THIS PROSPECTUS IS IMPORTANT AND REQUIRES YOUR IMMEDIATE ATTENTION. If you are in any doubt about the contents of this prospectus or the action you should take, you are recommended to seek your own financial advice immediately from an appropriately authorised stockbroker, bank manager, solicitor, accountant or other independent financial adviser who, if you are taking advice in the United Kingdom ("**UK**"), is duly authorised under the Financial Services and Markets Act 2000 ("**FSMA**").

If you have sold or otherwise transferred all of your registered holding of ordinary shares of nominal value 3 pence each (each, an "**Ordinary Share**") in the capital of Tiziana Life Sciences plc (the "**Company**" or "**Tiziana**"), please forward this prospectus at once to the purchaser or transferee or to the bank, stockbroker or other agent through whom or by whom the sale or transfer was made, for delivery to the purchaser or transferee. However, this prospectus and any accompanying documents should not be sent or transmitted in, or into, any jurisdiction where to do so might constitute a violation of local securities law or regulations. If you have sold only part of your holding of Ordinary Shares, please contact the bank, stockbroker or other agent through whom or by whom the sale or transfer was made immediately.

This prospectus comprises a prospectus relating to the Company prepared in accordance with the prospectus regulation rules of the Financial Conduct Authority (the "**FCA**") made under section 73A of FSMA (the "**Prospectus Regulation Rules**") and approved by the FCA as competent authority under Regulation (EU) 2017/1129 (the "**Prospectus Regulation**"). The FCA only approves this prospectus as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval shall not be considered an endorsement of the quality of the securities that are the subject of this prospectus. Investors should make their own assessment as to the suitability of investing in the securities.

This prospectus has been filed with the FCA and made available to the public in accordance with Rule 3.2 of the Prospectus Regulation Rules.

The Company's entire issued share capital comprising the Ordinary Shares (the "**Existing Issued Share Capital**") as at the date of this prospectus is admitted to trading on the AIM market of London Stock Exchange plc (the "**London Stock Exchange**").

Applications will be made for the Company's entire issued share capital comprising in aggregate 194,612,289 existing Ordinary Shares (the "**Existing Ordinary Shares**"), of which 67,127,894 Ordinary Shares are represented by American Depositary Shares ("**ADSs**") and traded on NASDAQ, to be admitted to a Standard Listing on the Official List and to trading on the Main Market of the London Stock Exchange (together, "**Admission**"). It is expected that Admission will become effective, and that unconditional dealings in the Ordinary Shares will commence, at 8.00 a.m. on 21 January 2021.

The whole of the text of this prospectus should be read by prospective investors. Your attention is specifically drawn to the discussion of certain risks and other factors that should be considered in connection with an investment in the Ordinary Shares, as set out in Part II – *Risk Factors* of this prospectus.

The Company and the directors, whose names appear on page 46 of this prospectus (the "**Directors**"), accept responsibility for the information contained in this prospectus. To the best of the knowledge of the Directors and the Company, the information contained in this prospectus is in accordance with the facts and this prospectus makes no omission likely to affect its import.

Tiziana Life Sciences plc

(Incorporated in England and Wales with registered number 03508592)

Admission of the Issued Share Capital to the Official List
(by way of a Standard Listing under Chapter 14 of the Listing Rules)
and to trading on the main market for listed securities of the London Stock Exchange

Sole Broker and Co-ordinator

Optiva Securities Limited ("**Optiva**"), which is authorised and regulated by the FCA, is acting solely for the Company and no-one else in connection with Admission and will not regard any other person (whether or not a recipient of this prospectus) as a client in relation to Admission and will not be responsible to anyone other than the Company for providing the protections afforded to its clients or for providing advice in relation to Admission or any other matter referred to herein. Optiva has not authorised the contents of, or any part of, this prospectus and no liability whatsoever is accepted by Optiva nor does it make any representation or warranty, express or implied, for the accuracy or completeness of any information or opinion contained in this prospectus or for the omission of any information. Nothing in this prospectus shall be relied upon as a promise or representation in this respect, whether as to the past or the future (without limiting the statutory rights of any person to whom this prospectus is issued). Optiva expressly disclaims all and any responsibility or liability, whether arising in tort, contract or otherwise which it might otherwise have in respect of this prospectus.

A copy of this prospectus is available, subject to certain restrictions relating to persons resident in any Restricted Jurisdiction (as defined below), at the Company's website at https://ir.tizianalifesciences.com/. Neither the content of the Company's website nor any website accessible by hyperlinks to the Company's website is incorporated in, or forms part of, this prospectus.

The Ordinary Shares comprising the Existing Issued Share Capital rank *pari passu* in all respects. No new Ordinary Shares are being issued in connection with Admission.

This prospectus does not constitute an offer to sell or an invitation to purchase or subscribe for, or the solicitation of an offer or invitation to purchase or subscribe for, Ordinary Shares in any jurisdiction where such an offer or solicitation is unlawful or would impose any unfulfilled registration, publication or approval requirements on the Company.

The distribution of this prospectus in or into jurisdictions other than the UK may be restricted by law and therefore persons into whose possession this prospectus comes should inform themselves about and observe any such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

Notice to overseas shareholders

The ADSs have been the subject of the filing of limited registration statements with the United States Securities and Exchange Commission (the "**SEC**"). No other Ordinary Shares have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (the "**U.S. Securities Act**"). The Ordinary Shares may not be offered or sold in the United States, except to qualified institutional buyers ("**QIBs**"), as defined in, and in reliance on, the exemption from the registration requirements of the U.S. Securities Act provided in Rule 144A under the U.S. Securities Act ("**Rule 144A**") or another exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act. Outside of the United States, the Admission is being made in offshore transactions as defined in Regulation S of the U.S. Securities Act. No actions have been taken to allow a public offering of the Ordinary Shares under the applicable securities laws of any jurisdiction, including Australia, Canada, Japan or South Africa. Subject to certain exceptions, the Ordinary Shares may not be, offered, sold, resold, transferred or distributed, directly or indirectly, within, into or in the United States or to or for the account or benefit of persons in the United States, Australia, Canada, Japan, South Africa or any other jurisdiction where such offer or sale would violate the relevant securities laws of such jurisdiction (a "**Restricted Jurisdiction**"). This prospectus does not constitute an offer of, or the solicitation of an offer to subscribe for or purchase any of the Ordinary Shares to any person in any Restricted Jurisdiction. The Ordinary Shares have not been recommended by any U.S. federal or state securities commission or regulatory authority. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this prospectus. Any representation to the contrary is a criminal offence in the United States.

No action has been taken or will be taken to permit the possession or distribution of this prospectus (or any other offering or publicity materials relating to the Ordinary Shares) in any Restricted Jurisdiction. Accordingly, neither this prospectus, nor any advertisement, nor any other offering material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. Persons into whose possession this prospectus comes should inform themselves about and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of the securities laws of any such jurisdiction. In particular, no actions have been or will be taken to permit a public offering of the Ordinary Shares under the applicable securities laws of any Restricted Jurisdiction. For a description of these and certain further restrictions on the offer, subscription, sale and transfer of the Ordinary Shares and distribution of this prospectus, please see *Part III — Important Information* of this prospectus.

Available information for investors in the United States

For so long as any of the Ordinary Shares are in issue and are "restricted securities" within the meaning of Rule 144(a)(3) under the U.S. Securities Act, the Company will, during any period in which it is not subject to section 13 or 15(d) under the U.S. Securities Exchange Act of 1934, as amended (the "**U.S. Exchange Act**"), nor exempt from reporting under the U.S. Exchange Act pursuant to Rule 12g3-2(b) thereunder, make available to any holder or beneficial owner of an Ordinary Share, or to any prospective purchaser of an Ordinary Share designated by such holder or beneficial owner, the information specified in, and meeting the requirements of, Rule 144A(d)(4) under the U.S. Securities Act.

A Standard Listing will afford investors in the Company a lower level of regulatory protection than that afforded to investors in companies with listings on the premium segment of the Official List ("**Premium Listing**") which are subject to additional obligations under the Listing Rules.

PART I

SUMMARY

This summary is made up of four sections and contains all the sections required to be included in a summary for this type of securities and issuer.

Even though a sub-section may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the sub-section. In this case, a short description of the sub-section is included in the summary with the mention of "not applicable".

