, 2020).
8.1*	Subsidiaries of Midatech Pharma PLC.
12.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002.
13.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002.
15.1*	Consent of Mazars LLP, independent registered public accounting firm.
15.2*	Consent of BDO LLP, independent registered public accounting firm.
16.1*	BDO LLP's Letter to the Securities and Exchange Commission regarding Item 16.F (Change in Certifying Accountant), dated April 30, 2021.

* Filed herewith.

Management contract or compensatory plan or arrangement.

† Confidential treatment has been granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

†† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to Midatech Pharma PLC if publicly disclosed.

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SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

MIDATECH PHARMA PLC
(Registrant)
By: /s/ Stephen Stamp
Name: Stephen Stamp
Title: Chief Executive Officer and Chief
Financial Officer

Date: April 30, 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Midatech Pharma plc

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statement of financial position of Midatech Pharma plc and its subsidiaries (the “Group”) as of December 31, 2020, and the related consolidated statements of comprehensive income, cash flow, changes in equity for the year ended December 31, 2020, and the related notes (collectively, referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Group as of December 31, 2020, and the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Material uncertainty related to going concern

The accompanying consolidated financial statements have been prepared assuming that the Group will continue as a going concern. We draw attention to Note 1 in the financial statements on pages F-13 and F-15, which indicates that there is a material uncertainty in relation to the Group’s ability to continue as a going concern. As detailed in Note 1, the Group’s future viability is dependent on its ability to generate cash from operating activities, to raise additional capital to finance its operations and to successfully obtain regulatory approval to allow marketing of its development products. The Group’s failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. Management has prepared cash flow forecasts that indicate that further financing will be required before the fourth quarter of 2021. This requirement for additional financing represents a material uncertainty that raises substantial doubt on the Group’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified in respect of this matter.

Basis for Opinion

These consolidated financial statements are the responsibility of the Group’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Group in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. The Group is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Group’s internal control over financial reporting. Accordingly, we express no such opinion.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

We have identified one critical audit matter, being the going concern basis of preparation. The nature of the critical audit matter, together with our conclusion, is set out above under *Material uncertainty related to going concern*. The circumstances described led us to conclude that the going concern basis of preparation is a critical audit matter.

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Our evaluation of the Directors’ assessment of the appropriateness of the going concern basis of preparation of these financial statements included, but was not limited to:

- Undertaking an initial assessment at the planning stage of the audit to identify events or conditions that may cast significant doubt on the group’s and the parent company’s ability to continue as a going concern;
- Reviewing the directors’ formal going concern assessment, including the supporting cash flow projections that included the twelve months from the date of approval of these financial statements;
- Evaluating the key assumptions used and judgements applied by the directors in forming their conclusions on going concern; and
- Reviewing the appropriateness of the disclosures made by the Directors in the financial statements.

/s/ Mazars LLP

Mazars LLP

We have served as the Group’s auditor since 2020.

London, England

April 30, 2021

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

Midatech Pharma plc

Cardiff, United Kingdom

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Midatech Pharma plc (the “Company”) as of 31 December 2019 and 2018, the related consolidated statements of comprehensive income, changes in equity, and cash flows for each of the two years in the period ended 31 December 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 31 December 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended 31 December 2019 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Adoption of New Accounting Standard

As discussed in Note 1 to the consolidated financial statements, effective on 1 January 2019, the Company changed its method of accounting for leases due to the adoption of IFRS 16, Leases.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO LLP

BDO LLP

We have served as the Company's auditor from 2014 through 2020.

Reading, United Kingdom

15 June 2020

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

For the year ended 31 December

	Note	2020 £'000	2019 £'000	2018 £'000
Revenue	3	180	312	149
Grant revenue		163	362	1,789
Total revenue		343	674	1,938
Other income		12	15	–
Research and development costs		(6,068)	(7,843)	(9,359)
Distribution costs, sales and marketing		(6)	(323)	–
Administrative costs		(4,952)	(3,841)	(4,394)
Impairment of intangible assets	12,13	(12,369)	–	–
Loss from operations	5	(23,040)	(11,318)	(11,815)
Finance income	7	1	492	2
Finance expense	7	(431)	(97)	(587)
Loss before tax		(23,470)	(10,923)	(12,400)
Taxation	8	1,281	1,785	2,032
Loss from continuing operations		(22,189)	(9,138)	(10,368)
Loss from discontinued operations net of tax	4	–	(947)	(4,662)
Loss for the year attributable to the owners of the parent		(22,189)	(10,085)	(15,030)
Other comprehensive income:				
Items that will or may be reclassified subsequently to profit or loss:				
Exchange (losses)/gains arising on translation of foreign operations		508	(207)	1,156
Exchange losses realised on disposal of subsidiaries	4	–	–	(3,842)
Total other comprehensive income/loss net of tax		508	(207)	(2,686)
Total comprehensive loss attributable to the owners of the parent		(21,681)	(10,292)	(17,716)
Loss per share				
Continuing operations				
Basic and diluted loss per ordinary share - pence	9	(52)p	(50)p	(339)p
Discontinued operations				
Basic and diluted loss per ordinary share - pence	9	–	(5)p	(153)p

The notes form an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

At 31 December

Company number 09216368	Note	2020 £'000	2019 £'000	2018 £'000
Assets				
Non-current assets				
Property, plant and equipment	10	542	2,154	1,983
Intangible assets	12	–	12,379	12,374
Other receivables due in greater than one year	15	–	2,625	469
		542	17,158	14,826
Current assets				
Inventories	17	–	–	–
Trade and other receivables	15	572	992	1,323
Taxation	8	1,157	1,817	1,952
Cash and cash equivalents	16	7,546	10,928	2,343
		9,275	13,737	5,618
Total assets		9,817	30,895	20,444
Liabilities				
Non-current liabilities				
Borrowings	19	60	5,670	884
Provisions	20	50	–	165
		110	5,670	1,049
Current liabilities				
Trade and other payables	18	1,230	4,494	2,103
Borrowings	19	200	412	368
Provisions	20	–	97	–
Derivative financial liability	21	1,559	664	–
		2,989	5,667	2,471
Total liabilities		3,099	11,337	3,520

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION_(CONTINUED)

At 31 December

	Note	2020 £'000	2019 £'000	2018 £'000
Issued capital and reserves attributable to owners of the parent				
Share capital	24	1,063	1,023	1,003
Share premium	25	74,364	65,879	52,939
Merger reserve	25	53,003	53,003	53,003
Warrant reserve	25	720	–	–
Foreign exchange reserve	25	–	(508)	(301)
Accumulated deficit	25	(122,432)	(99,839)	(89,720)
Total equity		6,718	19,558	16,924
Total equity and liabilities		9,817	30,895	20,444

The notes form an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

For the year ended 31 December

	Note	2020 £'000	2019 £'000	2018 £'000
Cash flows from operating activities				
Loss for the year		(22,189)	(10,085)	(15,030)
Adjustments for:				
Depreciation of property, plant and equipment	10	1,089	979	1,016
Depreciation of right of use asset	10	118	303	–
Amortisation of intangible fixed assets	12	10	3	434
(Profit)/Loss on disposal of fixed assets		(226)	–	165
Impairment of intangible assets	12,13	12,369	–	–
Finance income	7	(1)	(492)	(2)
Finance expense	7	431	97	587
Share-based payment credit	5	(404)	(34)	(36)
Taxation	8	(1,281)	(1,785)	(2,032)
Loss on sale of subsidiary	4	–	–	1,407
Loss from discontinued operations, net of tax	4	–	947	–
Foreign exchange (gains)/losses		387	(140)	130
Cash flows from operating activities before changes in working capital		(9,697)	(10,207)	(13,361)
Decrease in inventories			–	347
Decrease in trade and other receivables		493	725	1,030
(Decrease)/Increase in trade and other payables		(2,004)	1,141	(2,995)
(Decrease)/Increase in provisions		(47)	(68)	165
Cash used in operations		(11,255)	(8,409)	(14,814)
Taxes received		1,954	1,920	1,364
Net cash used in operating activities		(9,301)	(6,489)	(13,450)

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CONSOLIDATED STATEMENTS OF CASH FLOWS_(CONTINUED)

For the year ended 31 December

	Note	2020 £'000	2019 £'000	2018 £'000
Investing activities				
Purchases of property, plant and equipment	10	(209)	(310)	(244)
Proceeds from disposal of fixed assets		143	–	25
Purchase of intangibles	12	–	(9)	–
Long term deposit for guarantee for Government loan		2,639	(2,549)	–
Disposal of discontinued operation, net of cash disposed of	4	–	–	9,259
Deposit paid in connection with disposed subsidiary	4	–	(947)	–
Interest received		1	8	2
Net cash generated/(used in) from investing activities		2,574	(3,807)	9,042
Financing activities				
Interest paid		(34)	(30)	(587)
Receipts from sub-lessors		45	107	–

Amounts paid on lease liabilities (2018 & 2017: Amounts

paid on finance leases)		(258)	(450)	(64)
Repayment of Government grants		(229)	–	–
Repayment of borrowings		–	(577)	(5,821)
Proceeds from bank borrowings		–	–	–
(Repayment)/Proceeds from Government loan	19	(6,182)	4,436	–
Proceeds from Government subsidy		–	1,139	–
Share issues including warrants, net of costs	16	9,742	14,108	–
Net cash generated from/(used in) financing activities		3,084	18,733	(6,472)
Net (decrease)/increase in cash and cash equivalents		(3,643)	8,437	(10,880)
Cash and cash equivalents at beginning of year		10,928	2,343	13,204
Exchange gains/(losses) on cash and cash equivalents		261	148	19
Cash and cash equivalents at end of year	16	7,546	10,928	2,343

The notes form an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

For the year ended 31 December

	Share capital £'000	Share premium £'000	Merger reserve £'000	Warrant reserve £'000	Foreign exchange reserve £'000	Accumulated deficit £'000	Total equity £'000
At 1 January 2020	1,023	65,879	53,003	–	(508)	(99,839)	19,558
Loss for the year	–	–	–	–	–	(22,189)	(22,189)
Foreign exchange translation	–	–	–	–	508	–	508
Total comprehensive loss	–	–	–	–	(508)	(22,189)	(21,681)
Transactions with owners							
Shares issued on 18 May 2020 – note 16	16	2,527	–	720	–	–	3,263
Costs associated with share issue on 18 May 2020 – note 16		(544)	–	–	–	–	(544)
Shares issued on 27 July 2020 – note 16	21	5,729	–	–	–	–	5,750
Costs associated with share issue on 27 July 2020 – note 16		(489)	–	–	–	–	(489)
Shares issued on 19 August 2020 – note 16	3	1,278	–	–	–	–	1,281
Costs associated with share issue on 19 August 2020 – note 16		(16)	–	–	–	–	(16)
Share-based payment credit	–	–	–	–	–	(404)	(404)
Total contribution by and distributions to owners	40	8,485	–	720	–	(404)	8,841
At 31 December 2020	1,063	74,364	53,003	720	–	(122,432)	6,718

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)

	Share capital £'000	Share premium £'000	Merger reserve £'000	Foreign exchange reserve £'000	Accumulated deficit £'000	Total equity £'000
At 1 January 2019	1,003	52,939	53,003	(301)	(89,720)	16,924
Loss for the year	–	–	–	–	(10,085)	(10,085)
Foreign exchange translation	–	–	–	(207)	–	(207)
Total comprehensive loss	–	–	–	(207)	(10,085)	(10,292)
Transactions with owners						
Shares issued on 26 February 2019 – note 16	17	13,388	–	–	–	13,405
Costs associated with share issue on 26 February 2019 – note 16	–	(1,120)	–	–	–	(1,120)
Shares issued on 29 October 2019 – note						

16	3	1,211	–	–	–	1,214
Costs associated with share issue on 29 October 2019 – note 16	–	(539)	–	–	–	(539)
Share-based payment credit	–	–	–	–	(34)	(34)
Total contribution by and distributions to owners	20	12,940	–	–	(34)	12,926
At 31 December 2019	1,023	65,879	53,003	(508)	(99,839)	19,558
	Share capital £'000	Share premium £'000	Merger reserve £'000	Foreign exchange reserve £'000	Accumulated deficit £'000	Total equity £'000
At 1 January 2018	1,003	52,939	53,003	2,385	(74,654)	34,676
Loss for the year	–	–	–	–	(15,030)	(15,030)
Reclassification of foreign exchange on disposal	–	–	–	(3,842)	–	(3,842)
Foreign exchange translation	–	–	–	1,156	–	1,156
Total comprehensive loss	–	–	–	(2,686)	(15,030)	(17,716)
Share-based payment credit	–	–	–	–	(36)	(36)
Total contribution by and distributions to owners	–	–	–	–	(36)	(36)
At 31 December 2018	1,003	52,939	53,003	(301)	(89,720)	16,924

The notes form an integral part of these consolidated financial statements.

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NOTES FORMING PART OF THE FINANCIAL STATEMENTS

For the years ended 31 December 2020, 2019 and 2018

1 Accounting policies

General information

Midatech Pharma plc (the 'Company') is a company registered and domiciled in England and Wales. The Company was incorporated on 12 September 2014.

The Company is a public limited company, which has been listed on the Alternative Investment Market ('AIM'), which is a submarket of the London Stock Exchange, since 8 December 2014.

In addition, since 4 December 2015 the Company has American Depositary Receipts ('ADRs') registered with the US Securities and Exchange Commission ('SEC') and is listed on the NASDAQ Capital Market.

The financial statements were approved and authorised for issue by the Board of Directors on 29 April 2021.

Basis of preparation

The Group was formed on 31 October 2014 when Midatech Pharma plc entered into an agreement to acquire the entire share capital of Midatech Limited and its wholly owned subsidiaries through the issue equivalent of shares in the Company which took place on 13 November 2014.

The financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IASB).

The principal accounting policies adopted in the preparation of the financial statements are set out below. The policies have been consistently applied to all the periods presented.

On 2 March 2020 a resolution was passed at a general meeting of shareholders of the Company to consolidate its ordinary shares on a one for 20 basis into new ordinary shares of 0.1p each in the capital of the Company. At the same meeting a resolution was passed to change the ratio of the Company's American Depositary Receipts ("ADRs"). This changed from one ADR representing 20 Existing Ordinary Shares to one ADR representing five new ordinary shares. Comparative numbers of shares and share options/warrants and related exercise/issue prices and earnings per share reflect the impact of the March 2020 share consolidation.

The consolidated financial statements have been prepared on a historical cost basis, except for the following item (refer to individual accounting policies for details):

- Financial instruments – fair value through profit or loss.