INTRODUCTION AND WARNINGS	
Name and ISIN of the securities.	The securities are the Ordinary Shares, which have the ISIN GB00BKWNZY55
Identity and contact details of the issuer	The issuer is Tiziana Life Sciences plc, and its registered address is at 3RD Floor, 11-12 St James's Square, London SW1Y 4LB, United Kingdom and telephone number is +44 20 7495 2379. The Company's LEI is 213800CED47HI8PIOB36.
Identity and contact details of the offeror	The Company is the person asking for admission to trading of the Ordinary Shares on the Main Market, which is a regulated market.
Date of approval of the prospectus	The prospectus was approved on 18 December 2020.
Identity and contact details of the competent authority approving the prospectus	The competent authority approving the prospectus is the FCA. The FCA's registered address is at 12 Endeavour Square, London E20 1JN, United Kingdom and telephone number is +44 20 7066 1000.
Warnings	This summary should be read as an introduction to the prospectus. Any decision to invest in the Ordinary Shares should be based on consideration of the prospectus as a whole. An investor could lose all or part of the invested capital. Where a claim relating to the information contained in the prospectus is brought before a court, the plaintiff investor might, under national law, have to bear the costs of translating the prospectus before legal proceedings are initiated. Civil liability attaches only to those persons who have tabled this summary including any translation thereof, but only where the summary is misleading, inaccurate or inconsistent, when read together with the other parts of the prospectus, or where it does not provide, when read together with the other parts of the prospectus, key information in order to aid investors when considering whether to invest in such securities.
KEY INFORMATION ON THE ISSUER	
Who is the issuer of the securities?	
Domicile and legal form	The Company was incorporated in England and Wales on 11 February 1998 as a private company with limited liability under the Companies Act 2006 (the "**Companies Act**") with an indefinite life, and re-registered as a public limited company on 8 June 1998. The Company's name was ultimately changed to Tiziana Life Sciences plc in 24 April 2014. The Company's LEI is 213800CED47HI8PIOB36.
Principal activities	The Company's mission is to design and deliver next generation therapeutics for oncology and immune diseases of high unmet medical needs, by combining its expertise in disease biology and clinical development. The Company's lead immunotherapeutic candidate, Foralumab (TZLS-401), is being developed for Crohn's disease, Pro-MS and autoimmune diseases. The Directors believe that Foralumab is the only fully human anti-CD3 monoclonal antibody under clinical development and is expected to minimize adverse immune responses in patients. Tiziana has recently submitted a patent application on potential use of Foralumab, to improve success of chimeric antigen receptor T cells (CAR-T) therapy for cancer and other human diseases. The patent application covers inventions related to improving CAR-T expansion and/or survival. The Company is accelerating development and cGMP manufacturing of Anti-IL-6r (TZLS-501) monoclonal antibody for treatment of COVID-19 and other autoimmune disease. The Company's lead product candidate in oncology, Milciclib (TZLS-201), is an orally bioavailable, small molecule, broad spectrum inhibitor of cyclin-dependent kinases (CDKs), a family of highly conserved enzymes that regulate the cell cycle and cell division, and Src family kinases, involved in regulating cell growth and potential transformation of normal cells to cancer cells. The Company's product pipeline also included a pre-clinical candidate: StemPrintER™, a multi-gene signature diagnostic assay to identify patients at high risk for breast cancer. StemPrintER shows superiority to Oncotype Dx in predicting recurrence in ER+/HER2- postmenopausal breast cancer patients.

	On 29 May 2020 Tiziana announced the spin out of StemPrintER and SPARE (together "**StemPrintER**") into a separate company (the "**Demerger**"). The Demerger became effective on 30 October 2020. The Company employs a lean and virtual research and development model using highly experienced teams of experts for each business function to maximize value accretion by focusing resources on the drug discovery and development processes.
Major shareholders	Each of the following persons, directly or indirectly, has an interest in the Company's capital or voting rights which is notifiable under English law:

Name	Number of Existing Ordinary Shares held as at the date of this prospectus and as at Admission	Percentage of the Existing Issued Share Capital held as at the date of this prospectus and as at Admission
Planwise Group Limited	63,297,647	32.53%
Empory Asset Master, Ltd	10,153,770	5.22%
Laura Fonda	7,971,966	4.10%
Morris Silverman	7,994,457	4.08%
Harold Freedberg	6,296,221	3.24%

Key managing directors	Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer
Statutory auditors	Mazars LLP
What is the key financial information regarding the issuer?	
Selection of historical key financial information	Set out below are details of the significant changes in the financial position of the Company during, and subsequent to, the period ended 30 June 2020. • on 24 July 2020, the Company raised £82,379 in cash through the exercise of warrants; • on 31 July 2020 – the Company announced that during the calendar month of July, it had issued a total of 2,043,000 ordinary shares under the Company's ATM sales agreement (announced on 15 April 2020) to meet sales of a total of 408,600 ADSs under the ATM sales agreement, totalling gross proceeds of $4,371,289; • on 5 August 2020, the Company announced the closing of its registered direct offering of ADSs on the NASDAQ Global Market. As of 3 August 2020, the Company issued 11,009,615 ADSs (representing 22,019,230 new ordinary shares of nominal value £0.03 each in the capital of the Company at a price of $5.20 per ADS raising gross proceeds of approximately $57.25 million (before deducting placement agent fees and offering expenses); • on 27 August 2020, the Company, raised £300,000 in cash through the exercise of warrants; • on 21 September 2020, the Company allotted 281,250 Ordinary Shares, credited as fully paid at a price of £1.28 per share in respect of agreements reached with certain members of the scientific advisory board concerning the commuting of cash fees into equity; • on 16 September 2020, the Company entered into the Demerger Agreement with Accustem Sciences Limited pursuant to the terms of which the Tiziana declared a dividend in specie on the Ordinary Shares equal to the book value (of approximately £3.07m) of Tiziana's shareholding in StemPrintER Sciences Limited, the entity within the Group which holds all of the assets and intellectual property relating to StemPrintER and SPARE and £1.0 million in cash; • on 2 October 2020, resolutions were passed by Shareholders to approve the Demerger and to reduce the amount standing to the share premium account of the Company by £4,000,000 to facilitate the Demerger (the "**Capital Reduction**"). The Court sanctioned the Capital Reduction on 27 October 2020 and the Demerger became effective on 30 October 2020; • on 20 October 2020, the Company issued 35,714 Ordinary Shares credited as fully paid on the exercise of certain warrants held by the Company's broker, Optiva; • on 21 October 2020, the Company issued 1,750,000 Ordinary Shares of which 1,200,000 Ordinary Shares were issued credited as fully paid at a price of £0.15 per share and 550,000 shares were issued credited as fully paid at a price of £0.35 per share, both in respect of the exercise of share options by Gabriele Cerrone; • on 22 October 2020, the Company issued 285,714 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of warrants; • on 26 October 2020, the Company issued 329,225 shares credited as fully paid at a price of £0.35 per share on the exercise of share options held by, inter alia, Gabriele Cerrone and Keeren Shah; • on 28 October 2020, the Company issued 344,063 Ordinary Shares credited as fully paid at prices between £0.66 and £0.80 per share on the exercise of warrants; and • on 29 October 2020, the Company issued 426,500 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of share options by, inter alia, Dr. Kunwar Shailubhai, Vaseem Palejwala and Jules Jacob.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Continuing Operations	6 months to 30 June 2020 (unaudited) £'000	Restated 6 months to 30 June 2019 (unaudited) £'000	12 months to 31 December 2019 (audited) £'000	12 months to 31 December 2018 (audited) £'000	12 months to 31 December 2017 (audited) £'000
Research and development costs	(760)	(1,507)	(2,910)	(4,132)	(4,672)
Operating expenses	(3,169)	(2,138)	(4,864)	(3,268)	(3,574)
Operating loss	(3,929)	(3,645)	(7,774)	(7,400)	(8,246)
Finance costs	(5)	(5)	(9)	(9)	(9)
Loss before taxation	(3,934)	(3,650)	(7,846)	(7,409)	(8,255)
Taxation	—	27	540	(1,459)	1,485
Loss for the year attributable to equity owners	(3,934)	(3,623)	(7,306)	(5,950)	(6,770)
Other comprehensive income that may be classified to profit and loss in subsequent periods					
Exchange differences on translation of foreign operations	23	52	129	(113)	—
Total comprehensive loss for the year attributable to equity owners	(3,911)	(3,571)	(7,177)	(6,063)	(4,770)
Loss per share					
Basic and diluted (loss) per share on continuing operations	(2.6p)	(2.6p)	(5.4p)	(4.7p)	(6.4p)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	6 months to 30 June 2020 (unaudited) £'000	Restated 6 months to 30 June 2019 (unaudited) £'000	12 months to 31 December 2019 (audited) £'000	12 months to 31 December 2018 (audited) £'000	12 months to 31 December 2017 (audited) £'000
ASSETS					
Non-Current assets					
Property, plant and equipment	5	5	5	6	18
Finance lease receivables	236	—	113	—	—
Right of use asset	308	358	329	—	—
Other non-current assets	217	217	217	217	217
Total non-current assets	766	580	664	223	235
Current assets					
Finance lease receivable	—	—	109	—	—
Related party receivable	—	—	245	20	20
Other receivables	2,013	245	124	228	94
Taxation receivable	513	827	513	800	1,434
Cash and cash equivalents	7,200	445	153	4,165	48
Total current assets	9,726	1,517	1,144	5,213	1,596
TOTAL ASSETS	10,492	2,097	1,808	5,436	1,831
EQUITY AND LIABILITIES					
Equity					
Capital and reserves attributable to equity holders of the company					
Called up share capital	4,992	4,094	4,099	4,094	3,752
Share premium	38,390	25,120	25,194	25,117	18,113
Capital reduction reserve	31,183	31,183	31,183	31,183	31,183
Shares to be issued reserve (convertible notes)	1,265	1,398	1,099	1,399	1,076
Share based payment reserve (options)	4,806	3,021	3,850	2,857	2,354
Share based payment reserve (warrants)	—	—	1,812	—	—
Other reserve	(28,286)	(28,286)	(28,286)	(28,286)	(28,286)
Translation reserve	(90)	(61)	15	(113)	—
Retained earnings	(47,318)	(39,463)	(43,146)	(35,840)	(29,874)
Total equity	4,942	(2,994)	4,180	411	(1,683)
Liabilities					
Non-Current liabilities					
Lease Liability	308	277	411	—	—
Current liabilities					
Trade and other payables	4,597	4,727	4,851	4,673	3,270
Lease liability	322	87	212	—	—
Related party payable	323	—	451	352	244
Other liabilities	—	—	63	—	—
Total current and non-current labilities	5,550	5,091	5,988	5,025	3514
TOTAL EQUITY AND LIABILITIES	10,492	2,097	1,808	5,436	1,831

CONSOLIDATED STATEMENTS OF CASH FLOWS

	6 months to 30 June 2020 (unaudited) £'000	Restated 6 months to 30 June 2019 (unaudited) £'000	12 months to 31 December 2019 (audited) £'000	12 months to 31 December 2018 (audited) £'000	12 months to 31 December 2017 (audited) £'000
Cash flows from operating activities					
Total comprehensive loss for the period before tax	**(3,934)**	**(3,650)**	**(7,846)**	**(7,454)**	**(8,255)**
Convertible loan interest	215	5	39	9	9
Loan interest paid as equity	—	—	—	16	—
Loss on disposal of right of use asset	—	—	56	—	—
Amortisation of right of use asset	21	—	—	—	—
Shares issued in lieu of fees	—	—	82	41	—
Share based payment – options	979	164	992	504	419
Issue of share capital (Loan Conversion)	(190)	—	—	—	—
Cancellation of options	(23)	—	—	—	(105)
Share based payment – warrants	310	—	—	128	228
Net (increase) / decrease in operating assets – Trade/other receivables	(1,894)	3	(100)	(135)	40
Net increase / (decrease) in operating liabilities – Trade/other liabilities	(445)	(307)	325	1,592	1,790
Depreciation	2	7	198	12	11
Loss on foreign exchange	(105)	56	129	(222)	35
Lease adjustment	—	—	—	3	(24)
Net Cash used in operating activities	**(5,068)**	**(3,722)**	**(6,125)**	**(5,506)**	**(5,852)**
Cash inflow from taxation	—	—	800	2,093	—
Net cash used in operating activities	**(5,064)**	**(3,722)**	**(5,325)**	**(3,413)**	**(5,852)**
Cash flow from financing activities					
Proceeds from issuance of ordinary shares	10,899	2	—	7,437	1,198
Proceedings from issuance of warrants	1,940	—	1,473	1,132	—
Proceeds from issuance of options	91	—	—	—	—
Cost of fundraising	(824)	—	—	(1,039)	—
Repayment of leasing liabilities	7	—	(157)	—	—
Net cash generated from financing activities	**12,133**	**2**	**1,316**	**7,530**	**1,198**
Cash flows from investing activities					
Acquisition of property, plant and equipment	(2)	—	(3)	—	(1)
Acquisition of other investments	—	—	—	—	—
Net cash generated from investing activities	**(2)**	**—**	**(3)**	**—**	**(1)**
Net increase / (decrease) in cash and cash equivalents	**7,047**	**(3,720)**	**(4,102)**	**4,117**	**(4,655)**
Cash and cash equivalents at beginning of period	153	4,165	4,165	48	4,703
Cash and cash equivalents at end of period	**7,200**	**455**	**153**	**4,165**	**48**

The unaudited interim financial statements of the Company for the six months ended 30 June 2020 express concern that until and unless the Group secures sufficient investment to fund their clinical trials, there is a material uncertainty about the Group's ability to continue as a going concern. However, these financial statements pre-date the Company raising approximately $57.25 million through the direct offering of ADSs on the NASDAQ Global Market. All the proceeds from the fundraising have been received by the Company. The Directors expect that the Group has sufficient resources to fund its activities (including all clinical trials and programmes and operating expenditure) and execute its strategy for at least the next 24 months.

Selected key *pro forma* financial information	Not applicable. No *pro forma* financial information is included in this prospectus.
Brief description of any qualifications in the audit report	Not applicable. There are no qualifications in the accountant's report relating to the historical financial information.

What are the key risks that are specific to the issuer?	
Brief description of the most material risk factors specific to the issuer contained in the prospectus	• The Company is a clinical stage biotechnology company with a limited operating history and has no regulatory-approved products authorised for marketing and commercialisation. Its lead product candidates, Foralumab and Milciclib, are at varying stages of development. It is possible that the Company may never have a product that is commercially successful. • The Company's public accounting firm has expressed substantial doubt about the Company's ability to continue as a going concern, which may hinder the Company's ability to obtain future financing. • The unaudited interim financial statements of the Company for the six months ended 30 June 2020 express concern that until and unless the Group secures sufficient investment to fund their clinical trials, there is a material uncertainty about the Group's ability to continue as a going concern. However, these financial statements pre-date the Company raising approximately $57.25 million through the direct offering of ADSs on the NASDAQ Global Market. All the proceeds from the fundraising have been received by the Company. The Directors expect that the Group has sufficient resources to fund its activities (including all clinical trials and programmes and operating expenditure) and execute its strategy for at least the next 24 months. • Since the Company's inception in May 2013, the Company has incurred significant net losses. The Company has devoted substantially all of its efforts to research and development of its future product candidates, including clinical development of Foralumab and Milciclib, as well as to building out the Company's management team and infrastructure. The Company expects that its expenses and operating losses will continue to increase, particularly as it continues the R&D of, initiates further clinical trials of and seeks marketing approval for, its product candidates. It could be several years, if ever, before the Company has a commercialised product candidate. • The Company may need substantial additional funding to complete the development of its product candidates, which may not be available on acceptable terms. Failure to obtain this necessary capital when needed may force the Company to delay, limit or terminate certain of its product development, research operations or future commercialisation efforts. • The Company's current product candidates are being developed to treat oncology and immune diseases of high unmet medical need. If these products, once approved for commercialisation, do not achieve an adequate level of acceptance, or if the market opportunities for these products is smaller than the Company anticipates, the Company may not generate significant product revenue and may not become profitable. Even if some product candidates achieve market acceptance, the market may not prove to be large enough to generate significant revenues. • Before obtaining marketing approval from regulatory authorities for the sale of the Company's product candidates, the Company must conduct extensive clinical trials to demonstrate the safety and utility of the product candidates. Clinical testing is a time-consuming, expensive and uncertain process that takes years to complete, and the Company may never generate the necessary data or results required to obtain marketing approval and achieve product sales. • Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of the Company's product candidates. The Company cannot predict when, or if, the Company will obtain regulatory approval to commercialise its product candidates that have completed clinical trials, and the approval may be for a narrower indication than the Company seeks, and the Company's approved products will remain subject to regulatory oversight. • The Company's rights to develop and commercialise the Company's product candidates are subject to the terms and conditions of licenses granted to the Company by others. For example, licenses and sublicenses from Nerviano, Lonza and Novimmune to certain patent rights and proprietary technology are crucial to the development of the Company's technology and product candidates, including the patents and know-how relating to manufacture. If the Company fails to comply with its obligations under its intellectual property licenses with third parties, the Company could lose license rights that are important to its business. • Further, these licenses may not provide exclusive rights to use such intellectual property and technology or may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which the Company may wish to develop or commercialise its technology and product candidates. As a result, the Company may not be able to prevent competitors from developing and commercialising competitive products, including in territories covered by the Company's licenses. • The Company relies on enrolling patients in its clinical trials and other third parties to conduct its clinical trials and manufacture and test its products. The Company's reliance on these third parties subjects the Company to delays, disruptions, control oversight risk, contractual relationship risk, supply issues and regulatory oversight risk. • The Company does not have a marketing and sales force. If the Company cannot establish effective sales, marketing and distribution capabilities or enter into agreements with third parties to market, sell and distribute its approved products, the Company may not be successful in commercialising its approved products, materially reducing the Company's ability to generate product revenue.

	• The Company faces significant competition in an environment of rapid technological change and the possibility that the Company's competitors may achieve regulatory approval before the Company does, obtain more favourable regulatory approvals, or develop more advanced or effective therapies. • If the Company is unable to obtain and maintain patent protection for its product candidates and its technology, protect its intellectual property rights, or if the scope of its patent protection is not sufficiently broad, the Company's competitors could develop and commercialise similar products and technology that could impair the Company's profitability or revenue generation. • The Company may not be successful in its efforts to identify or discover new, additional product candidates and may fail to capitalise on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources, and the Company may fail to identify other potential product candidates for clinical development.
KEY INFORMATION ON THE SECURITIES	
What are the main features of the securities?	
Type, class and ISIN	The shares are Ordinary Shares with a nominal value of 3 pence each in the capital of the Company. Applications will be made for the Ordinary Shares to be admitted to the Official List with a Standard Listing and to trading on the main market for listed securities of the London Stock Exchange. The Ordinary Shares are registered with ISIN GB00BKWNZY55, SEDOL code BKWNZYZ5 and TIDM TILS.
Currency, denomination, par value, and the term of the securities	UK Pounds Sterling with nominal value of 3 pence each. 194,612,289 Ordinary Shares have been issued at the date of this prospectus (the "**Existing Ordinary Shares**"), all of which have been fully paid up. The term of the securities is perpetual.
Rights attached to the securities	Shareholders have the right to receive notice of and to attend and vote at any meetings of Shareholders. Each Shareholder entitled to attend and being present in person or by proxy at a meeting will, upon a show of hands, have one vote and upon a poll each such Shareholder present in person or by proxy will have one vote for each Ordinary Share held by such Shareholder. If two or more persons hold an Ordinary Share jointly, the vote of the senior who tenders a vote whether in person or by proxy, shall be accepted to the exclusion of the other joint holders. Pre-emption rights have been disapplied pursuant to the special resolutions passed at the annual general meeting of the Company held on 16 July 2020 (the "**2019 AGM**"). Subject to the Companies Act, on a winding-up of the Company the assets available for distribution shall be distributed, provided there are sufficient assets available, first to the holders of Ordinary Shares in an amount up to 1 pence per share in respect of each fully paid up Ordinary Share. If, following these distributions to holders of Ordinary Shares there are any assets of the Company still available, they shall be distributed to the holders of Ordinary Shares *pro rata* to the number of such fully paid up Ordinary Shares held (by each holder as the case may be) relative to the total number of issued and fully paid up Ordinary Shares.
Relative seniority of the securities in the issuer's capital structure in the event of insolvency	Not applicable. The Company does not have any other securities in issue or liens over its assets and so the Ordinary Shares are not subordinated in the Company's capital structure as at the date of this prospectus and will not be immediately following Admission.
Restrictions on the free transferability of the securities	Not applicable. The Ordinary Shares are freely transferable and tradable and there are no restrictions on transfer. Each Shareholder may transfer all or any of their Ordinary Shares which are in certificated form by means of an instrument of transfer in any usual form or in any other form which the Directors may approve. Each Shareholder may transfer all or any of their Ordinary Shares which are in uncertificated form by means of a 'relevant system' (i.e., the CREST System) in such manner provided for, and subject as provided in, the Uncertificated Securities Regulations 2001 (*SI 2001 No. 3755*) (the "**CREST Regulations**").
Dividend or pay-out policy	The Company's current intention is to retain any earnings for use in its business operations, and the Company does not anticipate declaring any dividends until the Company is generating significant revenue.
Where will the securities be traded?	
Application for admission to trading	Upon publication of this prospectus the AIM trading facility for the Existing Issued Share Capital will be cancelled, and applications will be made for the admission of the Existing Issued Share Capital to a Standard Listing on the Official List and to trading on the Main Market of the London Stock Exchange. It is expected that Admission will become effective and that unconditional dealings will commence on the Main Market of the London Stock Exchange at 8.00 a.m. on 21 January 2021. The Ordinary Shares will not be listed on any other regulated market. ADSs (each representing two Ordinary Shares will continue to be traded on the NASDAQ Capital Market segment under the symbol TLSA.