Adoption of new and revised standards

New standards, interpretations and amendments effective from 1 January 2020

New standards adopted by the Group in the annual financial statements for the year ended 31 December 2020 are:

- Definition of a Business (Amendments to IFRS 3);
- Interest Rate Benchmark Reform – IBOR 'phase 2' (Amendments to IFRS 9, IAS 39 and IFRS 7); and
- COVID-19-Related Rent Concessions (Amendments to IFRS 16).

The adoption of the above new standards has not had a material impact on the financial statements during the year ended 31 December 2020.

New standards, interpretations and amendments not yet effective

There are a number of standards, amendments to standards, and interpretations which have been issued by the IASB that are effective in future accounting periods that the group has decided not to adopt early. The following amendments are effective for the period beginning 1 January 2022:

- Contracts – Cost of Fulfilling a Contract (Amendments to IAS 37);
- Property, Plant and Equipment: Proceeds before Intended Use (Amendments to IAS 16);
- Annual Improvements to IFRS Standards 2018-2020 (Amendments to IFRS 1, IFRS 9, IFRS 16 and IAS 41); and
- References to Conceptual Framework (Amendments to IFRS 3).

In January 2020, the IASB issued amendments to IAS 1, which clarify the criteria used to determine whether liabilities are classified as current or non-current. These amendments clarify that current or non-current classification is based on whether an entity has a right at the end of the reporting period to defer settlement of the liability for at least twelve months after the reporting period. The amendments also clarify that 'settlement' includes the transfer of cash, goods, services, or equity instruments unless the obligation to transfer equity instruments arises from a conversion feature classified as an equity instrument separately from the liability component of a compound financial instrument. The amendments were originally effective for annual reporting periods beginning on or after 1 January 2022. However, in May 2020, the effective date was deferred to annual reporting periods beginning on or after 1 January 2023.

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1 Accounting policies (continued)

These new accounting standards and amendments are not expected to have a material impact on the Group.

The Group does not expect any other standards issued by the IASB, but not yet effective, to have a material impact on the group.

Basis for consolidation

The Group financial statements consolidate those of the parent company and all of its subsidiaries. The parent controls a subsidiary if it has power over the investee to significantly direct the activities, exposure, or rights to variable returns from its involvement with the investee, and the ability to use its power over the investee to affect the amount of the investor's returns. All subsidiaries have a reporting date of 31 December.

All transactions and balances between Group companies are eliminated on consolidation, including unrealised gains and losses on transactions between Group companies. Where unrealised losses on intra-Group asset sales are reversed on consolidation, the underlying asset is also tested for impairment from a Group perspective. Amounts reported in the financial statements of subsidiaries have been adjusted where necessary to ensure consistency with the accounting policies adopted by the Group.

The loss and other comprehensive income of Midatech Pharma US, Inc. ("MPUS"), formerly DARA Biosciences, Inc., acquired in December 2015 is recognised from the effective date of acquisition i.e. 4 December 2015 through to the date of sale on 1 November 2018. Similarly, the loss and other comprehensive income of Zuplenz®, acquired as a business by Midatech Pharma plc, is recognised from 24 December 2015 until 31 October 2018 (up to the formal completion of the sale of MPUS on 1 November 2018).

Discontinued operations are presented in the consolidated statement of comprehensive income as a single line which comprises the post-tax profit or loss of the discontinued operation along with the post-tax gain or loss recognised on the re-measurement to fair value less costs to sell or on disposal of the assets or disposal groups constituting discontinued operations.

The consolidated financial statements consist of the results of the following entities:

Entity	Summary description
Midatech Pharma plc	Ultimate holding company
Midatech Limited	Trading company
Midatech Pharma (Espana) SL (formerly Midatech Biogune SL)	In liquidation
PharMida AG	Dormant
Midatech Pharma (Wales) Limited (formerly Q Chip Limited)	Trading company
Midatech Pharma Pty	Dissolved - 2020
Midatech Pharma US, Inc. (formerly DARA Biosciences, Inc.) (until 1 November 2018)	Trading company
Dara Therapeutics, Inc. (until 1 November 2018)	Dormant

Going concern

The Group and Company are subject to a number of risks similar to those of other development and early-commercial stage pharmaceutical companies. These risks include, amongst others, generation of revenue from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of our pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include obtaining adequate financing to fulfill our commercial and development activities and generating a level of revenue adequate to support our cost structure.

We have experienced net losses and significant cash outflows from cash used in operating activities over the past years we develop our portfolio. For the year ended December 31, 2020, the Company incurred a consolidated loss from operations of £22.2million and negative cash flows from operations of £9.3million. As of December 31, 2020, we had an accumulated deficit of £122.4million.

Our future viability is dependent on our ability to generate cash from operating activities, to raise additional capital to finance our operations and to successfully obtain regulatory approval to allow marketing of our development products. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies.

Our Group's consolidated financial statements have been presented on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As at December 31, 2020, we had cash and cash equivalents of £7.5million. We believe we currently have enough cash to fund our planned operations into the fourth quarter of 2021.

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1 Accounting policies (continued)

Going concern (continued)

We have prepared cash flow forecasts and considered the cash flow requirement for the Company for our next three years, including the period twelve months from the date of the approval of the financial statements. These forecasts show that further financing will be required during the course of the next 12 months, assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2020 with respect to this uncertainty.

In addition, the global spread of pandemic novel coronavirus, COVID-19, places increased uncertainty over our forecasts. The restrictions placed and being placed on the movement of people have caused, and may in the future cause, delays to some of our plans. We have established a COVID-19 task force internally to monitor the impact of COVID-19 on our business and prioritize activities to minimize its effect. It is not currently possible to quantify the impact of COVID-19 and resultant delays on the Company until it becomes clear that the global crisis has abated and a normalization of the business environment can be foreseen with confidence.

In addition to utilizing the existing cash reserves, as part of our strategic review, we and our advisors are evaluating a number of near-term funding options potentially available to us, including fundraising, the partnering of assets or technologies or the sale of the Company. After considering the uncertainties, we considered it appropriate to continue to adopt the going concern basis in preparing the financial information.

Our ability to continue as a going concern is dependent upon our ability to obtain additional capital and/or dispose of assets, for which there can be no assurance we will be able to do on a timely basis, on favorable terms or at all.

Revenue

Revenue is accounted for in line with principles of IFRS 15 'Revenue from contracts with customers'

Revenue from licensing agreements

The Group entered into a Licence Agreement during 2019. The licence consists of two distinct performance conditions, which is the grant of the

license to use of its intellectual property (“IP”) and the supply of Product. After the Company has granted the license, and the Product is granted applicable marketing authorizations in the EU, the US, or the UK, France, Germany or Switzerland and China, there are no further obligations to participate in, or provide additional services to its customer. The transaction price for the grant of the license to use the Company’s IP comprises of fixed and variable payment streams and the grant of the license is considered to be a right to use IP. Upfront fees earned, are recognised as revenue at a point in time, upon transfer of control over the license to the licensee and the grant of the applicable marketing authorisation by the relevant statutory authority. Revenue from variable consideration, which is contingent on achievements of future milestones is recognised as revenue when it is highly probable the revenue will not reverse, that is when the underlying contingencies have been resolved. For future royalty payments associated with a license, the Company applies the IFRS 15 exception for sales-based royalties and recognises the revenue only when the subsequent sale occurs.

Supply of Goods

Revenue from sales of goods to customer are recognised when all performance obligations are met. These criteria are considered to be met when the goods are delivered to the customer. Revenue represents the full list price of products shipped to wholesalers and other customers less product returns, discounts, rebates and other incentives based on the sales price.

Supply of Services

Revenue from the supply of services is subject to specific agreement. This is recognised over the contract term, proportionate to the progress in overall satisfaction of the performance obligations (the services performed by the Group), measured by cost incurred to date out of total estimate of costs.

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1 Accounting policies (continued)

Milestones

The Group’s revenue also include milestone income from research and development contracts. Milestone income is recognised as revenue in the accounting period in which the milestones are achieved. Milestones are agreed on a project by project basis and will be evidenced by set deliverables.

Grant revenue

Where grant income is received, which is not a direct re-imbursement of related costs and at the point at which the conditions have been met for recognition as income, this has been shown within grant revenue.

Government grants and government loans

Where government grants are received as a re-imbursement of directly related costs they are credited to research and development expense in the same period as the expenditure towards which they are intended to contribute.

The Group receives government loans that have a below-market rate of interest. These loans are recognised and measured in accordance with IFRS 9. The benefit of the below-market rate of interest is measured as the difference between the initial carrying value of the loan discounted at a market rate of interest and the proceeds received.

The difference is held within deferred revenue as a government grant and is released as a credit to grant income or to research and development expense in line with the expenditure to which it relates. In a situation where the proceeds were invested in plant and equipment, the deferred revenue is credited to research and development within the income statement in line with the depreciation of the acquired asset.

Business combinations and externally acquired intangible assets

Business combinations are accounted for using the acquisition method at the acquisition date, which is the date at which the Group obtains control over the entity. The cost of an acquisition is measured as the amount of the consideration transferred to the seller, measured at the acquisition date fair value, and the amount of any non-controlling interest in the acquiree. The Group measures goodwill initially at cost at the acquisition date, being:

- the fair value of the consideration transferred to the seller, plus;
- the amount of any non-controlling interest in the acquiree, plus;
- if the business combination is achieved in stages, the fair value of the existing equity interest in the acquiree re-measured at the acquisition date, less;
- the fair value of the net identifiable assets acquired and assumed liabilities.

Acquisition costs incurred are expensed and included in administrative costs. Any contingent consideration to be transferred by the acquirer is recognised at fair value at the acquisition date. Subsequent changes to the fair value of the contingent consideration, whether it is an asset or liability, will be recognised either as a profit or loss or as a change to other comprehensive income. If the contingent consideration is classified as equity, it is not re-measured.

An intangible asset, which is an identifiable non-monetary asset without physical substance, is recognised to the extent that it is probable that the expected future economic benefits attributable to the asset will flow to the Group and that its cost can be measured reliably. The asset is deemed to be identifiable when it is separable or when it arises from contractual or other legal rights.

Externally acquired intangible assets other than goodwill are initially recognised at cost and subsequently amortised on a straight-line basis over their useful economic lives where they are in use. The amortisation expense is included within the distribution costs, sales and marketing in the consolidated statement of comprehensive income. Goodwill is stated at cost less any accumulated impairment losses.

The amounts ascribed to intangibles recognised on business combinations are arrived at by using appropriate valuation techniques (see section related to critical estimates and judgements below).

In-process research and development (‘IPRD’) programmes acquired in business combinations are recognised as assets even if subsequent expenditure is written off because the criteria specified in the policy for development costs below are not met. IPRD is subject to annual impairment testing until the completion or abandonment of the related project. No further costs are capitalised in respect of this IPRD unless they meet the criteria for research and development capitalisation as set out below.

As per IFRS 3, once the research and development of each defined project is completed, the carrying value of the acquired IPRD is reclassified as a finite-lived asset and amortised over its useful life.

The product and marketing rights recognised in 2017 related to various licenses, the Group held via its US subsidiary. These rights were disposed of with the sale of the subsidiary.

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1 Accounting policies (continued)

Business combinations and externally acquired intangible assets(continued)

The significant intangibles recognised by the Group and their useful economic lives are as follows:

- Goodwill – Indefinite life
- IPRD – In process, not yet amortising
- IT and website costs – 4 years

Product and marketing rights – Between 2 and 12 years

The useful economic life of IPRD will be determined when the in-process research projects are completed. Amortisation of product and marketing rights ceased in June 2018 when the US entity was classified as held for sale.

Internally generated intangible assets (development costs)

Expenditure on the research phase of an internal project is recognised as an expense in the period in which it is incurred. Development costs incurred on specific projects are capitalised when all the following conditions are satisfied:

- completion of the asset is technically feasible so that it will be available for use or sale;
- the Group intends to complete the asset and use or sell it;
- the Group has the ability to use or sell the asset and the asset will generate probable future economic benefits (over and above cost);
- there are adequate technical, financial and other resources to complete the development and to use or sell the asset; and
- the expenditure attributable to the asset during its development can be measured reliably.

Judgement is applied when deciding whether the recognition criteria are met. Judgements are based on the information available. In addition, all internal activities related to the research and development of new projects are continuously monitored by the Directors. The Directors consider that the criteria to capitalise development expenditure are not met for a product prior to that product receiving regulatory approval in at least one country.

Development expenditure not satisfying the above criteria, and expenditure on the research phase of internal projects are included in research and development costs recognised in the Consolidated Statement of Comprehensive Income as incurred. No projects have yet reached the point of capitalisation.

Impairment of non-financial assets

Assets that have an indefinite useful life, for example goodwill, or intangible assets not ready for use, such as IPRD, are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use.

An impairment charge of £12.4m has been recognised in 2020 within continuing operations. This charge is split £9.3m against the IPRD and £2.3m of goodwill, both of these relate to Midatech Pharma (Wales) Ltd cash generating unit and £0.8m against acquired IPRD on MTX110.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). After the disposal of the US operation on 1 November 2018, the Group at 31 December 2020 had only one cash generating unit (2019: one, 2018: one), as set out in note 13. Non-financial assets other than goodwill that suffered impairment are reviewed for possible reversal of impairment at each reporting date.

Impairment charges are included in profit or loss, except, where applicable, to the extent they reverse gains previously recognised in other comprehensive income. An impairment loss recognised for goodwill is not reversed.

Patents and trademarks

The costs incurred in establishing patents and trademarks are either expensed in accordance with the corresponding treatment of the development expenditure for the product to which they relate or capitalised if the development expenditure to which they relate has reached the point of capitalisation as an intangible asset.

Joint arrangements

The Group is a party to a joint arrangement when there is a contractual arrangement that confers joint control over the relevant activities of the arrangement to the Group and at least one other party. Joint control is assessed under the same principles as control over subsidiaries.

The Group classifies its interests in joint arrangements as either:

- Joint ventures: where the Group has rights to only the net assets of the joint arrangement; or
- Joint operations: where the Group has both the rights to assets and obligations for the liabilities of the joint arrangement.

In assessing the classification of interests in joint arrangements, the Group considers:

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1 Accounting policies (continued)

Joint arrangements(continued)

- the structure of the joint arrangement;
- the legal form of joint arrangements structured through a separate vehicle;
- the contractual terms of the joint arrangement agreement; and
- any other facts and circumstances (including any other contractual arrangements).