Identity of other markets where the securities are or are to be traded	The Company is seeking admission to trading of the Ordinary Shares on the Main Market. The Ordinary Shares are currently admitted to trading on AIM American Depositary Shares, each representing 2 Ordinary Shares, are listed for trading on the Nasdaq Global Market.
	What are the key risks specific to the securities?
Brief description of the most material risk factors specific to the securities contained in the prospectus	The Company has outstanding warrants and options. These convertible instruments will have a material dilutive effect on Shareholders when and if they are exercised. If all outstanding warrants and options were exercised, the 18,207,169 Ordinary Shares to be issued would represent 8.6 per cent. of the total Existing Issued Share Capital (as so enlarged) of the Company.
KEY INFORMATION ON THE OFFER OF SECURITIES TO THE PUBLIC AND/OR THE ADMISSION TO TRADING ON THE LONDON STOCK EXCHANGE	
	Under which conditions and timetable can I invest in this security?
General terms and conditions	Not applicable
Expected timetable of the offer	**Publication of this prospectus** **18 December 2020** Cancellation of the AIM trading facility 7:00 a.m. on 21 January 2021 Admission and commencement of dealings in Ordinary Shares 8:00 a.m. on 21 January 2021
Details of admission to trading on a regulated market	Application will be made for the Ordinary Shares to be admitted to a Standard Listing on the Official List and to trading on the Main Market of the London Stock Exchange. It is expected that Admission will become effective and that dealings in Ordinary Shares will commence at 8:00 a.m. on 21 January 2020.
Plan for distribution	Not applicable. There will be no offering or distribution of the Ordinary Shares in connection with Admission.
Amount and percentage of immediate dilution resulting from the offer	Not applicable. There will be no offering or distribution of the Ordinary Shares in connection with Admission.
Estimate of total expenses of the issue and/or offer	The expenses of Admission will be borne by the Company in full. These expenses (including listing and admission fees, printing, and professional advisory fees, including legal fees, and any other applicable expenses) are not expected to exceed £175,000.
	Why is this prospectus being produced?
Reasons for the offer or for the admission to trading on a regulated market	This prospectus is being produced solely in connection with the admission of the Issued Share Capital to a Standard Listing on the Official List and to trading on the Main Market of the London Stock Exchange. In 2018, the Company joined NASDAQ and much of the Company's activities are now carried on in the USA. The Company sees itself as an international issuer and that it is now the time to move from AIM to the Main Market as a natural development in its corporate evolution.
Use and estimated net amount of the proceeds	Not applicable.
Indication of whether the offer is subject to an underwriting agreement	Not applicable.
Indication of the most material conflicts of interests relating to the offer or admission to trading	Not applicable.

PART II

RISK FACTORS

Investment in the Company and the Ordinary Shares carries a significant degree of risk, including risks in relation to the Company's business strategy, risks relating to taxation and risks relating to the Ordinary Shares.

Prospective investors should note that the risks relating to the Company, its industry and the Ordinary Shares summarised in Part I – *Summary* of this prospectus are the risks that the Directors believe to be the most essential to an assessment by a prospective investor of whether to consider an investment in the Ordinary Shares. However, as the risks which the Company faces relate to events and depend on circumstances that may or may not occur in the future, prospective investors should consider not only the information on the key risks summarised in Part I – *Summary* of this prospectus but also, *inter alia*, the risks and uncertainties described below.

The risks referred to below are those risks the Company and the Directors consider to be the material risks relating to the Company. However, there may be additional risks that the Company and the Directors do not currently consider to be material or of which the Company and the Directors are not currently aware that may adversely affect the Company's business, financial condition, results of operations or prospects. Investors should review this prospectus carefully and in its entirety and consult with their professional advisers before acquiring any Ordinary Shares. If any of the risks referred to in this prospectus were to occur, the results of operations, financial condition and prospects of the Company could be materially adversely affected. If that were to be the case, the trading price of the Ordinary Shares and/or the level of dividends or distributions (if any) received from the Ordinary Shares could decline significantly. Further, investors could lose all or part of their investment.

PART A. RISKS RELATED TO THE DEVELOPMENT OF THE COMPANY'S PRODUCT CANDIDATES

If the Company encounters substantial delays in clinical trials of its product candidates, or fails to demonstrate the safety and therapeutic utility of its product candidates to the satisfaction of applicable regulatory authorities, the Company may be unable to obtain required regulatory approvals, and therefore will be unable to commercialise its product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of the Company's product candidates, the Company must conduct extensive clinical trials to demonstrate the safety and utility of the product candidates. Clinical testing is expensive, time-consuming and uncertain as to outcome. The Company cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, as a failure of one or more clinical trials can occur at any stage of testing.

Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with the U.S. Food and Drug Administration ("**FDA**"), European Medicines Agency ("**EMA**"), or other regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organisations ("**CROs**") and clinical trial sites;
- delays in execution of development due to financial instability of the Company's CROs or contract manufacturing organisations ("**CMOs**");
- delays in opening clinical trial sites or obtaining required institutional review board or independent ethics committee approval at each clinical trial site;
- delays in recruiting suitable patients to participate in the Company's future clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of the Company's clinical trial operations or clinical trial sites;
- failure by the Company, any CROs or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with good clinical practice ("**cGCP**") or applicable regulatory guidelines;
- delays in the testing, validation, manufacturing and delivery of the Company's product candidates to the clinical trial sites;
- delays in having patients complete participation in a clinical trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a clinical trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical and clinical development, such as registrational trial or future pivotal trials failing to demonstrate therapeutic utility of its product candidates or revealing safety concerns or serious adverse events associated with the its product candidates, could result in additional costs or impair the Company's ability to generate revenues from product sales, regulatory and commercialisation milestones and royalties. Specifically, the Company may:

- be delayed in obtaining marketing approval for the Company's product candidates, if at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labelling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy ("**REMS**");
- be subject to the addition of labelling statements, such as warnings or contraindications; or
- be sued or experience damage to the Company's reputation.

In addition, if the Company makes manufacturing or formulation changes to its product candidates, the Company may need to conduct additional studies to bridge the Company's modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which the Company may have the exclusive right to commercialise the Company's product candidates or allow the Company's competitors to bring products to market before the Company do, which could impair the Company's ability to successfully commercialise the Company's product candidates and may harm the Company's business, financial condition, results of operations and prospects.

Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of the Company's product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. To date, some of the Company's clinical trials have involved small patient populations and because of the small sample size in such trials, the interim results of these clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, there is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Moreover, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the Company may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of the Company's product candidate development. Any such delays could negatively impact the Company's business, financial condition, results of operations and prospects.

The Company depends on enrolling patients in the Company's clinical trials for its product candidates. If delays continue for a material period of time, they could materially adversely affect the Company's R&D efforts and business, financial condition and results of operations.

Identifying and qualifying patients to participate in clinical trials of the Company's product candidates is critical to the Company's success. The timing of the Company's clinical trials depends on the Company's ability to recruit patients to participate, and to see those patients through the completion of required follow-up periods. If, for any reason, patients are unwilling or unable to enrol in the Company's clinical trials, then the timeline for recruiting patients, conducting studies and obtaining regulatory approvals for the Company's product candidates may be delayed. These delays could result in increased costs, delays in advancing the Company's product candidates, delays in testing the effectiveness of the Company's product candidates or termination of clinical trials altogether. For example, the COVID-19 pandemic has delayed enrolment in the Company's clinical trials, which were already delayed due to related government orders and site policies, and some patients may

be unwilling or unable to travel to study sites, enrol in the Company's trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

The Company's current product candidates are being developed to treat oncology and immune diseases of high unmet medical need. However, the Company may not be able to initiate or continue clinical trials if the Company cannot enrol a sufficient number of eligible patients to participate in the required clinical trials. As a result, the Company may not be able to identify, recruit and enrol a sufficient number of patients, or those with required or desired characteristics, to complete the Company's clinical trials in a timely manner. In addition to COVID-19 related delays, patient enrolment can be affected by many other factors, including:

- size of the patient population and process for identifying patients;
- eligibility and exclusion criteria for the Company's clinical trials;
- perceived risks and benefits of the Company's product candidates;
- severity of the disease under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- competition with other clinical trials for product candidates competing in the same therapeutic areas as the Company's product candidates;
- ability to obtain and maintain patient consent;
- patient drop-outs prior to completion of clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

The Company's ability to successfully initiate, enrol and complete clinical trials in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- absence in some countries of established groups with sufficient regulatory expertise for review of certain treatment protocols;
- inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If the Company has difficulty enrolling a sufficient number of patients or finding additional clinical trial sites to conduct the Company's clinical trials as planned, the Company may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have an adverse effect on the Company's business, financial condition, results of operations and prospects.

The Company's product candidates and the process for administering the Company's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. For Milciclib, the most frequent drug-related side effects reported across studies, at all doses tested, were gastrointestinal ("**GI**"), adverse events (nausea and diarrhoea, followed by less frequent vomiting), neurological effects (mainly tremor, then ataxia, dizziness and dysgeusia), skin disorders and asthenia, fatigue, headache and anorexia. For Foralumab, the most frequent drug-related side effects reported following intravenous administration were infusion related reactions ("**IRR**"), including fever, headaches, chills, nausea, vomiting diarrhoea and hypotension considered the result of cytokine release also known as cytokine release syndrome ("**CRS**"). Other adverse events included

reactivation of Epstein-Barr virus (clinically silent); moderate lymphocytopenia, abnormalities in liver function tests. Since most of these changes are related to the infusion route of administration and dosage level, such systemic toxicities are not anticipated when administered orally or nasally due to what the Company assumes will be minimal systemic absorption.