The results and assets and liabilities of joint ventures are incorporated in the financial statements using the equity method of accounting, except when the investment is classified as held for sale, in which case it is accounted for in accordance with IFRS 5. Under the equity method, an investment in a joint venture is recognised initially in the consolidated statement of financial position at cost and adjusted thereafter to recognise the Group's share of the profit or loss and other comprehensive income of the joint venture. When the Group's share of losses of a joint venture exceeds the Group's interest in that joint venture (which includes any long-term interests that, in substance, form part of the Group's net investment in the joint venture), the Group discontinues recognising its share of further losses. Additional losses are recognised only to the extent that the Group has incurred legal or constructive obligations or made payments on behalf of the joint venture.

Foreign currency

Transactions entered into by subsidiary entities in a currency other than the currency of the primary economic environment, in which they operate, are recorded at the rates ruling when the transactions occur. Foreign currency monetary assets and liabilities are translated at the rates ruling at the reporting date. Exchange differences arising on the retranslation of unsettled monetary assets and liabilities are recognised immediately in profit or loss.

The presentational currency of the Group is Pounds Sterling, and the functional currency is also Pounds Sterling. Foreign subsidiaries use the local currencies of the country where they operate. On consolidation, the results of overseas operations are translated into Pounds Sterling at rates approximating to those ruling when the transactions took place. All assets and liabilities of overseas operations, including goodwill arising on the acquisition of those operations, are translated at the rate ruling at the reporting date. Exchange differences arising on translating the opening net assets at opening rate and the results of overseas operations at actual rate are recognised in other comprehensive income and accumulated in the foreign exchange reserve.

Exchange differences recognised in the profit or loss of Group entities on the translation of long-term monetary items forming part of the Group's net investment in the overseas operation concerned are reclassified to other comprehensive income and accumulated in the foreign exchange reserve on consolidation.

On disposal of a foreign operation, the cumulative exchange differences recognised in the foreign exchange reserve relating to that operation up to the date of disposal are transferred to the consolidated statement of comprehensive income as part of the gain or loss on disposal.

Financial assets and liabilities

Assets at amortised cost

The Group does not have any financial assets which it would classify as fair value through profit or loss. Therefore, all financial assets are classed as assets at amortised cost as defined below.

These assets are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise principally through the provision of goods and services to customers (e.g. trade receivables), but also incorporate other types of contractual monetary asset. They are initially recognised at fair value plus transaction costs that are directly attributable to their acquisition or issue, and are subsequently carried at amortised cost using the effective interest rate method, less provision for impairment.

For impairment provisions, the Group applies the IFRS 9 simplified approach to measure expected credit losses using a lifetime expected credit loss provision for trade receivables to measure expected credit losses on a collective basis. Trade receivables are grouped based on a similar credit risk and ageing.

The expected loss rates are based on the Group's historic credit losses experienced over the three-year period prior to the period end. The historic loss rates are then adjusted for current and forward-looking information on macroeconomic factors.

The Group's assets at amortised costs comprise trade and other receivables and cash and cash equivalents in the consolidated statement of financial position.

Cash and cash equivalents include cash in hand, deposits held at call with original maturities of three months or less.

Financial liabilities

The Group classifies its financial liabilities into one of two categories, depending on the purpose for which the liability was acquired.

Fair value through profit and loss ('FVTPL')

The Group has outstanding warrants in the ordinary share capital of the company. The number of ordinary shares to be issued when exercised is fixed, however the exercise price is denominated in US Dollars being different to the functional currency of the parent company. Therefore, the warrants are classified as equity settled derivative financial liabilities recognised at fair value through the profit and loss account.

The financial liability is valued using the either the Monte Carlo model or the Black-Scholes option pricing model. Financial liabilities at FVTPL are stated at fair value, with any gains or losses arising on re-measurement recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest paid on the financial liability and is included in the 'finance income' or 'finance expense' lines item in the income statement. Fair value is determined in the manner described in note 22.

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1 Accounting policies (continued)

Financial liabilities (continued)

Other financial liabilities include the following items:

- Borrowings are initially recognised at fair value net of any transaction costs directly attributable to the issue of the instrument. Such interest-bearing liabilities are subsequently measured at amortised cost using the effective interest rate method, which ensures that any interest expense over the period to repayment is at a constant rate on the balance of the liability carried in the consolidated statement of financial position. Interest expense in this context includes initial transaction costs and premium payable on redemption, as well as any interest or coupon payable while the liability is outstanding.
- Government loans received on favourable terms below market rate are discounted at a market rate of interest. The difference between the present value of the loan and the proceeds is held as a government grant within deferred revenue and is released to research and development expenditure or grant income in line with when the asset or expenditure is recognised in the income statement.
- Trade payables and other short-term monetary liabilities are initially recognised at fair value and subsequently carried at amortised cost using the effective interest method.

Share capital

Financial instruments issued by the Group are classified as equity only to the extent that they do not meet the definition of a financial liability or financial asset. The Group has two classes of share in existence:

- ordinary shares of £0.001 each are classified as equity instruments;
- deferred shares of £1 each are classified as equity instruments.

On 2 March 2020 a resolution was passed at a general meeting of shareholders of the Company to consolidate its ordinary shares on a one for 20 basis into new ordinary shares of £0.001 each in the capital of the Company.

Comparative figures in these financial statements reflect the impact of the share consolidation.

Retirement benefits: defined contribution schemes

Contributions to defined contribution pension schemes are charged to the consolidated statement of comprehensive income in the year to which they relate.

Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

Share-based payments

The Group operates a number of equity-settled, share-based compensation plans, under which the entity receives services from employees as consideration for equity instruments (options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognised as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including any market performance conditions (including the share price);
- excluding the impact of any service and non-market performance vesting conditions (for example, remaining an employee of the entity over a specified time period); and
- including the impact of any non-vesting conditions (for example, the requirement for employees to save).

Non-market performance and service conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognised over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. Where vesting conditions are accelerated on the occurrence of a specified event, such as a change in control or initial public offering, such remaining

unvested charge is accelerated to the income statement.

In addition, in some circumstances employees may provide services in advance of the grant date and therefore the grant date fair value is estimated for the purposes of recognising the expense during the period between service commencement period and grant date.

At the end of each reporting period, the Group revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions. It recognises the impact of the revision to original estimates, if any, in the income statement, with a corresponding adjustment to equity. When the options are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

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1 Accounting policies (continued)

Leases

Identifying Leases

The Group accounts for a contract, or a portion of a contract, as a lease when it conveys the right to use an asset for a period of time in exchange for consideration. Leases are those contracts that satisfy the following criteria:

- (a) There is an identified asset;
- (b) The Group obtains substantially all the economic benefits from use of the asset; and
- (c) The Group has the right to direct use of the asset.

The Group considers whether the supplier has substantive substitution rights. If the supplier does have those rights, the contract is not identified as giving rise to a lease.

In determining whether the Group obtains substantially all the economic benefits from use of the asset, the Group considers only the economic benefits that arise from the use of the asset, not those incidental to legal ownership or other potential benefits.

In determining whether the Group has the right to direct use of the asset, the Group considers whether it directs how and for what purpose the asset is used throughout the period of use. If there are no significant decisions to be made because they are pre-determined due to the nature of the asset, the Group considers whether it was involved in the design of the asset in a way that predetermines how and for what purpose the asset will be used throughout the period of use. If the contract or portion of a contract does not satisfy these criteria, the Group applies other applicable IFRSs rather than IFRS 16.

All leases are accounted for by recognising a right-of-use asset and a lease liability except for:

- Leases of low value assets; and
- Leases with a duration of 12 months or less.

Lease liabilities are measured at the present value of the contractual payments due to the lessor over the lease term, with the discount rate determined by reference to the group's incremental borrowing rate on commencement of the lease.

Right of use assets are initially measured at the amount of the lease liability, reduced for any lease incentives received, and increased for lease payments made at or before commencement of the lease.

Subsequent to initial measurement lease liabilities increase as a result of interest charged at a constant rate on the balance outstanding and are reduced for lease payments made. Right-of-use assets are amortised on a straight-line basis over the remaining term of the lease.

When the group revises its estimate of the term of any lease (because, for example, it re-assesses the probability of a lessee extension or termination option being exercised), it adjusts the carrying amount of the lease liability to reflect the payments to make over the revised term, which are discounted using a revised discount rate. An equivalent adjustment is made to the carrying value of the right-of-use asset, with the revised carrying amount being amortised over the remaining (revised) lease term. If the carrying amount of the right-of-use asset is adjusted to zero, any further reduction is recognised in profit or loss.

In 2018 the Group entered into a sublease agreement to mitigate the impact of an otherwise onerous lease on the closure of its Abingdon site. This has been recognised as a lease receivable as the Group determined that the sublease meets the definition of a finance lease under the transitional provisions of IFRS16 and therefore, no right-of-use asset is recognised. During 2020 the lease and sub-lease ended.

Nature of leasing activities (in the capacity as lessee)

The group leased a number of properties in the jurisdictions from which it operates. In some jurisdictions it is customary for lease contracts to provide for payments to increase each year by inflation or and in others to be reset periodically to market rental rates. As at 31 December 2020 the Group had one property lease in place in the UK.

Deferred taxation

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability in the consolidated statement of financial position differs from its tax base, except for differences arising on:

- the initial recognition of goodwill;
- the initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting or taxable profit; and
- investments in subsidiaries and jointly controlled entities where the Group is able to control the timing of the reversal of the difference and it is probable that the difference will not reverse in the foreseeable future.

Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the reporting date and are expected to apply when the deferred tax assets or liabilities are recovered or settled.

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1 Accounting policies (continued)

Property, plant and equipment

Items of property, plant and equipment are initially recognised at cost. As well as the purchase price, cost includes directly attributable costs. Depreciation is provided on all items of property, plant and equipment so as to write off their carrying value over their expected useful economic lives. It is provided at the following rates:

Fixtures and fittings	– 25% per annum straight line
Leasehold improvements	– the shorter of 10% per annum straight line or over the lease term
Computer equipment	– 25% per annum straight line
Laboratory equipment	– 15% – 25% per annum straight line

Right of use asset – Economic life of contractual relationship

Inventories

Inventories are stated at the lower of cost or net realisable value. Net realisable value is the market value. In evaluating whether inventories are stated at the lower of cost or net realisable value, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life, and current and expected market conditions, including levels of competition.

If net realisable value is lower than the carrying amount a write down provision is recognised for the amount by which the carrying value exceeds its net realisable value.

Inventory is valued at the lower of cost or market value using the FIFO method. Inventory is charged to the income statement as cost of sales as it is sold.

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2 Critical accounting estimates and judgements

The preparation of these consolidated financial statements requires the Group to make estimates, assumptions and judgments that can have a significant impact on the reported amounts of assets and liabilities, revenue and expenses and related disclosure of contingent assets and liabilities, at the respective dates of our financial statements. The Group bases its estimates, assumptions and judgments on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. Management evaluates estimates, assumptions and judgments on a regular basis and makes changes accordingly, and discusses critical accounting estimates with the board of Directors.

The following are considered to be critical accounting estimates:

Impairment of goodwill and intangible assets not yet ready for use

Goodwill and intangibles not yet ready for use are tested for impairment at the cash generating unit level on an annual basis at the year end and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a cash generating unit below its carrying value. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of a significant portion of a reporting unit.

Application of the goodwill impairment test requires judgment, including the identification of cash generating units, assignment of assets and liabilities to such units, assignment of goodwill to such units and determination of the fair value of a unit and for intangible assets not yet ready for use, the fair value of the asset. The fair value of each cash generating unit or asset is estimated using the income approach, on a discounted cash flow methodology. This analysis requires significant judgments, including estimation of future cash flows, which is dependent on internal forecasts, including for revenues and development costs, estimation of the long term rate of growth for the business, estimation of the useful life over which cash flows will occur and determination of our weighted-average cost of capital.

The carrying value of goodwill was £Nil (2019: £2.3m; 2018:£2.3m) and intangibles not yet ready for use was £Nil (2019:£10.1m; 2018:£10.1m) as at 31 December 2020 (note 12).

The estimates used to calculate the fair value of a cash generating unit change from year to year based on operating results and market conditions. Changes in these estimates and assumptions could materially affect the determination of fair value and goodwill impairment for each such unit.

As a result of the Strategic Review undertaken by the Group in March 2020 as set out in the Chief Executives Review on page ● an impairment charge of £2.3m has been recognised against goodwill in the year ended 31 December 2020 (2019:£Nil; 2018:£Nil) and an impairment charge against the IPRD of the Midatech Pharma (Wales) Ltd cash generating unit of £9.3m (2019:£Nil; 2018: £Nil). As a result of the purported termination of our license to panobinostat by Secura Bio in June 2020 there is an impairment charge of £0.8m against the acquired IPRD in relation to MTX110. See note 12 and 13.

Share-based payments

The Group accounts for share-based payment transactions for employees in accordance with IFRS 2 Share-based Payment, which requires the measurement of the cost of employee services received in exchange for the options on our ordinary shares, based on the fair value of the award on the grant date.

The Directors selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. For performance-based options that include vesting conditions relating to the market performance of our ordinary shares, a Monte Carlo pricing model was used in order to reflect the valuation impact of price hurdles that have to be met as conditions to vesting.

The resulting cost of an equity incentive award is recognised as expense over the requisite service period of the award, which is usually the vesting period. Compensation expense is recognised over the vesting period using the straight-line method and classified in the consolidated statements of comprehensive income.

The assumptions used for estimating fair value for share-based payment transactions are disclosed in note 27 to our consolidated financial statements and are estimated as follows:

- volatility is estimated based on the average annualised volatility of a number of publicly traded peer companies in the biotech sector;
- the estimated life of the option is estimated to be until the first exercise period, which is typically the month after the option vests; and
- the dividend return is estimated by reference to our historical dividend payments. Currently, this is estimated to be zero as no dividend has been paid in the prior periods.

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2 Critical accounting estimates and judgements (continued)

Financial liabilities

Fair value through profit and loss ('FVTPL')

The Group has outstanding warrants in the ordinary share capital of the company. The number of ordinary shares to be issued when exercised is fixed, however the exercise price is denominated in US Dollars being different to the functional currency of the parent company. Therefore, the warrants are classified as equity settled derivative financial liabilities recognised at fair value through the profit and loss account.

The financial liability is valued using either the Monte Carlo model or the Black-Scholes option pricing model. Financial liabilities at FVTPL are stated at fair value, with any gains or losses arising on re-measurement recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest paid on the financial liability and is included in the 'finance income' or 'finance expense' lines item in the income statement. Fair value is determined in the manner described in note 22.

The following are considered to be critical accounting judgments:

Revenue

Supply of Services

There are significant management judgements and estimates involved in the recognition of revenue from the supply of services. Revenue on services is recognised over the contract term, proportionate to the progress in overall satisfaction of the performance obligations (the services performed by the Group), measured by cost incurred to date out of total estimate of costs.

Income taxes

Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgment is required to determine the amount of deferred tax assets that can be recognised based upon the likely timing and the level of future taxable profits together with future tax planning strategies.

In 2020, there were approximately £63.2m of gross unutilised tax losses carried forward (2019: £49.6m; 2018: £40.7m). No deferred tax asset has been provided in respect of these losses as there was insufficient evidence to support their recoverability in future periods.

Research and development costs

Research and development costs are charged to expense as incurred and are typically made up of salaries and benefits, clinical and preclinical activities, drug development and manufacturing costs, and third-party service fees, including for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are periodically recognised as intangible assets based on an evaluation of the progress to completion of specific tasks using data such as patient enrolment, clinical site activations, or information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued expenses.

Leases

IFRS 16 defines the lease term as the non-cancellable period of a lease together with the options to extend or terminate a lease, if the lessee were reasonably certain to exercise that option. This will take into account the length of time remaining before the option is exercisable, current trading, future trading forecasts as to the ongoing profitability of the organisation and the level and type of planned future capital investment. The judgement is reassessed at each reporting period. A reassessment of the remaining life of the lease could result in a recalculation of the lease liability and a material adjustment to the associated balances.

During 2020 following the closure of Midatech Pharma (España) SL and the termination of a property lease occupied by the Company a profit on disposal has been recognised in the financial statements of £109,000.

During 2019 Management considered the appropriate life of a new property lease entered into in Spain. The lease was for an initial period of 5 years, however the lease allowed the Group to break the lease at any-time with one-month notice, provided it returned the property to its original condition. At 31 December 2019, Management assessed it was reasonably certain the expected life of the lease would be 5 years.

The discount rate used in the calculation of the lease liability involves estimation. The discount rate used is the incremental borrowing rate. This rates represents the rate the Group would have had to pay to borrow, over a similar term and with similar security, the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment.

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2 Critical accounting estimates and judgements (continued)

Discontinued Operations

Under the terms of the Sale Agreement the Group agreed to indemnify the Purchaser against, inter alia, any liability related to any prescription drug user fee amounts owed to the United States Food and Drug Administration (“FDA”) under the Prescription Drug Fee User Act (“PDUFA”) by MPUS for the United States government’s fiscal year ended 30 September 2018.

MPUS had successfully obtained waivers for user fees for all prior fiscal periods in which it was liable under PDUFA and entered into the Sale Agreement with the Purchaser confident that a further waiver would be obtained. However, during 2019 MPUS sought approval from the FDA for a filing relating to one of its commercial products and was informed by the FDA that the approval would not be forthcoming whilst the PDUFA fee remained unpaid. Consequently, MPUS paid the PDUFA fee of £0.95m and then, in accordance with the terms of the SPA, Midatech deposited the same amount with MPUS, pending completion of the waiver application process.

At 30 June 2019 Management considered the amount recoverable from MPUS, this was based on the waiver application process being on-going and the historical success MPUS have had in obtaining the waiver.

At 31 December 2019 Management reconsidered the recoverability of the sum paid under the warranty, and although the waiver process was still on-going, Management concluded, based on third party advice, that the probability of successfully achieving the waiver had diminished and therefore took the decision to expense the cost of the warranty claim in the second half of 2019.

During 2020 Fortovia Therapeutics Inc (formerly MPUS) filed for bankruptcy.

Going Concern

We have experienced net losses and significant cash outflows from cash used in operating activities over the past years we develop our portfolio. For the year ended December 31, 2020, the Company incurred a consolidated loss from operations of £22.2million and negative cash flows from operations of £9.3million. As of December 31, 2020, we had an accumulated deficit of £122.4million.

Our future viability is dependent on our ability to generate cash from operating activities, to raise additional capital to finance our operations and to successfully obtain regulatory approval to allow marketing of our development products. Our failure to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies.

Our Group's consolidated financial statements have been presented on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As at December 31, 2020, we had cash and cash equivalents of £7.5million. We believe we currently have enough cash to fund our planned operations into the fourth quarter of 2021.

We have prepared cash flow forecasts and considered the cash flow requirement for the Company for our next three years, including the period twelve months from the date of the approval of the financial statements. These forecasts show that further financing will be required during the course of the next 12 months, assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing represents a material uncertainty that raises substantial doubt about our ability to continue as a going concern.

In addition, the global spread of pandemic novel coronavirus, COVID-19, places increased uncertainty over our forecasts. The restrictions placed and being placed on the movement of people have caused, and may in the future cause, delays to some of our plans. We have established a COVID-19 task force internally to monitor the impact of COVID-19 on our business and prioritize activities to minimize its effect. It is not currently possible to quantify the impact of COVID-19 and resultant delays on the Company until it becomes clear that the global crisis has abated and a normalization of the business environment can be foreseen with confidence.

In addition to utilizing the existing cash reserves, as part of our strategic review, we and our advisors are evaluating a number of near-term funding

options potentially available to us, including fundraising, the partnering of assets or technologies or the sale of the Company. After considering the uncertainties, we considered it appropriate to continue to adopt the going concern basis in preparing the financial information. Our ability to continue as a going concern is dependent upon our ability to obtain additional capital and/or dispose of assets, for which there can be no assurance we will be able to do on a timely basis, on favorable terms or at all.

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3 Segment Information

Revenue from contracts with customers

Geographical analysis of revenue by destination of customer

	2020 £'000	2019 £'000	2018 £'000
Revenue from continuing operations:			
United Kingdom	4	197	149
Rest of Europe	114	55	–
Rest of the World	62	60	–
	180	312	149
Revenue from discontinued operations			
United States	–	–	3,882

All revenue from continuing operations came from the sale of services in 2020, 2019 and 2018.

In 2020, all revenue from continuing operations came from 3 customers (2019: 3 customers; 2018: 1 customer). Within revenue from discontinued operations for 2018, reported in the consolidated statement of comprehensive income under loss from discontinued operations, four customers each accounted for at least 10% of revenue from discontinued operations:

	2020 £'000	2019 £'000	2018 £'000
Customer A	64%	63%	100%
Customer B	34%	19%	–
Customer C	2%	18%	–

Following the disposal of the US commercial business in 2018, the Group contains one reportable operating segment, Pipeline Research and Development ('Pipeline R&D'). This segment seeks to develop products using the Group's nanomedicine and sustained release technology platforms.

The accounting policies of the reportable segments are consistent with the Group's accounting policies described in note 1. Segment results represent the result of each segment without the allocation of head office expenses, interest expense, interest income and tax.

No measures of segment assets and segment liabilities are reported to the Group's Board of Directors in order to assess performance and allocate resources. There is no intersegment activity and all revenue is generated from external customers.

Both the UK and Spanish entities meet the aggregation criteria and have therefore been presented as a single reportable segment under Pipeline R&D. The research and development activities involve the discovery and development of pharmaceutical products in the field of nanomedicine and sustained release technology. The US operating company was engaged in the sale and marketing of cancer supportive care products and was reported historically under the Commercial segment.

In the following segmented results tables, depreciation and amortisation allocated to research and development costs, and administrative costs in the consolidated statements of comprehensive income, are presented separately.

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3 Segment Information (continued)

Segmented results for the year ended 31 December 2020

	Pipeline R&D £'000	Commercial (discontinued) £'000	Consolidated (including discontinued operations) £'000
Revenue	180	–	180
Grant revenue	163	–	163
Total revenue	343	–	343
Other income	12	–	12
Cost of sales	–	–	–
Research and development costs	(4,886)	–	(4,886)
Distribution costs, sales and marketing	(6)	–	(6)
Administrative costs	(4,917)	–	(4,917)
Depreciation	(1,207)	–	(1,207)
Amortisation	(10)	–	(10)
Impairment	(12,369)	–	(12,369)
Loss from operations	(23,040)	–	(23,040)
Finance income	1	–	1
Finance expense	(431)	–	(431)
Loss before tax	(23,470)	–	(23,470)
Taxation	1,281	–	1,281
Loss for the year	(22,189)	–	(22,189)
Loss from continuing operations			(22,189)
Loss from discontinued operations			–

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3 Segment Information (continued)

Segmented results for the year ended 31 December 2019

	Pipeline R&D £'000	Commercial (discontinued) £'000	Consolidated (including discontinued operations) £'000
Revenue	312	–	312
Grant revenue	362	–	362
Total revenue	674	–	674
Other income	15	–	15
Cost of sales	–	–	–
Research and development costs	(6,624)	–	(6,624)
Distribution costs, sales and marketing	(323)	–	(323)
Administrative costs	(3,775)	–	(3,775)
Loss from discontinued operations, net of tax	–	(947)	(947)
Depreciation	(1,282)	–	(1,282)
Amortisation	(3)	–	(3)
Loss from operations	(11,318)	(947)	(12,265)
Finance income	492	–	492
Finance expense	(97)	–	(97)
Loss before tax	(10,923)	(947)	(11,870)
Taxation	1,785	–	1,785
Loss for the year	(9,138)	(947)	(10,085)
Loss from continuing operations			(9,138)
Loss from discontinued operations			(947)

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3 Segment Information (continued)

Segmented results for the year ended 31 December 2018

	Pipeline R&D £'000	Commercial (discontinued) £'000	Consolidated (including discontinued operations) £'000
Revenue	149	3,882	4,031
Grant revenue	1,789	–	1,789
Total revenue	1,938	3,882	5,820
Cost of sales	–	(1,286)	(1,286)
Research and development costs	(8,555)	(283)	(8,838)
Distribution costs, sales and marketing	–	(4,357)	(4,357)
Administrative costs	(4,087)	(872)	(4,959)
Loss on disposal of discontinued operations	–	(1,407)	(1,407)
Depreciation	(1,011)	(5)	(1,016)
Amortisation	(100)	(334)	(434)
Loss from operations	(11,815)	(4,662)	(16,477)
Finance income	2	–	2
Finance expense	(587)	–	(587)
Loss before tax	(12,400)	(4,662)	(17,062)
Taxation	2,032	–	2,032
Loss for the year	(10,368)	(4,662)	(15,030)
Loss from continuing operations			(10,368)
Loss from discontinued operations			(4,662)

All material additions to non-current assets in 2020, 2019 and 2018 were in the Pipeline R&D segment.

Non-current assets by location of assets

	2020 £'000	2019 £'000	2018 £'000
United Kingdom	542	12,775	12,966
Spain		4,383	1,860
	542	17,158	14,826

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4 Discontinued operations

During 2018 the group made the decision to sell its Commercial business based in the US. The sale completed on 1 November 2018 to Barings LLC, a member of the MassMutual Financial Group, for total consideration of up to \$19m. This included \$6m of consideration contingent payable on the achievement of various net revenue milestones for the MPUS business for the financial years 2018 and 2019. MPUS did not achieve the net revenue

milestones in either 2018 or 2019, as a result no contingent consideration was received during 2019.

During 2019 a claim was made by MPUS under the warranties provided by Midatech under the disposal agreement, see note 2. The statement of cash flows includes the following amounts relating to discontinued operations:

	2020 £'000	2019 £'000	2018 £'000
Cash consideration received	–	–	9,350
Other consideration received	–	–	–
Total consideration received	–	–	9,350
Cash disposed of	–	–	(91)
Net cash inflow on disposal of discontinued operation	–	–	9,259
Net assets disposed (other than cash):	–	–	3
Property, plant and equipment	–	–	15,662
Intangibles	–	–	948
Inventory	–	–	629
Trade and other payables	–	–	(2,734)
Total net assets disposed of (other than cash)	–	–	(14,508)
Loss on disposal of discontinued operation before and after tax	–	–	(5,249)
Foreign exchange gain realised on disposal	–	–	3,842
Loss on disposal	–	–	(1,407)

The post-tax loss on disposal of discontinued operations was determined as follows:

	2020 £'000	2019 £'000	2018 £'000
Result of discontinued operations			
Revenue	–	–	3,882
Expenses other than finance costs	–	(947)	(7,137)
Finance costs	–	–	–
Impairment	–	–	–
Loss from discontinued operations before tax	–	(947)	(3,255)
Taxation	–	–	–
Loss on disposal of discontinued operations	–	–	(1,407)
Loss for the year from discontinued operations after tax	–	(947)	(4,662)

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4 Discontinued operations (continued)

	2020 £'000	2019 £'000	2018 £'000
Statement of cash flows			
The statement of cash flows includes the following amounts relating to discontinued operations:			
Operating activities	–	–	(5,368)
Investing activities	–	(947)	–
Financing activities	–	–	(7)
Net cash flow from discontinued operations	–	(947)	(5,375)

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5 Loss from operations

	2020 £'000	2019 £'000	2018 £'000
Loss from operations is stated after charging/(crediting):			
Changes in inventories of finished goods and work in progress	–	–	(976)
Depreciation of property, plant and equipment			
– From continuing operations	1,089	979	1,011
– From discontinued operations	–	–	5
Depreciation of right of use asset			
– From continuing operations	118	303	–
– From discontinued operations	–	–	–
Amortisation of intangible assets – product and marketing rights			
– From continuing operations	10	3	100
– From discontinued operations	–	–	334
Impairment of intangible assets	12,369	–	–
Fees payable to the Company's auditor for the audit of the parent Company	87	110	111
Fees payable to the Company's subsidiary auditors for the audits of the subsidiary accounts	43	48	143
Fees payable to the Company's auditor for:			
– Other services	7	66	83
Fees payable to the Company's previous auditor for the audit of the parent Company	15	–	–
Fees payable to the Company's previous auditor for:			
- Other services	171	–	–
Operating lease expense:			

– Property	–	–	386
– Plant and machinery	–	–	–
Arrangement/penalty fees for loan facility	–	–	469
Foreign exchange(gain)/loss	96	131	212
Profit/(Loss)			
on disposal of property, plant and equipment	(226)	–	165
Equity settled share-based payment	(404)	(34)	(36)

Amortisation of product and marketing rights are included with distribution costs, sales and marketing expenses. Amortisation ceased when the assets were reclassified as held for sale on 30 June 2018 and were sold on 1 November 2018.

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6 Staff costs

Staff costs (including Directors), for continuing and discontinued operations, comprise:

	2020 £'000	2019 £'000	2018 £'000
Wages and salaries	2,727	2,762	5,393
Defined contribution pension cost (note 26)	75	90	149
Social security contributions and similar taxes	397	565	639
Share-based payment	(404)	(34)	(36)
	2,795	3,383	6,145
Continuing operations	2,795	3,383	4,352
Discontinued operations	-	-	1,793
	2,795	3,383	6,145

Employee numbers

The average number of staff employed by the Group during the financial year, for continuing and discontinued operations, amounted to:

	2020	2019	2018
Research and development	31	52	63
General and administration	9	13	16
Sales and marketing	-	-	6
	40	65	85

Key management personnel compensation

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Group, including the Directors of the Company and the Chief Operating Officer.