In addition, it is possible that as the Company tests its product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, patients will report illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that the Company's product candidates cause serious or life-threatening side effects, the development of the Company's product candidates may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm the Company's business, prospects, operating results and financial condition.

If the Company is unable to demonstrate that such adverse events were caused by the administration process or related procedures, the FDA, EMA or other regulatory authorities could order the Company to cease further development of, or deny approval of, the Company's product candidates for any or all targeted indications. Even if the Company were able to demonstrate that any serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the clinical trial. Moreover, if the Company elects or is required to delay, suspend or terminate any clinical trial of any of the Company's product candidates, the commercial prospects of such product candidate may be harmed and the Company's ability to generate product revenues from such product candidate may be delayed or eliminated. Any of these occurrences may harm the Company's ability to develop other product candidates, and may harm the Company's business, financial condition and prospects.

Additionally, if the Company or others later identify undesirable side effects caused by any of the Company's product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- the Company may be required to change the way a product candidate is administered or conduct additional clinical trials;
- the Company could be sued and held liable for harm caused to patients; and
- the Company's reputation may suffer.

Any of these events could prevent the Company from achieving or maintaining market acceptance of its product candidates.

Any contamination in the Company's manufacturing process, shortages of raw materials or failure of any of the Company's key suppliers to deliver necessary components could result in delays in the Company's clinical development or marketing schedules.

Given the nature of biologics and new chemical entity manufacturing, there is a risk of contamination. Any contamination could adversely affect the Company's ability to produce product candidates on schedule and could, therefore, harm the Company's results of operations and cause reputational damage. In addition, some of the raw materials required in the Company's manufacturing process are derived from biologic sources and are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of the Company's product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect the Company's development timelines and the Company's business, financial condition, results of operations and prospects.

PART B. RISKS RELATED TO THE COMPANY'S FINANCIAL POSITION AND NEED FOR CAPITAL

The Company's independent registered public accounting firm has expressed substantial doubt about the Company's ability to continue as a going concern, which may hinder the Company's ability to obtain future financing.

Mazars LLP, the Company's independent registered public accounting firm for the fiscal year ended 31 December 2019, has included an explanatory paragraph in their opinion that accompanies the Company's audited consolidated financial statements as of and for the year ended 31 December 2019, indicating that the Company's current liquidity position raises substantial doubt about the Company's ability to continue as a going concern. If the Company were unable to improve its liquidity position, the Company may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if the Company were unable to continue as a going concern and, therefore, be required to realise its assets and discharge its liabilities other than in the normal course of business.

However, the Company is currently able to continue as a going concern and there is sufficient working capital available to the Group for the Group's present requirements for at least 12 months from the date of this prospectus. In August 2020, the Company raised approximately $57.25 million through the direct offering of ADSs on the NASDAQ Global Market. All the proceeds from the fundraising have been received by the Company. The Directors expect that the Group has sufficient resources to fund its activities (including all clinical trials and programmes and operating expenditure) and execute its strategy for at least the next 24 months. The Directors do not expect that further funds will have to be raised following Admission within the 12 months from the date of this prospectus.

If the Company is unable to continue as a going concern it may enter into administration, receivership or other insolvency process, which may cause investors to suffer the loss of all or a substantial portion of their investment in the Company.

The Company's financial statements have previously disclosed concern about the Company's ability to continue as a going concern.

The unaudited interim financial statements of the Company for the six months ended 30 June 2020 express concern that until and unless the Group secures sufficient investment to fund their clinical trials, there is a material uncertainty about the Group's ability to continue as a going concern. The Company also notes that the Company incurred losses during the year and has net liabilities at the year end. The Company is in the early stages of developing its business focusing on the discovery and development of novel molecules that treat human disease in oncology and immunology. The Directors expect the Company to incur further losses and to require significant capital expenditure in continuing to develop clinical stage development therapeutic candidates in both oncology and immunology. The Company has successfully funded clinical trials to date and in August 2020 secured approximately $57.25 million additional investment for purposes of continuing to fund their clinical trials moving forward. All the proceeds from the fundraising have been received by the Company.

The Directors have prepared cash flow projections that include the costs associated with the continued clinical trials and additional investment to fund that operation. On the basis of those projections, the Directors expect that following the financing in August 2020, the Group has sufficient resources to fund its activities (including all clinical trials and programmes and operating expenditure) and execute its strategy for at least the next 24 months.

The Company has incurred net losses in every year since its inception. The Company anticipates that it will continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

The Company is a clinical stage biotechnology company with a limited operating history. Since the Company's inception in May 2013, the Company has incurred significant net losses. The Company's net losses were $9.3 million, $8.0 million and $8.6 million for the years ended 31 December 2019, 2018 and 2017, respectively. As of 31 December 2019, the Company had an accumulated loss of $60.0 million. The Company has devoted substantially all of its efforts to research and development of its product candidates, including clinical development of its lead product candidates, Foralumab

and Milciclib, as well as to building out the Company's management team and infrastructure. The Company expects that it could be several years, if ever, before it has a commercialised product candidate. The Company expects to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact the Company's shareholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

The Company anticipates that its expenses will increase substantially if, and as, the Company:

- continues research and development of Foralumab, including the initiation of the Company's orally administered Phase 2 trials in patients with Crohn's disease and progressive multiple sclerosis (MS);
- initiates a Phase 2b trial for Milciclib in combination with a tyrosine kinase inhibitor (sorafenib or regorafenib) in HCC patients;
- accelerates development and cGMP manufacturing of anti-IL6R mAb for treatment of COVID-19 and multiple myeloma and initiate clinical trials and preclinical studies for any additional product candidates that the Company may pursue in the future;
- manufactures its product candidates in accordance with current GMPs for clinical trials or potential commercial sales;
- establishes a sales, marketing and distribution infrastructure to commercialise any product candidate for which it may obtain marketing approval;
- develops, maintains, expands and protects its intellectual property portfolio;
- identifies, assesses, and acquires or in-licenses other product candidates and technologies;
- secures, maintains or obtains freedom to operate for any in-licensed technologies and products;
- addresses any competing technological and market developments; and
- expands its operations in the United States and Europe.

The Company may never succeed in any or all of these activities and, even if it does, the Company may never generate revenues that are significant or large enough to achieve profitability. If the Company does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company's failure to become and remain profitable would decrease its value and could impair the Company's ability to raise capital, maintain its R&D efforts, expand its business or continue its operations.

The Company needs substantial additional funding to complete the development of its product candidates, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force the Company to delay, limit or terminate certain of its product development, research operations or future commercialisation efforts, if any.

The Company's operations have consumed substantial amounts of cash since inception, and the Company expects its expenses to increase in connection with its ongoing activities, particularly as it continues the R&D of, initiates further clinical trials of and seeks marketing approval for, its product candidates. In addition, if the Company obtains marketing approval for its product candidates, the Company expects to incur significant expenses related to product sales, marketing, manufacturing and distribution. Furthermore, the Company expects to incur additional costs associated with operating as a public company listed on both the Main Market of the London Stock Exchange in the U.K. and NASDAQ in the United States. The Company's future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of laboratory testing, manufacturing, preclinical and clinical development for the Company's current and future product candidates;
- the costs, timing and outcome of regulatory review of the Company's product candidates;
- the extent to which the Company acquires or in-licenses and develops other product candidates and technologies;

- the Company's ability to establish and maintain collaborations and license agreements on favourable terms, if at all;
- the costs, timing and outcome of potential future commercialisation activities, including manufacturing, marketing, sales and distribution for the Company's product candidates for which the Company receives marketing approval;
- the costs of developing, maintaining and enforcing the Company's intellectual property rights and defending intellectual property-related claims; and
- the sales price and availability of adequate third-party coverage and reimbursement for the Company's product candidates, if and when approved.

Developing product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and the Company may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, the Company's product candidates, if approved, may not achieve commercial success. The Company's product revenues, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Further to the raise of approximately $57.25 million through the direct offering of ADSs on the NASDAQ Global Market in August 2020, the Directors expect that the Company will continue to rely on additional financing to achieve its business objectives, which may be inadequate or on unfavourable terms. The Company does not expect to raise further significant finance in the 18 months from the date of this prospectus, however it may take advantage of at-the-market facilities on NASDAQ if opportunistic to do so. Furthermore, the potential economic impact brought by, and the duration of the COVID-19 pandemic is difficult to assess or predict. While the Directors are of the opinion that the working capital available to the Group is sufficient for the Group's present requirements, and that the impact of the COVID-19 pandemic does not pose a risk to the Group's working capital in the 24 months following the date of this prospectus, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital in the future, which could negatively impact the Group's medium-term and long-term liquidity.

If the Company is unable to obtain adequate funding on a timely basis, the Company may be required to significantly curtail, delay or discontinue its R&D programs of its product candidates or any future commercialisation efforts, be unable to expand its operations or be unable to otherwise capitalise on its business opportunities, as desired, which could harm the Company's business and potentially cause a discontinuation of operations.

The Company may be unable to use net operating loss and tax credit carry forwards and certain built-in losses to reduce future tax payments or benefit from favourable United Kingdom ("U.K.") tax legislation.

As a U.K. resident trading entity, the Company is subject to U.K. corporate taxation. Due to the nature of the Company's business, it has generated losses since inception. As of 31 December 2019, the Company had cumulative carryforward tax losses of $27.4 million. Subject to any relevant restrictions, the Company expects these to be available to carry forward and offset against future operating profits. As a company that carries out extensive research and development activities, the Company benefits from the U.K. research and development tax credit regime for small and medium-sized companies, whereby the Company is able to surrender the trading losses that arise from its qualifying research and development activities for a payable tax credit of up to 33.35 per cent. of eligible research and development expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. Certain subcontracted qualifying research expenditures are eligible for a cash rebate of up to 21.67 per cent. The majority of the Company's pipeline research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. The Company's ability to continue to claim payable research and development tax credits in the future may be limited because the Company may no longer qualify as a small or medium-sized company.