	2020 £'000	2019 £'000	2018 £'000
Wages and salaries	394	656	900
Defined contribution pension cost	24	42	39
Payments made to third parties	63	82	142
Social security contributions and similar taxes	29	72	77
Benefits in kind	16	2	3
	526	854	1,161
Share-based payment	(472)	(58)	(92)
	54	796	1,069

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6 Staff costs (continued)

Emoluments disclosed above include the following amounts in respect of the highest paid Director.

	2020 £'000	2019 £'000	2018 £'000
Salary	175	266	110
Total pension and other post-employment benefit costs	17	22	4
Benefits in kind	1	1	1
Termination benefits	-	-	99
	193	289	214

None of the Directors have exercised share options during the year (2019: nil, 2018: nil).

During the year 2 Directors (2019:3; 2018: 3) participated in a defined contribution pension scheme.

7 Finance income and expense

	2020 £'000	2019 £'000	2018 £'000
Finance income			
Interest received on bank deposits	1	8	2
Gain on equity settled derivative financial liability	-	484	-
Total finance income	1	492	2
	2020 £'000	2019 £'000	2018 £'000
Finance expense			
Bank loans	-	-	582
Interest expense on lease liabilities	20	30	5

Other loans	14	67	–
Loss on equity settled derivative financial liability	397	–	–
Total finance expense	431	97	587

The gain/(loss) on the equity settled derivative financial liability in 2020 and 2019 arose as a result of the movement in share price (note 21).

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8 Taxation

	2020 £'000	2019 £'000	2018 £'000
Current tax credit			
Current tax credited to the income statement	1,144	1,782	1,952
Taxation payable in respect of foreign subsidiary	(21)	–	(67)
Adjustment in respect of prior year	158	3	128
	1,281	1,785	2,013
Deferred tax credit			
Reversal of temporary differences	–	–	19
Total tax credit	1,281	1,785	2,032

There was no tax charge relating to discontinued operations for 2020, 2019 and 2018.

The reasons for the difference between the actual tax charge for the year and the standard rate of corporation tax in the United Kingdom applied to losses for the year are as follows:

	2020 £'000	2019 £'000	2018 £'000
Loss before tax	(23,470)	(11,870)	(17,062)
Expected tax credit based on the standard rate of United Kingdom corporation tax at the domestic rate of 19% (2019: 19%; 2018: 19%)	(4,459)	(2,255)	(3,241)
Expenses not deductible for tax purposes	596	1,087	2,492
Income not taxable	(75)	–	–
Unrelieved tax losses and other deductions	–	(114)	–
Adjustment in respect of prior period	(158)	(3)	(129)
Surrender of tax losses for R&D tax refund	(491)	(1,810)	(1,955)
Unrelieved tax losses and other deductions arising in the period	–	–	(220)
Foreign exchange differences	–	1	(26)
Deferred tax not recognised	3,306	1,309	1,047
Total tax credited to the income statement	(1,281)	(1,785)	(2,032)

The taxation credit arises on the enhanced research and development tax credits accrued for the respective periods.

An adjustment has been recognised in 2020 in respect of the prior period of £158k, this is as a result of a more detailed review of cost classification prior to the submission of tax returns to HMRC in 2020.

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9 Loss per share

	2020 £'000	2019 £'000	2018 £'000
Numerator			
Loss used in basic EPS and diluted EPS:			
Continuing operations	(22,189)	(9,138)	(10,368)
Discontinued operations	–	(947)	(4,662)
Denominator			
Weighted average number of ordinary shares used in basic EPS:	42,839,961	18,330,588	3,056,303
Basic and diluted loss per share:			
Continuing operations – pence	(52)p	(50)p	(339)p
Discontinued operations – pence	–	(5)p	(153)p

On 2 March 2020 a resolution was passed at a general meeting of shareholders of the Company to consolidate its ordinary shares on a one for 20 basis into new ordinary shares of 0.1p each in the capital of the Company. The comparative denominator has been calculated to reflect the share consolidation.

The Group has made a loss in the current and previous years presented, and therefore the options and warrants are anti-dilutive. As a result, diluted earnings per share is presented on the same basis for all periods shown.

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10 Property, plant and equipment

	Fixtures and fittings £'000	Leasehold improvements £'000	Computer equipment £'000	Laboratory equipment £'000	Right of use asset £'000	Total £'000
Cost						
At 1 January 2018	252	2,112	342	3,669	–	6,375
Additions	4	106	40	353	–	503
Disposal	(5)	(229)	–	(401)	–	(635)

Exchange differences	2	24	1	30	–	57
At 31 December 2018	253	2,013	383	3,651	–	6,300
Adoption of IFRS 16 Leases	–	–	–	–	395	395
Additions	4	137	23	223	822	1,209
Effect of modification to lease terms	–	–	–	–	(82)	(82)
Exchange differences	(9)	(112)	(3)	(136)	(11)	(271)
At 31 December 2019	248	2,038	403	3,738	1,124	7,551
Additions	–	58	16	135	–	209
Effect of modification to lease terms	–	–	–	–	(678)	(678)
Disposal	(202)	(2,184)	(185)	(2,323)	(316)	(5,210)
Exchange differences	7	92	2	112	58	271
At 31 December 2020	53	4	236	1,662	188	2,143

	Fixtures and fittings £'000	Leasehold improvements £'000	Computer equipment £'000	Laboratory equipment £'000	Right of use asset £'000	Total £'000
Accumulated depreciation						
At 1 January 2018	196	1,238	192	2,220	–	3,846
Charge for the year	43	403	72	499	–	1,016
Disposals	–	(175)	(3)	(421)	–	(599)
Exchange differences	2	19	4	28	–	53
At 31 December 2018	241	1,485	265	2,326	–	4,317
Charge for the year	2	400	70	507	303	1,282
Exchange differences	(8)	(91)	(3)	(93)	(7)	(202)
At 31 December 2019	235	1,794	332	2,740	296	5,397
Charge for the year	9	310	50	720	118	1,207
Disposals	(202)	(2,183)	(185)	(2,300)	(316)	(5,186)
Exchange differences	7	81	2	79	14	183
At 31 December 2020	49	2	199	1,239	112	1,601
Net book value						
At 31 December 2020	4	2	37	423	76	542
At 31 December 2019	13	244	71	998	828	2,154
At 31 December 2018	12	528	118	1,325	–	1,983

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11 Leases

	2020 £'000	2019 £'000
Right of Use Asset		
At 1 January	828	395
Additions	–	822
Effect of modification to lease terms	(678)	(82)
Depreciation	(118)	(303)
Exchange differences	44	(4)
At 31 December	76	828
Lease Liabilities		
At 1 January	907	546
Additions	–	822
Effect of modification to lease terms	(788)	(82)
Interest expenses	15	24
Lease payments	(105)	(391)
Exchange differences	47	(12)
At 31 December	76	907

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11 Leases (continued)

During 2020 as a result of the closure of the Group's operations in Spain two property leases were terminated early, this impacted both the right of use asset and the lease liability. Management considered the appropriate life of a lease in the UK in 2020 and 2019 and adjusted the right of use asset and lease liability accordingly.

The group had commitments under non-cancellable operating leases as set out below, from 1 January 2019, the group has recognised right-of-use assets for these leases, exception for low value leases.

	Land and Buildings £'000	Other £'000
2020		
Expiring In one year or less	–	–

Expiring over one year	-	-
	-	-
2019		
Expiring In one year or less	-	-
Expiring over one year	-	-
	-	-
2018		
Expiring In one year or less	383	1
Expiring over one year	189	4
	572	5
Low value leases expensed in year:		
	2020 £'000	2019 £'000
Low value leases expensed	10	29
	10	29

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12 Intangible assets

	In-process research and development £'000	Product and marketing rights £'000	Goodwill £'000	IT/Website costs £'000	Total £'000
Cost					
At 1 January 2018	13,378	19,856	13,444	27	46,705
Disposals	-	(21,022)	(11,808)	-	(32,830)
Foreign exchange	-	1,166	655	1	1,822
At 31 December 2018	13,378	-	2,291	28	15,697
Additions	-	-	-	9	9
Foreign exchange	-	-	-	(2)	(2)
At 31 December 2019	13,378	-	2,291	35	15,704
Disposal	-	-	-	(36)	(36)
Foreign exchange	-	-	-	1	1
At 31 December 2020	13,378	-	2,291	-	15,669
	In-process research and development £'000	Product and marketing rights £'000	Goodwill £'000	IT/Website Costs £'000	Total £'000
Accumulated amortisation and impairment					
At 1 January 2018	3,300	15,739	-	19	19,058
Amortisation charge for the year	-	431	-	3	434
Disposal	-	(17,103)	-	-	(17,103)
Foreign exchange	-	933	-	1	934
At 31 December 2018	3,300	-	-	23	3,323
Amortisation charge for the year	-	-	-	3	3
Foreign exchange	-	-	-	(1)	(1)
At 31 December 2019	3,300	-	-	25	3,325
Amortisation charge for the year	-	-	-	10	10
Disposal	-	-	-	(36)	(36)
Impairment	10,078	-	2,291	-	12,369
Foreign exchange	-	-	-	1	1
At 31 December 2020	13,378	-	2,291	-	15,669
Net book value					
At 31 December 2020	-	-	-	-	-
At 31 December 2019	10,078	-	2,291	10	12,379
At 31 December 2018	10,078	-	2,291	5	12,374

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12 Intangible assets (continued)

The individual intangible assets, excluding goodwill, which are material to the financial statements are:

	Carrying amount			Remaining amortisation period		
	2020 £'000	2019 £'000	2018 £'000	2020 (years)	2019 (years)	2018 (years)
Midatech Pharma (Wales) Limited acquired IPRD	-	9,300	9,300	n/a	n/a in process	n/a in process

Midatech Pharma US, Inc., product and marketing rights	–	–	–	n/a	n/a	n/a
Zuplenz® product and marketing rights	–	–	–	n/a	n/a	n/a
MTX110 acquired IPRD	–	778	778	n/a	n/a in process	n/a in process
				–	10,078	10,078

13 Impairment testing

Midatech Pharma (Wales) Ltd

Details of goodwill and IPRD allocated to the acquired cash generating unit and the valuation basis are as follows:

Name	Indefinite lived						Valuation Basis
	IPRD carrying amount			Goodwill carrying amount			
	2020 £'000	2019 £'000	2018 £'000	2020 £'000	2019 £'000	2018 £'000	
CGU – Midatech Pharma (Wales) Ltd	–	9,300	9,300	–	2,291	2,291	Value in use
MTX110 acquired IPRD	–	778	778	–	–	–	–

An impairment charge of £11.6m was recorded in 2021 in the assets of Midatech Pharma Wales Ltd ('MPW') CGU as a result of the Board's decision on 31 March 2020 to terminate the MTD201. The impairment charge was £9.3m of IPRD and £2.3m acquired goodwill.

In 2020 an impairment charge of £0.8m was recorded in relation to the acquire IPRD on MTX110. The impairment is as a result of the termination of a License Agreement between the Company and Secura Bio Inc. Pursuant to the License Agreement, Midatech Limited was granted a non-exclusive worldwide, sub-licenseable license to certain patents of Panobinostat, the active pharmaceutical ingredient of the Company's development product MTX110.

The assets of MPW were valued as at 31 December 2019 and 2018 and were found to support the IPRD and goodwill carrying amounts set out above. The IPRD was valued using (2019: 12-13 year; 2018: 12-13 year), risk adjusted cash flow forecasts, in line with patent life, that have been approved by the Board. A period longer than 5 years was appropriate on the basis that the investment was long term and the development and commercialisation process is typically in excess of 5 years. Beyond the period from product launch and initial market penetration, a long term growth rate of Nil was used.

The key assumptions used in the valuation model examining the MPW Ltd cash generating unit include the following:

Assumptions	2020	2019	2018
Pre-tax discount rate	n/a	18.4%	17.7%
Cumulative probability of success of projects	n/a	81%	81%

The discount rate is an estimated market-based weighted average cost of capital for the MPW business, determined at the date of acquisition.

Cumulative probability of success of projects is the product of the probability of success of each remaining major phase of development for each individual IPRD component. These phase probabilities were determined by management with reference to the risks associated with each remaining development stage.

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13 Impairment testing (continued)

Sensitivity analysis

If any one of the following changes were made to the above key assumptions, the carrying value and recoverable amount would be equal.

Assumptions	2020	2019	2018
Pre-tax discount rate for all projects	n/a	increase to 21%	increase to 29.8%
Cumulative probability of success of project	n/a	59%	34%

14 Subsidiaries

The subsidiaries of Midatech Pharma plc, all of which are 100% owned, either directly or through subsidiaries where indicated, and have been included in these financial statements in accordance with the details set out in the basis of preparation and basis of consolidation note 1, are as follows:

Name	Registered Office	Nature of Business	Notes
Midatech Limited	Oddfellows House, 19 Newport Road, Cardiff, CF24 0AA	Trading company	
Midatech Pharma (España) SL	Parque Tecnológico de Vizcaya, Edificio 800 Planta 2, Derio, 48160, Vizcaya, Spain	In liquidation	(a)
PharMida AG	c/o Kellerhals, Hirschgässlein 11, 4051 Basel, Switzerland	Dormant	(a) (b)
Midatech Pharma (Wales) Limited	Oddfellows House, 19 Newport Road, Cardiff, CF24 0AA	Trading company	
Midatech Pharma PTY		Dissolved - 2020	(c)

Notes:

(a) Wholly owned subsidiary of Midatech Limited.

(b) PharMida AG became dormant in January 2016.

(c) Midatech Pharma PTY was incorporated on 16 February 2015 and dissolved November 2020.

15 Trade and other receivables

	2020 £'000	2019 £'000	2018 £'000
Trade receivables	95	22	89

Prepayments	258	151	139
Other receivables	219	3,444	1,564
Total trade and other receivables	572	3,617	1,792
Less: non-current portion (rental deposit and on bond)	–	(2,625)	(469)
Current portion	572	992	1,323

Trade and other receivables do not contain any impaired assets. The Group does not hold any collateral as security and the maximum exposure to credit risk at the consolidated statement of financial position date is the fair value of each class of receivable.

Book values approximate to fair value at 31 December 2020, 2019 and 2018.

During 2019 a cash-backed guarantee was provided to the Spanish Government in relation to a loan provided to the Group under its Reindustrialization programme, see note 19. As a result of the closure of Midatech Pharma (España) SL during 2020 the cash-back guarantee was released on the repayment of the loan to the Spanish Government.

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16 Cash and cash equivalents and cash flow supporting notes

Cash and cash equivalents for purposes of the consolidated statement of cash flows comprises:

	2020	2019	2018
	£'000	£'000	£'000
Cash at bank available on demand	7,546	10,928	2,343

During 2020 and 2019, cash inflows arose from equity financing transactions, included within financing activities on the face of the cash flow statement. As part of the equity transaction in May 2020 warrants to the value of £1.0m (October 2019 : £1.1m) were issued as disclosed in note 21.

	2020	2019	2018
	£'000	£'000	£'000
Gross proceeds	10,792	15,767	–
Transaction costs	(1,050)	(1,659)	–
	9,742	14,108	–

The following changes in loans and borrowings arose as a result of financing activities during the year:

	Non-current liabilities	Current liabilities	Total
	£'000	£'000	£'000
At 1 January 2020	5,670	412	6,082
Cash flows	(6,182)	(258)	(6,440)
Non-cashflows:			
Foreign Exchange	252	23	275
Fair value changes	1,176	–	1,176
Effect of modification to lease term – IFRS 16	(877)	89	(788)
Loans and borrowings classified as non-current 31 December 2019 becoming current in 2020	51	(51)	–
Interest accruing in period	(30)	(15)	(45)
At 31 December 2020	60	200	260

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16 Cash and cash equivalents and cash flow supporting notes(continued)

	Non-current liabilities	Current liabilities	Total
	£'000	£'000	£'000
At 1 January 2019	884	368	1,252
Cash flows	5,575	(1,027)	4,548
Non-cashflows:			
Foreign Exchange	(42)	(29)	(71)
Fair value changes	(1,139)	–	(1,139)
Adoption of IFRS16 leases	163	383	546
Effect of modification to lease term – IFRS 16	–	(82)	(82)
New leases	805	95	900
Loans and borrowings classified as non-current 31 December 2018 becoming current in 2019	(685)	685	–
Transfer to grant income	–	(14)	(14)
Interest accruing in period	108	34	142
At 31 December 2019	5,670	412	6,082
	Non-current liabilities, bank loans	Current liabilities, bank loans	Total
	£'000	£'000	£'000
At 1 January 2018	6,185	361	6,546
Cash flows	(5,580)	(305)	(5,885)
Non- cashflows:			
Foreign Exchange	296	4	300
New leases	168	76	244
Loans and borrowings classified as non-current 31 December 2018			

becoming current in 2019	(232)	232	–
Interest accruing in period	47	–	47
At 31 December 2018	884	368	1,252

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17 Inventories

	2020 £'000	2019 £'000	2018 £'000
Finished goods	–	–	–
Total inventories	–	–	–

There was no stock held at 31 December 2020.

18 Trade and other payables

	2020 £'000	2019 £'000	2018 £'000
Current			
Trade payables	337	725	286
Other payables	26	13	–
Accruals	768	1,765	1,025
Total financial liabilities, excluding loans and borrowings, classified as financial liabilities measured at amortised cost	1,131	2,503	1,311
Tax and social security	31	86	347
Deferred revenue and government grants	68	1,905	445
Total trade and other payables	1,230	4,494	2,103

Book values approximate to fair value at 31 December 2020, 2019 and 2018.

All current trade and other payables are payable within 3 months of the period end date shown above.

Government grants

The Group received development grant funding from the European Union under the Horizon 2020 ‘Nanofabrication’ project, a European Union funded programme to develop a scalable manufacturing platform for the production of nanopharmaceutical products. Midatech participated in this programme, along with seven other entities, through two Group companies, Midatech Pharma España SL (‘MPE’), which acted as project coordinator, and Midatech Limited (‘MTL’). The project commenced in February 2015 and completed in January 2019. During the year ended (2019: £124k, 2018: £1,610k) revenue was recognised in relation to this project and the deferred revenue balance as at 31 December 2020 was £nil (2019: £nil, 2018: £124k).

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19 Borrowings

	2020 £'000	2019 £'000	2018 £'000
Current			
Bank loans	–	–	4
Lease liabilities	93	233	80
Government and research loans	107	179	284
Total	200	412	368
Non-current			
Bank loans	–	–	–
Lease liabilities	60	912	170
Government and research loans	–	4,758	714
Total	60	5,670	884

During 2020 £4.8m government and research loans were repaid.

Book values approximate to fair value at 31 December 2020, 2019 and 2018.

Obligations under finance leases are secured by a fixed charge over the fixed assets to which they relate.

Government loans in Spain

In September 2019, Midatech Pharma España SL received €6.6m of funding awarded under the Spanish Government Reindustrialization programme. The Spanish Government required the Company to provide a €2.9 million cash-backed guarantee as security for the loan. The funds were used to support Midatech’s manufacturing scale-up facilities construction. As a result of the Group’s decision on 31 March 2020 to terminate further in-house development of MTD201 and the subsequent closure of its dedicated manufacturing facilities in Bilbao the Group repaid the loans during 2020. As a result of the early termination of the loan interest was charged at market rates up to the date of satisfaction of the loan.

There remains one outstanding government loan which was received by Midatech Pharma España SL for the finance of research, technical innovation and the construction of their laboratory. The loan is a term loan which carries an interest rate below the market rate and is repayable in 2021. The Group made requests to the Spanish Government during 2020 to repay the loan early but were unsuccessful with their request, the loan was repaid in February 2021. During 2020 the Group repaid two government loans.

The loans carried default interest rates in the event of scheduled repayments not being met. On initial recognition, the loans are discounted at a market rate of interest with the credit being classified as a grant within deferred revenue. The deferred grant revenue is released to the consolidated statement of comprehensive income within research and development costs in the period to which the expenditure is recognised.

The deferred revenue element of the government loans is designated within note 18 as deferred revenue and Government grants, the gross contractual repayment of the loans is disclosed in note 22. As a result of the repayment of the loans these were fully amortised during 2020.

Midcap Loan Facility

In December 2017, Midatech Pharma entered into a secured loan agreement with Midcap Financial Trust (MidCap). The total facility was for \$15m to be drawn down in three separate tranches. Interest was charged on the outstanding balance of the loan at an annual rate of LIBOR plus 7.5% subject to a LIBOR floor of 1.25%. MidCap was granted 247,881 warrants to purchase shares which was equal to 2% of the amount funded divided by the Exercise Price of £0.42. The Exercise Price was calculated as the average closing price for the 30-day period prior to the date of grant. The

loan was secured against the assets of the Group.

The first tranche of \$7m was drawn down on 28 December 2017 and is disclosed under bank loans. This loan was repaid on 31 October 2018.

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20 Provisions

	2020 £'000	2019 £'000	2018 £'000
Opening provision at 1 January	97	165	–
Provision (released)/recognised in the year	(47)	(68)	165
At 31 December	50	97	165
Less: non-current portion	(50)	–	(165)
Current portion	–	97	–

The provision as at 31 December 2020 relates to the 'making good' clause on the Cardiff office which is due to be vacated during 2021. The provision in previous years relates to the 'making good' clause on the Abingdon office which was vacated in December 2018. The Abingdon office was sub-let for the remaining period of the lease, which terminated in February 2020.

21 Derivative financial liability – current

	2020 £'000	2019 £'000	2018 £'000
Equity settled derivative financial liability			
At 1 January	664	–	–
Warrants issued	997	1,148	–
Transfer to share premium on exercise of warrants	(499)		
Gain recognised in finance income within the consolidated statement of comprehensive income	397	(484)	–
At 31 December	1,559	664	–

Equity settled derivative financial liability is a liability that is not to be settled for cash.

In May 2020 the Group issued 9,545,456 warrants in the ordinary share capital of the company as part of a Registered Direct Offering. The number of ordinary shares to be issued when exercised is fixed, however the exercise price is denominated in US Dollars being different to the functional currency of the parent company. Therefore, the warrants are classified as equity settled derivative financial liabilities recognised at fair value through the profit and loss account ('FVTPL'). The financial liability is valued using the Monte Carlo model. Financial liabilities at FVTPL are stated at fair value, with any gains or losses arising on re-measurement recognised in profit or loss. The net gain or loss recognised in profit or loss incorporates any interest paid on the financial liability and is included in the 'finance income' or 'finance expense' lines item in the income statement. Fair value is determined in the manner described in note 22. A key input in the valuation of the instrument is the Company share price. On 19 August 2020 2,500,000 pre-existing warrants were exercised at \$0.41. The gross proceeds received by the company was \$1,025,000. The fair value of the warrants on the date of exercise was £498,502.

At 31 December 2020 7,045,455 warrants were outstanding.

In October 2019 the Group issued 3,150,000 warrants in the ordinary share capital of the company as part of a Registered Direct Offering. The number of ordinary shares to be issued when exercised is fixed, however the exercise price is denominated in US Dollars. The warrants are classified equity settled derivative financial liabilities and accounted for in the same way as those issued in May 2020. The financial liability is valued using the Monte Carlo model.

At 31 December 2020 and 31 December 2019, 3,150,000 warrants were outstanding.

The Group also assumed fully vested warrants and share options on the acquisition of DARA Biosciences, Inc. (which took place in 2015). The number of ordinary shares to be issued when exercised is fixed, however the exercise prices are denominated in US Dollars. The warrants are classified equity settled derivative financial liabilities and accounted for in the same way as those issued in May 2020. The financial liability is valued using the Black-Scholes option pricing model.

At 31 December 2018 a further 8,846 options and 38,844 warrants had lapsed and the share price had fallen to £1.20. As the liability had already been reduced to zero there was no movement on re-measurement.

At 31 December 2019 a further 3,332 options and 111,582 warrants had lapsed and the share price had fallen to £0.56. As the liability had already been reduced to zero there was no movement on re-measurement.

During 2020 no options or warrants lapsed and the share price had fallen to £0.265. As the liability had already been reduced to zero there was no movement on re-measurement.

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22 Financial instruments – risk management

The Group is exposed through its operations to the following financial risks:

- Credit risk
- Foreign exchange risk
- Liquidity risk

In common with all other businesses, the Group is exposed to risks that arise from its use of financial instruments. This note describes the Group's objectives, policies and processes for managing those risks and the methods used to measure them. The Board does not believe that its risk exposure to financial instruments, its objectives, policies and processes for managing those risks or the methods used to measure them from previous periods unless otherwise stated in this note has changed in the past year.

Principal financial instruments

The principal financial instruments used by the Group, from which financial instrument risk arises, are as follows:

- Trade and other receivables
- Cash and cash equivalents
- Trade and other payables
- Accruals
- Loans and borrowings

- Derivative financial liability

A summary of the financial instruments held by category is provided below:

Financial assets – amortised cost

	2020 £'000	2019 £'000	2018 £'000
Cash and cash equivalents	7,546	10,928	2,343
Trade receivables	95	22	89
Other receivables	–	2,625	469
Total financial assets	7,641	13,575	2,901

Financial liabilities – amortised cost

	2020 £'000	2019 £'000	2018 £'000
Trade payables	337	725	286
Other payables	26	13	–
Accruals	768	1,765	1,025
Borrowings	260	6,082	1,252
Total financial liabilities – amortised cost	1,391	8,585	2,563

Financial liabilities – fair value through profit and loss – current

	2020 £'000	2019 £'000	2018 £'000
Equity settled derivative financial liability	1,559	664	–

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22 Financial instruments – risk management (continued)

General objectives, policies and processes

The Board has overall responsibility for the determination of the Group's risk management objectives and policies and, whilst retaining ultimate responsibility for them, it has delegated the authority for designing and operating processes that ensure the effective implementation of the objectives and policies to the Group's management.

The overall objective of the Board is to set policies that seek to reduce risk as far as possible without unduly affecting the Group's competitiveness and flexibility. Further details regarding these policies are set out below:

Fair value hierarchy

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1: quoted (unadjusted) prices in active markets for identical assets and liabilities;
- Level 2: other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly; and
- Level 3: techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

The fair value of the Group's derivative financial liability is measured at fair value on a recurring basis. The following table gives information about how the fair value of this financial liability is determined, additional disclosure is given in note 21:

Financial liabilities	Fair value as at 31/12/2020	Fair value hierarchy	Valuation technique(s) and key input(s)	Significant unobservable input(s)	Relationship of unobservable inputs to fair value
Equity settled financial derivative liability	£1,187,000	Level 3	Monte Carlo simulation model	Volatility rate of 105.0% determined using historical volatility of comparable companies.	The higher the volatility the higher the fair value.
				Expected life between a range of 0.1 and 4.49 years determined using the remaining life of the share options.	The shorter the expected life the lower the fair value.
				Risk-free rate of 0.07% determined using the expected life assumptions.	The higher the risk-free rate the higher the fair value.
Equity settled financial derivative liability	£372,000	Level 3	Monte Carlo simulation model	Volatility rate of 105.0% determined using historical volatility of comparable companies.	The higher the volatility the higher the fair value.
				Expected life between a range of 0.1 and 4.888 years determined using the remaining life of the share options.	The shorter the expected life the lower the fair value.
				Risk-free rate of 0.08% determined using the expected life assumptions.	The higher the risk-free rate the higher the fair value.
Equity settled financial derivative liability	–	Level 3	Black-Scholes option pricing model	Volatility rate of 105.0% determined using historical volatility of comparable companies.	The higher the volatility the higher the fair value.
				Expected life between a range of 1.0 and 1.9 years determined using the remaining life of the	The shorter the expected life the lower the fair value.

share options.

Risk-free rate of 0.8% determined using the expected life assumptions.

The higher the risk-free rate the higher the fair value.

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22 Financial instruments – risk management (continued)

Financial liabilities	Fair value as at 31/12/2019	Fair value hierarchy	Valuation technique(s) and key input(s)	Significant unobservable input(s)	Relationship of unobservable inputs to fair value
Equity settled financial derivative liability	£664,000	Level 3	Monte Carlo simulation model	Volatility rate of 78.4% determined using historical volatility of comparable companies. Expected life between a range of 0.1 and 5.68 years determined using the remaining life of the share options.	The higher the volatility the higher the fair value. The shorter the expected life the lower the fair value.
				Risk-free rate between a range of 0.59% and 1.69 % determined using the expected life assumptions.	The higher the risk-free rate the higher the fair value.
Equity settled financial derivative liability	–	Level 3	Black-Scholes option pricing model	Volatility rate of 78.3% determined using historical volatility of comparable companies. Expected life between a range of 2.0 and 2.9 years determined using the remaining life of the share options.	The higher the volatility the higher the fair value. The shorter the expected life the lower the fair value.
				Risk-free rate between a range of 0.0% and 0.26 % determined using the expected life assumptions.	The higher the risk-free rate the higher the fair value.
Financial liabilities	Fair value as at 31/12/2018	Fair value hierarchy	Valuation technique (s) and key input(s)	Significant unobservable input(s)	Relationship of unobservable inputs to fair value
Equity settled financial derivative liability	–	Level 3	Black-Scholes option pricing model	Volatility rate of 42.5% determined using historical volatility of comparable companies. Expected life between a range of 0.1 and 7.6 years determined using the remaining life of the share options.	The higher the volatility the higher the fair value. The shorter the expected life the lower the fair value.
				Risk-free rate between a range of 0.0% and 1.14% determined using the expected life assumptions.	The higher the risk-free rate the higher the fair value.