The Company may benefit in the future from the U.K.'s "patent box" regime, which allows certain profits attributable to revenues from patented products to be taxed at an effective rate of 10 per cent. The Company is the exclusive licensee or owner of several patent applications which, if issued, would cover the Company's product candidates, and accordingly, future upfront fees,

milestone fees, product revenues and royalties could be taxed at this tax rate. When taken in combination with the enhanced relief available on the Company's research and development expenditures, the Company expects a long-term lower rate of corporation tax to apply. If, however, there are unexpected adverse changes to the U.K. research and development tax credit regime or the "patent box" regime, or for any reason the Company is unable to qualify for such advantageous tax legislation, or the Company is unable to use net operating loss and tax credit, the amount of tax it pays and its results of operations would be adversely affected.

PART C. RISKS RELATED TO THE TRIALS, MANUFACTURING AND TESTING OF ITS PRODUCTS

The Company relies on third parties to conduct its preclinical studies and clinical trials and manufacture and test its products.

The Company relies upon third parties, including independent clinical investigators and third-party CROs, to conduct its preclinical studies and clinical trials and to monitor and manage data for its ongoing preclinical and clinical programs. There are a limited number of qualified third-party service providers that specialise or have the expertise required to achieve the Company's business objectives, and so it may be challenging to find alternative investigators or CROs or do so on commercially reasonable terms. The Company relies on these parties for execution of its preclinical studies and clinical trials. The Company is responsible for ensuring that each of its preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and the Company's reliance on these third parties does not relieve the Company of the Company's regulatory responsibilities; however, the Company controls only certain aspects of their activities. Regulatory authorities enforce their cGCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If any of the Company's CROs fail to comply with applicable cGCP requirements, the clinical data generated in the Company's clinical trials may be deemed unreliable, and the FDA, EMA or other regulatory authorities may require the Company to perform additional clinical trials before approving the Company's marketing applications, which would delay the regulatory approval process. Repeating clinical trials or switching or engaging additional CROs involves additional cost, creates a transition period and requires the Company's management's time and focus, which could materially impact the Company's ability to meet its desired clinical development timelines.

In addition, the Company has engaged CMOs to manufacture Foralumab and Milciclib and to perform quality testing. Because the Company collaborates with various organisations and academic institutions for the advancement of its platforms, the Company must share its proprietary technology and confidential information, including trade secrets, with them. The Company seeks to protect its proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with the Company's collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose the Company's confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by the Company's competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that the Company's proprietary position is based, in part, on the Company's know-how and trade secrets, a competitor's discovery of the Company's proprietary technology and confidential information or other unauthorised use or disclosure of such technology or information would impair its competitive position and may have an adverse effect on the Company's business, financial condition, results of operations and prospects.

In addition to the Company's current CMOs, the Company may rely on additional third parties to manufacture ingredients of the Company's product candidates in the future and to perform quality testing, and reliance on these third parties entails risks to which the Company would not be subject if it manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities, including control over CMOs to maintain adequate quality control, quality assurance and qualified personnel;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to the Company; and
- disruptions to the operations of the Company's third-party manufacturers and service providers caused by conditions unrelated to the Company's business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact the Company's ability to successfully commercialise its product candidates. Some of these events could be the basis for FDA, EMA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

PART D. RISKS RELATED TO COMMERCIALISATION OF THE COMPANY'S PRODUCT CANDIDATES

The Company does not have a marketing and sales force. If the Company cannot establish effective sales, marketing and distribution capabilities or enter into agreements with third parties to market, sell and distribute the Company's product candidates that may be approved, the Company may not be successful in commercialising the Company's product candidates if and when approved, and the Company may be unable to generate any product revenue.

The Company does not have a marketing or sales team for the marketing, sales and distribution of any of its product candidates. The Company intends to build, on a territory-by-territory basis, marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. These efforts will require significant capital expenditures, management resources and time, and the Company faces competition in its search for qualified personnel or third parties to assist with marketing, sales and distribution of its product candidates.

There are risks involved with both establishing the Company's own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which the Company recruits a sales force and establishes marketing and/or distribution capabilities is delayed or does not occur for any reason, the Company would have prematurely or unnecessarily incurred these commercialisation expenses. This may be costly, and the Company's investment would be lost if the Company cannot retain or reposition the Company's sales and marketing personnel.

Factors that may inhibit the Company's efforts to commercialise its product candidates on its own include:

- the Company's inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product that the Company may develop;
- the lack of complementary treatments to be offered by sales personnel, which may put the Company at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organisation.

If the Company enters into arrangements with third parties to perform sales, marketing and distribution services, the Company's product revenue or the profitability to the Company from these revenue streams is likely to be lower than if the Company were to market and sell any product candidates that it develops itself. In addition, the Company may not be successful in entering into arrangements with third parties to sell and market the Company's product candidates or may be unable to do so on favourable terms. The Company likely will have little control over such third parties and any of them may fail to devote the necessary resources and attention to sell and market the Company's product candidates effectively. If the Company does not establish sales and marketing capabilities successfully, either on its own or in collaboration with third parties, the Company may not be successful in commercialising its product candidates.

The Company faces significant competition in an environment of rapid technological change and the possibility that the Company's competitors may achieve regulatory approval before the Company does, obtain more favourable regulatory approvals, or develop more advanced or effective therapies.

The biotechnology and pharmaceutical industries are characterised by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. The Company faces substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render the Company's product candidates obsolete or non-competitive. The Company anticipates that it will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

Many of the Company's potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger R&D, clinical, sales and marketing and manufacturing organisations. These third parties also compete with the Company in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of the Company's products. In addition, mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. The Company's commercial opportunity could be reduced or eliminated if competitors develop and commercialise products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidate that the Company may develop. Competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly or earlier than the Company may obtain its approval, which could result in the Company's competitors establishing a strong market position before the Company can enter the market. Additionally, technologies developed by the Company's competitors may render the Company's product candidates uneconomical or obsolete, and the Company may not be successful in marketing the Company's product candidates against competitors.

If the Company's competitors obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as the Company's product candidates, the Company may not be able to have competing products approved by applicable regulatory authorities for a significant period of time. In addition, even if the Company obtains orphan drug exclusivity for any of its products, such exclusivity may not protect it from competition. Regulatory authorities in the United States and the European Union may designate products for relatively small patient populations as orphan drugs, as further discussed under Part IX – *Regulatory and Operating Environment*. If a competitor receives orphan drug approval before the Company does, it will be precluded from receiving marketing approval for its product for the applicable exclusivity period. If the Company obtains orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Any such limitations on the Company's ability to commercialise its products.

The market opportunities for the Company's product candidates may be smaller than the Company anticipates.

The Company focus its R&D efforts on treatments for cancer and autoimmune disease. The Company's understanding of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with the Company's product candidates, is based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with the Company's product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect the Company's business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive the Company's potential products, if and when approved, less than the potentially addressable market, such as the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

The future commercial success of the Company's product candidates will depend upon the degree of each product candidates' market acceptance by physicians, patients, third-party payors and others in the medical community.

The Company has no product authorised for marketing; its product candidates are at varying stages of development, and the Company may never have a product that is commercially successful. The commercial success of the Company's product candidates will depend, in part, their acceptance by

physicians, patients and third-party payors as medically necessary, cost-effective and safe. If these products do not achieve an adequate level of acceptance, the Company may not generate significant product revenue and may not become profitable. Even if some product candidates achieve market acceptance, the market may not prove to be large enough to generate significant revenues. The degree of market acceptance of the Company's product candidates, if approved for commercial sale, will depend on several factors, including:

- the effectiveness and safety of the Company's product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of the Company's product candidates over alternative treatments;
- the availability and cost of treatment relative to alternative treatments;
- changes in the standard of care for the targeted indications for any product candidate;
- the willingness of physicians to prescribe, and the target patient population to try, new therapies;
- the prevalence and severity of any side effects;
- product labelling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labelling;
- the timing of market introduction of competitive products;
- sales, distribution and marketing support;
- publicity concerning the Company's product candidates or competing products and treatments;
- potential product liability claims;
- any restrictions on the use of the Company's products together with other medications; and
- favourable third-party payor coverage and adequate reimbursement.

Even if a potential product displays favourable clinical properties and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for the Company's approved product candidates could limit the Company's ability to market those products.

The Company expects that coverage and adequate reimbursement by government and private payors will be essential for most patients to be able to afford the Company's approved product candidates. Accordingly, sales of the Company's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of the Company's product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organisations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. For a discussion of the insurance coverage and reimbursement situation for pharmaceutical products in the United States and Europe, see Part IX – *Regulatory and Operating Environment*. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under the Company's health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require the Company to provide to the payor supporting scientific, clinical and cost-effectiveness data. The Company may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not

available, or are available only at limited levels, the Company may not be able to successfully commercialise the Company's product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realise a sufficient return on the Company's investment.

PART E. RISKS RELATED TO THE COMPANY'S INTELLECTUAL PROPERTY

The Company's rights to develop and commercialise the Company's product candidates are subject to the terms and conditions of licenses granted to the Company by others. If the Company fail to comply with its obligations under its existing and any future intellectual property licenses with third parties, the Company could lose license rights that are important to the business.

The Company is heavily reliant upon licenses and sublicenses from Nerviano, Lonza and Novimmune to certain patent rights and proprietary technology that are important or necessary to the development of the Company's technology and product candidates, including the patents and know-how relating to manufacture. These and other licenses may not provide exclusive rights to use such intellectual property and technology or may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which the Company may wish to develop or commercialise its technology and product candidates in the future. As a result, the Company may not be able to prevent competitors from developing and commercialising competitive products, including in territories covered by the Company's licenses.

In some circumstances, the Company may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that the Company license from third parties. If the Company's licensors fail to maintain such patents or patent applications, or lose rights to those patents or patent applications, the rights the Company has licensed may be reduced or eliminated and the Company's right to develop and commercialise any of the Company's product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that the Company license from third parties will also apply to patent rights the Company may own in the future.

Licenses to additional third-party technology and materials that may be required for the Company's development programs, including additional technology and materials owned by any of the Company's current licensors, may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have an adverse effect on the Company's business and financial condition.

If the Company is unable to obtain and maintain patent protection for its product candidates and its technology, or if the scope of its patent protection is not sufficiently broad, the Company's competitors could develop and commercialise similar products and technology.

The Company's success depends, in large part, on its ability to seek, obtain and maintain patent protection in the United States and other countries with respect to its product candidates and to future innovation related to its manufacturing technology. The Company's licensors have sought, and the Company intends to seek, to protect the Company's proprietary position by filing patent applications in the United States, the U.K. and elsewhere, related to certain technologies and the Company's product candidates that are important to its business. The Company's current patent portfolio contains a limited number of patent applications, all of which are in-licensed from third parties and relate to either composition of matter, formulation, method of use or process of manufacturing Foralumab, Milciclib and a fully human anti-interleukin-6 receptor, or IL-6r, mAb. However, the risks associated with patent rights generally apply to patent rights that the Company in-licenses now or in the future, as well as patent rights that the Company may own in the future. Moreover, the risks apply with respect to patent rights and other intellectual property applicable to the Company's product candidates, as well as to any intellectual property rights that the Company may acquire in the future related to future product candidates, if any.

The patent prosecution process is expensive, time-consuming, and complex, and the Company may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office ("**USPTO**") and various government patent agencies outside of the United States over the lifetime of the Company's licensed patents and/or applications and any patent rights the Company may own in the future. Failing to pay required fees could cause patent rights to expire.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the Company's intellectual property rights in some countries outside the United States could be less extensive than those in the United States. The Company may not be able to prevent third parties from practicing the Company's inventions in all countries outside the United States, and competitors may use the Company's technologies in jurisdictions where the Company has not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection, but enforcement is not as strong as that in the United States. These products may compete with the Company's product candidates, and the Company's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In some cases, the work of certain academic researchers in the oncology and immunology fields has entered the public domain, which the Company believes precludes its ability to obtain patent protection for certain inventions relating to such work.

Consequently, the Company will not be able to assert any such patents to prevent others from using its technology for, and developing and marketing competing products to treat, these indications. It is also possible that the Company will fail to identify patentable aspects of its R&D output before it is too late to obtain patent protection.

The Company's existing license agreements impose, and the Company expect that future license agreements will impose, various assignment restrictions, due diligence, development and commercialisation timelines, insurance, milestone payments, royalties, and other obligations, as further discussed under paragraph 16 of Part XIV – *Additional Information*. If the Company fails to comply with its obligations under these agreements, the licensor can terminate the license, preventing the Company from marketing product candidates covered by the license.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. The Company has filed a new patent application covering the composition of matter of Foralumab that remains pending and may not be granted. The Company's licensed patent applications may not result in patents being issued which protect the Company's technology or product candidates, effectively prevent others from commercialising competitive technologies and product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. Even assuming patents issue from patent applications in which the Company has rights, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the Company's patents or narrow the scope of the Company's patent protection.

Other parties have developed technologies that may be related or competitive to the Company's own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in the Company's own patent applications or issued patents. The Company may not be aware of all third-party intellectual property rights potentially relating to the Company's current and future product candidates.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in other jurisdictions are typically not published until 18 months after filing, or, in some cases, not at all. Therefore, the Company cannot know with certainty whether the inventors of its licensed patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Similarly, should the Company own any patents or patent applications in the future, the Company may not be certain that it was the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of the Company's patent rights cannot be predicted with any certainty.

The degree of patent protection the Company requires to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect the Company's rights or permit the Company to gain or keep any competitive advantage. The Company cannot provide any assurances that any of the Company's licensed patents have, or that any of the

Company's pending licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect the Company's product candidates or otherwise provide any competitive advantage. In addition, the laws of foreign countries may not protect the Company's rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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 commercialised. As a result, the Company's licensed patent portfolio may not provide the Company with adequate and continuing patent protection sufficient to exclude others from commercialising products similar to the Company's product candidates, including "highly similar," or biosimilar, versions of such products. In addition, the intellectual property portfolio licensed to the Company by Nerviano and Novimmune may be used by them or licensed to third parties, and such third parties may have certain enforcement rights. Thus, patents licensed to the Company could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against the Company's licensors or another licensee or in administrative proceedings brought by or against the Company's licensors or another licensee in response to such litigation or for other reasons.

Even if the Company acquires patent protection that it expects will maintain some competitive advantage, third parties, including competitors, may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. In litigation, a competitor could claim that the Company's patents, if issued, are not valid for several reasons. If a court agrees, the Company would lose the Company's rights to those challenged patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and the Company's licensed patents may be challenged in courts or patent offices in the United States and abroad. For example, the Company may be subject to a third-party submission of prior art to the USPTO challenging the validity of one or more claims of the Company's licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of the Company's pending licensed patent applications. The Company may become involved in opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings challenging the patent rights of others from whom the Company has obtained licenses to such rights. Competitors may claim that they invented the inventions claimed in the Company's licensed issued patents or patent applications prior to the inventors of such patents or applications. A competitor who can establish an earlier filing or invention date may also claim that the Company are infringing their patents and that the Company therefore cannot practice the Company's technology as claimed under the Company's licensed patents, if issued. Competitors may also contest the Company's licensed patents, if issued, by showing that the invention was not patent-eligible, was not novel, was obvious or that the patent claims failed any other requirement for patentability.

An adverse determination by former employees or consultants asserting ownership rights to the Company's patents may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit its ability to stop others from using or commercialising similar technology and therapeutics, without payment to the Company, or could limit the duration of the patent protection covering its technology and product candidates. Such challenges may also result in the Company's inability to manufacture or commercialise its product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by the Company's patents and patent applications is threatened, it could dissuade companies from collaborating with the Company to license, develop or commercialise current or future product candidates.

Even if they are unchallenged, the Company's licensed patents and pending patent applications, if issued, may not provide the Company with any meaningful protection or prevent competitors from designing around the Company's patent claims to circumvent its licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapeutic that provides benefits similar to one or more of the Company's product candidates but that uses a different antibody or molecular active ingredient that falls outside the scope of the Company's patent protection. If the patent protection provided by the

patents and patent applications the Company holds or pursues with respect its product candidates is not sufficiently broad to impede such competition, the Company's ability to successfully commercialise its product candidates could be negatively affected, which would harm the Company's business.

The Company's intellectual property licenses with third parties may be subject to disagreements over contract interpretation or terminated.

The Company depends on license agreements whereby it obtains rights in certain patents and patent applications owned by third parties. Further development and commercialisation of the Company's product candidates will require the Company to enter into license or collaboration agreements, which are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what the Company believes to be the scope of its rights to the relevant intellectual property or technology, or increase what the Company believes to be its financial or other obligations under the relevant agreement, either of which could have an adverse effect on the Company's business, financial condition, results of operations and prospects.

If any of the Company's licenses or material relationships or any in-licenses upon which the Company's licenses are based are terminated or breached, the Company may:

- lose the Company's rights to develop and market the Company's product candidates;
- lose patent protection for the Company's product candidates;
- experience significant delays in the development or commercialisation of the Company's product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

In addition, a third party may in the future bring claims that the Company's performance under the Company's license agreements, including the Company's sponsoring of clinical trials, interferes with such third party's rights under its agreement with one of the Company's licensors. If any such claim were successful, it may adversely affect the Company's rights and ability to advance the Company's product candidates as clinical candidates or subject the Company to liability for monetary damages, any of which would have an adverse effect on the Company's business, financial condition, results of operations and prospects.

These risks apply to any agreements that the Company may enter into in the future for the Company's current or any future product candidates. If the Company experiences any of the foregoing, it could have a negative impact on the Company's business, financial condition, results or operations and prospects.

The Company's license agreements with Nerviano and Novimmune also require the Company to meet development thresholds to maintain each license, including establishing a set timeline for developing and commercialising product candidates. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which the Company's technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights pursuant to the Company's collaborative development relationships;
- the Company's diligence obligations under the license agreements and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by the Company's licensors and the Company and the Company's partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that the Company has licensed prevent or impair the Company's ability to maintain the Company's current licensing arrangements on acceptable terms, the Company may be unable to successfully develop and commercialise the Company's product candidates.

The Company may not be able to protect its intellectual property rights.

In addition to the protection afforded by patents, the Company relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that the Company elects not to patent, processes for which patents are difficult to enforce and any other elements of the Company's product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and the Company could lose its trade secrets protection. In addition, the Company's trade secrets may otherwise become known or be independently discovered by competitors.

Competitors could purchase the Company's product candidates and attempt to replicate some or all of the competitive advantages the Company derives from the Company's development efforts, wilfully infringe the Company's intellectual property rights, design around the Company's protected technology or develop their own competitive technologies that fall outside of the Company's intellectual property rights. If the Company are unable to successfully protect its intellectual property rights, the Company may have to abandon development of its product candidates and the Company's business, financial condition, results of operations and prospects could suffer and its competitive position could be adversely affected.

Third parties may initiate legal proceedings alleging that the Company infringes their intellectual property rights.

The biotechnology and pharmaceutical industries are characterised by extensive and complex litigation regarding patents and other intellectual property rights. The Company may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to the Company's product candidates and technology, alleging that the Company's therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Given the vast number of patents in the Company's field of technology, the Company cannot be certain or guarantee that the Company do not infringe existing patents or that the Company will not infringe patents that may be granted in the future. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional R&D programs expected in the future. Furthermore, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of the Company's product candidates and the Company may not be aware of such patents. If a patent holder believes the manufacture, use, sale or importation of one of the Company's product candidates infringes its patent, the patent holder may sue the Company even if the Company has licensed other patent protection for the Company's technology. Moreover, the Company may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom the Company's licensed patent portfolio may therefore have no deterrent effect.