Changing the unobservable risk free rate input to the valuation model by 10% higher while all other variables were held constant, would not impact the carrying amount of shares (2019: nil, 2018: nil).

There were no transfers between Level 1 and 2 in the period.

The financial liability measured at fair value on Level 3 fair value measurement represents consideration relating to warrants issued in May 2020 and October 2019 as part of Registered Direct offerings and also a business combination. In 2018 this only related to consideration relating to a business combination.

Credit risk

Credit risk is the risk of financial loss to the Group if a development partner or a counterparty to a financial instrument fails to meet its contractual obligations. The Group is mainly exposed to credit risk from amounts due from collaborative partners which is deemed to be low.

Credit risk also arises from cash and cash equivalents and deposits with banks and financial institutions. For banks and financial institutions, only independently rated parties with high credit status are accepted.

The Group does not enter into derivatives to manage credit risk.

The consolidated entity recognises a loss allowance for expected credit losses on financial assets which are either measured at amortised cost or fair value through other comprehensive income. The measurement of the loss allowance depends upon the consolidated entity's assessment at the end of each reporting period as to whether the financial instrument's credit risk has increased significantly since initial recognition, based on reasonable and supportable information that is available, without undue cost or effort to obtain.

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22 Financial instruments – risk management (continued)

Where there has not been a significant increase in exposure to credit risk since initial recognition, a 12-month expected credit loss allowance is estimated. This represents a portion of the asset's lifetime expected credit losses that is attributable to a default event that is possible within the next 12 months. Where a financial asset has become credit impaired or where it is determined that credit risk has increased significantly, the loss allowance is based on the asset's lifetime expected credit losses. The amount of expected credit loss recognised is measured on the basis of the probability weighted present value of anticipated cash shortfalls over the life of the instrument discounted at the original effective interest rate. For financial assets measured at fair value through other comprehensive income, the loss allowance is recognised within other comprehensive income. In all other cases, the loss allowance is recognised in profit or loss.

The gross carrying amount of a financial asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery. Quantitative disclosures of the credit risk exposure in relation to financial assets are set out in note 15. This includes details regarding trade and other receivables, which are neither past due nor impaired.

The total exposure to credit risk of the Group is equal to the total value of the financial assets held at each year end as noted above.

Cash in bank

The Group is continually reviewing the credit risk associated with holding money on deposit in banks and seeks to mitigate this risk by holding deposits with banks with high credit status.

Foreign exchange risk

Foreign exchange risk arose because the Group had a material operation located in Bilbao, Spain, until 2020, whose functional currency was not the same as the functional currency of the Group. The Group's net assets arising from the overseas operation were exposed to currency risk resulting in gains or losses on retranslation into sterling. Given the levels of materiality, the Group did not hedge its net investments in overseas operations as the cost of doing so would be disproportionate to the exposure.

Foreign exchange risk also arises when individual Group entities enter into transactions denominated in a currency other than their functional currency; the Group's transactions outside the UK to the US, Europe and Australia drive foreign exchange movements where suppliers invoice in currency other than sterling. These transactions are not hedged because the cost of doing so is disproportionate to the risk.

The table below shows analysis of the Pounds Sterling equivalent of year-end cash and cash equivalent balances by currency:

	2020 £'000	2019 £'000	2018 £'000
Cash and cash equivalents:			
Pounds Sterling	7,247	3,153	457
US Dollar	120	2,021	1,421
Euro	179	5,750	459
Other	-	4	6
Total	7,546	10,928	2,343

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22 Financial instruments – risk management (continued)

The table below shows the foreign currency exposure that gives rise to net currency gains and losses recognised in the consolidated statement of comprehensive income. Such exposures comprise the net monetary assets and monetary liabilities of the Group that are not denominated in the functional currency of the relevant Group entity. As at 31 December, these exposures were as follows:

	2020 £'000	2019 £'000	2018 £'000
Net Foreign Currency Assets/(Liabilities):			
US Dollar	120	2,021	1,421
Euro	54	1,460	552
Other	1	7	8
Total	175	3,488	1,981

Foreign currency sensitivity analysis

The most significant currencies in which the Group transacts, other than Pounds Sterling, are the US Dollar and the Euro. The Group also trades in other currencies in small amounts as necessary.

The following table details the Group's sensitivity to a 10% change in year-end exchange rates, which the Group feels is the maximum likely change in rate based upon recent currency movements, in the key foreign currency exchange rates against Pounds Sterling:

	US Dollar £'000	Euro £'000	Other £'000
Year ended 31 December 2020			
Loss before tax	12	(293)	(4)
Total equity	12	(293)	(4)
	US Dollar £'000	Euro £'000	Other £'000
Year ended 31 December 2019			
Loss before tax	202	54	-
Total equity	202	31	1
	US Dollar £'000	Euro £'000	Other £'000
Year ended 31 December 2018			
Loss before tax	-	168	-
Total equity	142	168	-

The sale of the Midatech Pharma US, Inc. operation prior to 31 December 2018 resulted in there not being any US Dollar denominated assets or liabilities to report on other than a US Dollar cash balance held by Midatech Pharma PLC. In management's opinion, the sensitivity analysis for the year ended 31 December 2018 is unrepresentative of the inherent foreign exchange risk as the year-end exposure does not reflect the exposure during the year.

Liquidity risk

Liquidity risk arises from the Group's management of working capital. It is the risk that the Group will encounter difficulty in meeting its financial obligations as they fall due. It is the Group's aim to settle balances as they become due.

In May 2020, the Company completed a concurrent Registered Direct Offering in the US and a Placing in the UK whereby the Company raised £4.26m before expenses. In July 2020, the Company completed a UK Placing which raised £5.75m before expenses. In August 2020, previously

issued warrants were exercised resulting in the Company receiving £0.78m before expenses.

The Directors have prepared cash flow forecasts and considered the cash flow requirement for the Company for the next three years including the period twelve months from the date of approval of the consolidated financial statements. These forecasts show that further financing will be required during the fourth quarter of 2021 assuming, inter alia, that certain development programs and other operating activities continue as currently planned. This requirement for additional financing in the short term represents a material uncertainty that may cast significant doubt upon the Group and parent company's ability to continue as a going concern.

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22 Financial instruments – risk management (continued)

In addition, the global pandemic COVID-19 virus places increased uncertainty over the Directors' forecasts. The restrictions being placed on the movement of people will likely cause delays to some of the Group's plans. It is difficult to assess to what extent, and for how long, COVID-19 will cause delays to the Group's operations. The Directors have established a COVID-19 task force internally to monitor the impact of COVID-19 on the business and prioritize activities to minimize its effect.

The Directors are evaluating a number of near-term funding options potentially available to the Group, including fundraising and the partnering of assets and technologies of the Company. After considering the uncertainties, the Directors consider it is appropriate to continue to adopt the going concern basis in preparing these financial statements.

The following table sets out the contractual maturities (representing undiscounted contractual cash-flows) of financial liabilities:

	Up to 3 months £'000	Between 3 and 12 months £'000	Between 1 and 2 years £'000	Between 2 and 5 years £'000	Over 5 years £'000
2020					
Trade and other payables	1,131	–	–	–	–
Bank loans	–	–	–	–	–
Lease liabilities	25	75	61	8	–
Government research loans	107	–	–	–	–
Total	1,263	75	61	8	–
	Up to 3 months £'000	Between 3 and 12 months £'000	Between 1 and 2 years £'000	Between 2 and 5 years £'000	Over 5 years £'000
2019					
Trade and other payables	2,503	–	–	–	–
Bank loans	–	–	–	–	–
Lease liabilities	79	165	317	735	–
Government research loans	–	272	238	2,851	3,317
Total	2,582	437	555	3,586	3,317
	Up to 3 months £'000	Between 3 and 12 months £'000	Between 1 and 2 years £'000	Between 2 and 5 years £'000	Over 5 years £'000
2018					
Trade and other payables	1,311	–	–	–	–
Bank loans	3	2	–	–	–
Finance leases	22	65	79	117	–
Government research loans	44	240	406	414	–
Total	1,380	307	485	531	–

More details with regard to the line items above are included in the respective notes:

- Trade and other payables – note 18
- Borrowings – note 19

As a result of the Strategic Review undertaken in March 2020 the Group repaid all but one Government Research loans during 2020. The remaining loan will be repaid in 2021.

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22 Financial instruments – risk management (continued)

Capital risk management

The Group monitors capital which comprises all components of equity (i.e. share capital, share premium, foreign exchange reserve and accumulated deficit).

The Group's objectives when maintaining capital are:

- to safeguard the entity's ability to continue as a going concern; and
- to have sufficient resource to take development projects forward towards commercialisation.

The Group continues to incur substantial operating expenses. Until the Group generates positive net cash inflows from the commercialisation of its products it remains dependent upon additional funding through the injection of equity capital and government funding. The Group may not be able to generate positive net cash inflows in the future or to attract such additional required funding at all, or on suitable terms. In such circumstances the development programmes may be delayed or cancelled, and business operations cut back.

The Group seeks to reduce this risk by keeping a tight control on expenditure, avoiding long term supplier contracts (other than clinical trials), prioritising development spend on products closest to potential revenue generation, obtaining government grants (where applicable), maintaining a focussed portfolio of products under development and keeping shareholders informed of progress.

There have been no changes to the Group's objectives, policies and processes for managing capital and what the Group manages as capital, unless otherwise stated in this note, since the previous year.

23 Deferred tax

Deferred tax is calculated in full on temporary differences under the liability method using tax rates applicable in the tax jurisdictions where the tax

asset or liability would arise

The movement on the deferred tax account in 2020 is £nil (2019: £nil, 2018: £nil) as the net credit arising on the amortisation of intangible assets and other timing differences has been matched by a reduction in the deferred tax asset recognised on the losses offsetting the liability remaining.

Unused tax losses carried forward, subject to agreement with local tax authorities, were as follows:

	Gross losses £'000	Potential deferred tax asset £'000
31 December 2020	63,183	13,076
31 December 2019	49,565	8,426
31 December 2018	40,741	6,926

During 2020 the remaining deferred tax asset and liability arising on the business combination of Midatech Pharma (Wales) Ltd (2019: £1.6m) was de-recognised as a result of the impairment of the assets through the Consolidated Statements of Comprehensive Income.

The deferred tax asset which qualifies for offset against the deferred tax liability, mainly arising on the acquisitions of Midatech Pharma (Wales) Limited in 2020 is nil (2019: £1.6m, 2018: £1.7m). The remaining potential deferred tax asset of £13.1m (2019 £9.0m, 2018: £7.3m) has not been provided in these accounts due to uncertainty as to whether the asset would be recovered.

Deferred tax asset balances disclosed as at 31 December 2020 have been calculated at 19%. The Finance Bill 2021 enacts an increase in the tax rate to 25% from 1 April 2023. The deferred tax assets balance using a rate of 25% would be £17.2m.

Unrecognised deferred tax asset balances include £0.9m in relation to Midatech Pharma (España) SL, this company was put into liquidation in 2021.

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23 Deferred tax (continued)

Details of the deferred tax liability are as follows:

	Asset £'000	Liability £'000	Net £'000
2020			
Business Combinations	–	–	–
	Asset £'000	Liability £'000	Net £'000
2019			
Business Combinations	1,581	(1,581)	–
	Asset £'000	Liability £'000	Net £'000
2018			
Business Combinations	1,690	(1,690)	–

24 Share capital

Authorised, allotted and

fully paid – classified as equity	2020 Number	2020 £	2019 Number	2019 £	2018 Number	2018 £
At 31 December						
Ordinary shares of £0.001 each	63,073,852	63,074	23,494,981	23,495	3,059,207	3,059
Deferred shares of £1 each	1,000,001	1,000,001	1,000,001	1,000,001	1,000,001	1,000,001
Total		1,063,075		1,023,496		1,003,060

On 2 March 2020 a resolution was passed at a general meeting of shareholders of the Company to consolidate its ordinary shares on a one for 20 basis into new ordinary shares of 0.1p each in the capital of the Company. The above table reflects the share consolidation in the comparative figures.

In accordance with the Articles of Association for the Company adopted on 13 November 2014, the share capital of the Company consists of an unlimited number of ordinary shares of nominal value £0.001 each. Ordinary and deferred shares were recorded as equity.

Rights attaching to the shares following the incorporation of Midatech Pharma plc

Shares classified as equity

The holders of ordinary shares in the capital of the Company have the following rights:

(a) to receive notice of, to attend and to vote at all general meetings of the Company, in which case shareholders shall have one vote for each share of which he is the holder; and,

(b) to receive such dividend as is declared by the Board on each share held.

The holders of deferred shares in the capital of the Company:

(a) shall not be entitled to receive notice of or to attend or speak at any general meeting of the Company or to vote on any resolution to be proposed at any general meeting of the Company; and

(b) shall not be entitled to receive any dividend or other distribution of out of the profits of the Company.

In the event of a distribution of assets, the deferred shareholders shall receive the nominal amount paid up on such share after the holder of each ordinary share shall have received (in cash or specie) the amount paid up or credited as paid up on such ordinary share together with an additional payment of £100 per share. The Company has the authority to purchase the deferred shares and may require the holder of the deferred shares to sell them for a price not exceeding 1p for all the deferred shares.

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24 Share capital (continued)

	Ordinary Shares Number	Deferred Shares Number	Share Price £	Total consideration £'000
At 1 January				
2018	3,054,207	1,000,001		69,870
2018				

1 August 2018	Share issue to SIPP trustee (see note 27)	5,000	0.001	–
At 31 December 2018		3,059,207	1,000,001	69,870
2019				
26 February 2019	Subscription, Placing and Open Offer	17,410,774	0.77	13,406
8 October 2019	Share issue to SIPP trustee (see note 27)	25,000	0.001	–
29 October 2019	Registered Direct Offering	3,000,000	0.7874	2,362
At 31 December 2019		23,494,981	1,000,001	85,638
2020				
18 May 2020	Placing & Registered Direct Offering	15,757,576	0.27	4,255
27 July 2020	Placing	21,296,295	0.27	5,750
19 August 2020	Exercise of warrants	2,500,000		783
30 September 2020	Share issue to SIPP trustee (see note 27)	25,000	0.001	–
At 31 December 2020		63,073,852	1,000,001	96,426

25 Reserves

The following describes the nature and purpose of each reserve within equity:

Reserve	Description and purpose
Share premium	Amount subscribed for share capital in excess of nominal value.
Merger reserve	Represents the difference between the fair value and nominal value of shares issued on the acquisition of subsidiary companies where the Company has elected to take advantage of merger relief.
Foreign exchange reserve	Gains/losses arising on retranslating the net assets of overseas operations into sterling.
Warrant reserve	Represents the fair value of warrants denominated in £ at the date of grant.
Accumulated deficit	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

On 18 May 2020, 6,999,999 warrants were granted as part of the UK placing. Their fair value at the date of grant has been recognised in the Warrant Reserve.

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26 Retirement benefits

The Group operates a defined contribution pension scheme for the benefit of its employees. The assets of the scheme are administered by trustees in funds independent from those of the Group.

27 Share-based payments

Share Options

The Group has issued options over ordinary shares under the 2014 Midatech Pharma plc Enterprise Management Incentive Scheme, the Midatech Pharma plc 2016 U.S. Option Plan, which is a sub-plan of the approved UK plan, and unapproved share options awarded to non-UK or non-US staff. In addition, certain share options originally issued over shares in Midatech Limited under the Midatech Limited 2008 unapproved share option scheme or Midatech Limited 2013 approved Enterprise Incentive scheme were reissued in 2015 over shares in Midatech Pharma plc under the 2014 Midatech Pharma plc Enterprise Management Incentive Scheme. Exercise of an option is subject to continued employment.

On 2 March 2020 a resolution was passed at a general meeting of shareholders of the Company to consolidate its ordinary shares on a one for 20 basis into new ordinary shares of 0.1p each in the capital of the Company. The following tables reflect the share consolidation in the comparative tables.

Details of all share options granted under the Schemes are set out below:

Date of grant	At 1 January 2020	Granted in 2020	Exercised in 2020	Forfeited in 2020	At 31 December 2020	Exercise Price
1 April 2010	1,255	–	–	(1,255)	–	£ 80.00
20 August 2010	2,088	–	–	(2,088)	–	£ 83.80
13 September 2011	150	–	–	–	150	£ 83.80
20 April 2012	1,589	–	–	–	1,589	£ 83.80
9 May 2014	10,000	–	–	–	10,000	£ 1.50
30 June 2014	18,500	–	–	(18,000)	500	£ 1.50
11 July 2014	100	–	–	(100)	–	£ 1.50
31 October 2016	16,271	–	–	(8,350)	7,921	£ 53.60
14 December 2016	400	–	–	(400)	–	£ 31.00
14 December 2016	500	–	–	(500)	–	£ 34.00
14 December 2016	2,000	–	–	(2,000)	–	£ 37.40
14 December 2016	1,625	–	–	(1,625)	–	£ 37.60
15 December 2016	4,600	–	–	(4,600)	–	£ 24.20
19 December 2016	22,391	–	–	(12,373)	10,018	£ 24.20

15 December 2017	29,560	—	—	(26,260)	3,300	£	9.20
2 April 2018	997	—	—	(997)	—	£	16.60
2 April 2018	4,500	—	—	(4,500)	—	£	24.20
24 April 2019	169,500	—	—	(124,000)	45,500	£	1.46
2 October 2019	50,000	—	—	(20,000)	30,000	£	1.05
17 April 2020	—	100,000	—	—	100,000	£	0.24
17 June 2020	—	1,363,000	—	(89,000)	1,274,000	£	0.202
	336,026	1,463,000	—	(316,048)	1,482,978		

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27 Share-based payments (continued)

Options exercisable at 31 December 2020	195,171
Weighted average exercise price of outstanding options at 31 December 2020	£ 0.835
Weighted average exercise price of options exercised in 2020	n/a
Weighted average exercise price of options forfeited in 2020	£ 7.192
Weighted average exercise price of options granted in 2020	£ 0.205
Weighted average remaining contractual life of outstanding options at 31 December 2020	9.2

Date of grant	At 1 January 2019	Granted in 2019	Exercised in 2019	Forfeited in 2019	At 31 December 2019	Exercise Price
1 April 2010	1,255	—	—	—	1,255	£ 80.00
20 August 2010	2,088	—	—	—	2,088	£ 83.80
13 September 2011	150	—	—	—	150	£ 83.80
20 April 2012	1,589	—	—	—	1,589	£ 83.80
9 May 2014	10,000	—	—	—	10,000	£ 1.50
30 June 2014	21,500	—	—	(3,000)	18,500	£ 1.50
11 July 2014	100	—	—	—	100	£ 1.50
31 October 2016	2,500	—	—	(2,500)	—	£ 34.20
31 October 2016	23,411	—	—	(7,140)	16,271	£ 53.60
14 December 2016	400	—	—	—	400	£ 31.00
14 December 2016	500	—	—	—	500	£ 34.00
14 December 2016	2,000	—	—	—	2,000	£ 37.40
14 December 2016	1,625	—	—	—	1,625	£ 37.60
15 December 2016	4,600	—	—	—	4,600	£ 24.20
19 December 2016	35,866	—	—	(13,475)	22,391	£ 24.20
15 December 2017	45,885	—	—	(16,325)	29,560	£ 9.20
2 April 2018	997	—	—	—	997	£ 16.60
2 April 2018	4,500	—	—	—	4,500	£ 24.20
24 April 2019	—	219,000	—	(49,500)	169,500	£ 1.46
2 October 2019	—	50,000	—	—	50,000	£ 1.05
	158,966	269,000	—	(91,940)	336,026	

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27 Share-based payments (continued)

Options exercisable at 31 December 2019	131,094
Weighted average exercise price of outstanding options at 31 December 2019	£ 8.48
Weighted average exercise price of options exercised in 2019	n/a
Weighted average exercise price of options forfeited in 2019	£ 13.26
Weighted average exercise price of options granted in 2019	£ 1.38
Weighted average remaining contractual life of outstanding options at 31 December 2019	7.9 years

Date of grant	At 1 January 2018	Granted in 2018	Exercised in 2018	Forfeited in 2018	At 31 December 2018	Exercise Price
31 December 2008	1,306	—	—	(1,306)	—	£ 28.50
31 December 2008	150	—	—	(150)	—	£ 79.70
1 April 2010	1,255	—	—	—	1,255	£ 80.00
20 August 2010	2,088	—	—	—	2,088	£ 83.80
13 September 2011	150	—	—	—	150	£ 83.80
20 April 2012	1,789	—	—	(200)	1,589	£ 83.80
9 May 2014	10,000	—	—	—	10,000	£ 1.50
30 June 2014	44,000	—	—	(22,500)	21,500	£ 1.50
11 July 2014	100	—	—	—	100	£ 1.50
31 October 2016	2,500	—	—	—	2,500	£ 34.20
31 October 2016	30,380	—	—	(6,969)	23,411	£ 53.60
14 December 2016	400	—	—	—	400	£ 31.00
14 December 2016	500	—	—	—	500	£ 34.00
14 December 2016	2,000	—	—	—	2,000	£ 37.40

14 December 2016	2,000	—	—	(375)	1,625	£	37.60
15 December 2016	5,100	—	—	(500)	4,600	£	24.20
19 December 2016	55,210	—	—	(19,344)	35,866	£	24.20
15 December 2017	67,560	—	—	(21,675)	45,885	£	9.20
2 April 2018	—	997	—	—	997	£	16.60
2 April 2018	—	4,500	—	—	4,500	£	24.20
	226,488	5,497	—	(73,019)	158,966		

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27 Share-based payments (continued)

Options exercisable at 31 December 2018	112,393
Weighted average exercise price of outstanding options at 31 December 2018	£ 22.02
Weighted average exercise price of options exercised in 2018	n/a
Weighted average exercise price of options forfeited in 2018	£ 15.98
Weighted average exercise price of options granted in 2018	£ 16.60
Weighted average remaining contractual life of outstanding options at 31 December 2018	5.7 years

The following information is relevant in the determination of the fair value of options granted during the year 2020 under the equity share based remuneration schemes operated by the Group.

	April 2020	June 2020
Number of options	100,000	1,363,000
Option pricing models used	Black-Scholes	Black-Scholes
Share price	£ 0.24*	£ 0.213*
Exercise price of options issued in year	£ 0.24	£ 0.202
Contractual life	10 years	10 years
Expected life	5 years	5 years
Volatility	84.76%**	92.55%**
Expected dividend yield	0%	0%
Risk free rate	0.11%	0.10%

* The share price used in the determination of the fair value of the options granted in 2020 was the share price on the date of grant.

** Volatility was calculated with reference to the historic share price volatility of comparable companies measured over a five-year period.

The following information is relevant in the determination of the fair value of options granted during the year 2019 under the equity share based remuneration schemes operated by the Group.

	April 2019	October 2019
Number of options	219,000	50,000
Option pricing models used	Black-Scholes	Black-Scholes
Share price	£ 2.30*	£ 1.126*
Exercise price of options issued in year	£ 1.46	£ 1.05
Contractual life	10 years	10 years
Expected life	5 years	5 years
Volatility	75.3%**	78.3%**
Expected dividend yield	0%	0%
Risk free rate	0.85%	0.26%

* The share price used in the determination of the fair value of the options granted in 2019 was the share price on the date of grant.

** Volatility was calculated with reference to the historic share price volatility of comparable companies measured over a five-year period.

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27 Share-based payments (continued)

The following information is relevant in the determination of the fair value of options granted during the year 2018 under the equity share based remuneration schemes operated by the Group.

	2018
Number of options	5,500
Option pricing models used	Monte-Carlo
Share price	£ 5.40*
Exercise price of options issued in year	£16.60–£24.40
Contractual life	10 years
Expected life	5 years
Volatility	45.2%**
Expected dividend yield	0%
Risk free rate	1.03%

* The share price used in the determination of the fair value of the options granted in 2018 was the share price on the date of grant.

** Volatility was calculated with reference to the historic share price volatility of comparable companies measured over a five-year period.

All other share options relate to the Midatech Limited 2008 unapproved share option scheme.

Share Incentive Plan

In April 2017 the Group set up the Midatech Pharma Share Incentive Plan (MPSIP). Under the MPSIP, Group employees and Directors can acquire ordinary shares in the Company via a salary sacrifice arrangement. Midatech grants matching shares for every share bought. In order to retain these shares, scheme participants must remain employed by the Group for three years from the date of acquisition. All shares purchased by the MPSIP are held by an Employee Benefit Trust that is not under the control of Midatech. Shares must be left in the plan for 5 years to qualify for full income tax and NIC relief.

28 Capital commitments

The Group had no capital commitments at 31 December 2020, 31 December 2019 and 31 December 2018.

29 Related party transactions

Details of Directors' remuneration are given in the Company's Annual Report on Form 20-F for the year ended 31 December 2020 and note 6.

Trading Transactions

The Directors consider BioConnection BV to be a related party by virtue of the fact that there is a common Director with the Company. 2019 was the first year where this relationship existed.

During the year Group companies entered into the following transactions with related parties who are not members of the Group.

	Purchase of good			Amounts owed by related parties		
	2020	2019	2018	2020	2019	2018
	€'000	€'000	€'000	€'000	€'000	€'000
BioConnection BV	296	18	—	—	8	—

During 2019 Midatech Pharma (España) SL entered into a commercial contract with BioConnection BV in connection with the Group's MTD201 program, this contract was subsequently terminated in 2020 as a result of the termination of the program.

The Group has not made any allowances for bad or doubtful debts in respect of related party debtors nor has any guarantee been given or received during 2020, 2019 or 18 regarding related party transactions.

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30 Contingent liabilities

As at 31 December 2019 the Group was party to a claim by the estate of a former employee for unfair dismissal. The claim comprised various elements totalling €258,000. During the year the case was settled by the Group for €190,000. This has been recognised in Administrative costs in the Consolidated Statement of Comprehensive Income.

The Group had no contingent liabilities at 31 December 2020 and 31 December 2018.

31 Ultimate controlling party

The Directors do not consider that there is an ultimate controlling party.

32 Results of Midatech Pharma (España) SL

Included within the Group Consolidated Statements of Comprehensive Income are the results of the Group's Spanish operation that was closed on 3 June 2020. The Group appointed a liquidator to liquidate the company with documentation being submitted to the Spanish Authorities in February 2021.

Management assessed whether Midatech Pharma (España) SL should be accounted for as a discontinued operation under IFRS 5 and concluded that it did not meet the criteria as it did not meet the definition of a cash generating unit, as the activity of the company was the same as the remaining operations of the Group.

The unaudited results of Midatech Pharma (España) SL for the year to 31 December 2020 are as follows:

	Year ended 31 December 2020 £'000
Grant revenue	163
Total revenue	163
Research and development costs	(2,820)
Administrative costs	(1,146)
Loss from operations	(3,803)
Finance expense	(11)
Loss before tax	(3,814)
Taxation	(21)
Loss from operations after tax	(3,835)

33 Post balance sheet events

In February 2021 the Group received a fine of €149,835 from the Spanish Tax Authorities in relation to the late repayment of a Government loan in 2020 as a result of the closure of its operation in Spain. The Group consider the fine is without foundation and are currently appealing the fine. The directors note that in the event of an unfavourable outcome the Group would not be able to recoup the loss from another party. This liability has been recognised in the Statement of Financial Position and the related expenses in Administrative costs in the Income Statement.

On January 26, 2021, the Company announced that it was engaged in tentative discussions with a third party around the potential co-development of MTX110. On March 25, 2021, the Company announced these discussions had now advanced and a non-binding Heads of Terms had been agreed. The Heads of Terms envisage that, if the deal progresses to definitive agreements, the Company would expect to receive a modest upfront payment upon execution, success-based development and sales milestones and royalties typical for a licensing agreement with products in a similar stage of development. R&D expenses would be assumed by the two parties with the apportionment to be agreed based on their respective territories. There can be no assurance on the timing for concluding the discussions nor any assurance that the parties will enter into definitive agreements.

On 23 April 2021 the Group signed an agreement for lease on new premises in Cardiff to house our corporate offices and laboratories. The new premises comprises 8,118 square feet and is for a 5 year term.

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