Patent litigations, with or without merit, are complex, unpredictable, generally expensive and time-consuming. Any such litigation could substantially increase the Company's operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. If the Company is found or believes there is a risk that it may be found to infringe a third party's patent or intellectual property rights, the Company could be required or may choose to obtain a license from such third party to continue developing, manufacturing and marketing the Company's product candidates and technology. However, the Company may not be able to obtain any required license on commercially reasonable terms or at all. Even if the Company were able to obtain a license, it could be non-exclusive, thereby giving the Company's competitors and other third parties access to the same technologies licensed to the Company, and it could require the Company to make substantial licensing and royalty payments. The Company could be forced, including by court order, to cease developing, manufacturing and commercialising

the infringing technology or product candidate. In addition, the Company could be found liable for monetary damages, including treble damages and attorneys' fees, if the Company is found to have wilfully infringed a patent or other intellectual property right. A finding of infringement could prevent the Company from manufacturing and commercialising the Company's product candidates or force the Company to cease some or all of the Company's business operations, which could harm the Company's business. Claims that the Company has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on the Company's business, financial condition, results of operations and prospects.

PART F. RISKS RELATED TO GOVERNMENT REGULATION

The Company cannot predict when, or if, the Company will obtain regulatory approval to commercialise its product candidates that have completed clinical trials, and the approval may be for a narrower indication than the Company seeks.

The Company cannot commercialise a product candidate that has completed the necessary clinical trials until the appropriate regulatory authorities have reviewed and approved the product candidate. For a discussion of the regulatory review process, see Part IX – *Regulatory and Operating Environment*. Even if the Company's product candidates meet the FDA's safety and effectiveness endpoints in clinical trials, the FDA may not complete their review processes in a timely manner, or the Company may not be able to obtain regulatory approval. The FDA has substantial discretion in the review and approval process and may refuse to file the Company's application for substantive review or may determine after review of the Company's data that the Company's application is insufficient to allow approval of the Company's product candidates. The FDA may require that the Company conduct additional preclinical studies, clinical trials or manufacturing validation studies and submit that data before it will reconsider the Company's application. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, the Company may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to the Company's product candidates.

The FDA, EMA or other regulatory authorities also may approve a product candidate for more limited indications than requested or may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require precautions or contraindications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials. In addition, the FDA, EMA or other regulatory authorities may not approve the labelling claims that are necessary or desirable for the successful commercialisation of the Company's product candidates. Any of the foregoing scenarios could harm the commercial prospects for the Company's product candidates and negatively impact the Company's business, financial condition, results of operations and prospects.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for the Company and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays, and failing to receive regulatory approvals in other major markets would limit the market available to the Company for its products.

Delays in obtaining regulatory approval of the Company's manufacturing process and facility or disruptions in the Company's manufacturing process may delay or disrupt the Company's product development and commercialisation efforts.

The Company does not currently operate manufacturing facilities for clinical or commercial production of its product candidates. Before the Company can begin to commercially manufacture its product candidates, whether in a third-party facility or in its own facility, if and when established, the Company must obtain regulatory approval from the FDA for the Company's manufacturing process and facility. A manufacturing authorisation must also be obtained from the appropriate European Union regulatory authorities and from other applicable foreign regulatory authorities. In order to obtain approval, the Company will need to ensure that its processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of the Company's vendors, contract laboratories or suppliers are found to be non-compliant with cGMP, the Company may experience delays or disruptions in manufacturing while the Company work with these third parties to remedy the violation or while the Company work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, the

Company will be obligated to expend time, money and effort in production, record keeping and quality assurance to confirm that the product meets applicable specifications and other requirements. If the Company fails to comply with these requirements, the Company would be subject to possible regulatory action and may not be permitted to sell any product candidate that the Company may develop.

If the Company or its third-party manufacturers fail to comply with applicable cGMP regulations, regulatory authorities can impose regulatory sanctions, which could include a refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause the Company's business, financial condition, results of operations and prospects to be harmed.

Additionally, the Company's products may be subject to significant disruption due to an interruption in the supply of the Company's products from its third-party manufacturers to the Company, including due to COVID-19 pandemic-related delays to the global supply chain or government measures imposed to address the spread of the virus, or regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions or labour shortages or disputes. The Company does not currently have a backup manufacturer of its product candidate supply for clinical trials or commercial sale. An alternative manufacturer would need to be qualified through a supplement to its regulatory filing, which could result in further delays. The regulatory authorities also may require additional clinical trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and could result in a delay in the Company's desired clinical and commercial timelines.

Even if the Company obtains regulatory approval for a product candidate, the Company's product candidates will remain subject to regulatory oversight.

Even if the Company obtains regulatory approval for its product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that the Company receives for its product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and clinical effectiveness of the product. For a discussion of regulatory oversight, see Part IX – *Regulatory and Operating Environment*.

Any government investigation of alleged violations of law could require the Company to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit the Company's ability to commercialise its product candidates and adversely affect its business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of the EMA and other regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of the Company's product candidates. The Company cannot predict the likelihood, nature or extent of government regulation that may arise from any future legislation or administrative action. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if the Company is not able to maintain regulatory compliance, the Company may lose any marketing approval that it may have obtained and the Company may not achieve or sustain profitability, which would negatively impact the Company's business, financial condition, results of operations and prospects.

The Company's relationships with customers, physicians and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If the Company violates these laws and regulations, it may be required to pay a penalty or be suspended from participation in federal or state healthcare programs, which may adversely affect the Company's business, financial condition and results of operations.

If the Company commercialises its products in the United States, its operations will be directly, or indirectly through the Company's prescribers, customers and purchasers, subject to various federal and state fraud, abuse and patient privacy laws and regulations, which are discussed under Part IX

– *Regulatory and Operating Environment*, that will impact, among other things, the Company's proposed sales, marketing and educational programs. Efforts to ensure that the Company's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. The Company's business activities could be challenged under these laws in part due to their breadth and the narrowness of the statutory exceptions and safe harbours available, the lack of robust interpretation by the regulatory authorities or the courts, and potential for a variety of interpretations, which could lead governmental authorities to conclude that the Company's business practices are not in compliance. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to the Company, the Company may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if the Company becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the Company may be required to curtail or restructure its operations, any of which could adversely affect the Company's ability to operate the Company's business and the Company's results of operations. Any action against the Company for violation of these laws, even if the Company successfully defends against it, could cause the Company to incur significant legal expenses and divert the Company's management's attention from the operation of the Company's business.

PART G. RISKS RELATED TO THE COMPANY'S BUSINESS OPERATIONS

The Company may not be successful in its efforts to identify or discover additional product candidates and may fail to capitalise on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.

The success of the Company's business depends upon the Company's ability to identify, develop and commercialise product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. Although a substantial amount of the Company's efforts will focus on the continued preclinical and clinical testing and potential approval of the Company's product candidates, a key element of the Company's long-term growth strategy is to develop and market additional products and product candidates. However, the Company may fail to identify other potential product candidates for clinical development for several reasons. For example, the Company's research may be unsuccessful in identifying potential product candidates or the Company's potential product candidates may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because the Company has limited resources, the Company may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. The Company's spending on current and future R&D programs may not yield any commercially viable products. If the Company does not accurately evaluate the commercial potential for a particular product candidate, the Company may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for the Company to retain sole development and commercialisation rights to such product candidate. Alternatively, the Company may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

The Company's long-term growth strategy to develop and market additional products and product candidates is heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising pharmaceutical product candidates and products. The Company's business decisions may therefore be adversely influenced by improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by the Company to determine its focus in R&D of product candidates and products could have a material adverse effect on the Company's business, prospects, financial condition and results of operations.

If any of these events occur, the Company may be forced to abandon the Company's development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a negative impact on the Company's business, financial condition, results of operations and prospects.

COVID-19 has adversely affected the Company's business, and any new pandemic, epidemic or outbreak of an infectious disease may further adversely affect its business.

In December 2019, a novel strain of coronavirus, COVID-19, spread globally, substantially impacting the global economy and the Company's operations, including interrupting preclinical and clinical trial activities and disrupting the Company's supply chain. The spread of an infectious disease, including COVID-19, may also result in the inability of the Company's suppliers to source or deliver components or raw materials necessary for its clinical supply on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in the Company's clinical trials, any of which could materially affect the Company's business, financial condition and results of operations. The extent to which COVID-19 impacts the Company's business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. A significant pandemic as with COVID-19, or any other infectious disease, could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact the Company's business, financial condition and results of operations, however the Company's current cash resources are sufficient for its planned activities for at least the 24 month period from

the date of this prospectus and, accordingly, this risk does not have the potential to impact the Company's working capital position in the next 24 months.

Product liability lawsuits against the Company could cause it to incur substantial liabilities and could limit commercialisation of any product candidate that it may develop.

The Company faces an inherent risk of product liability exposure related to the testing of the Company's current and future product candidates in clinical trials and may face an even greater risk if the Company commercialise any product candidate that the Company may develop. For example, the Company may be sued if its current or future product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If the Company cannot successfully defend itself against product liability claims, the Company could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that the Company may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialise any product candidates that the Company may develop; or
- injury to the Company's reputation and significant negative media attention.

Although the Company maintains product liability insurance coverage, such insurance may not be adequate to cover all liabilities that the Company may incur. The Company anticipates that it will need to increase its insurance coverage each time it commences a clinical trial and if it successfully commercialises any product candidate. Insurance coverage is increasingly expensive. The Company may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Legal, political and economic uncertainty surrounding the U.K.'s planned exit from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect the Company's operations in the U.K. and pose additional risks to the Company's business, revenue, financial condition, and results of operations.

Following a national referendum and enactment of legislation by the U.K. government, the U.K. formally withdrew from the European Union on 31 January 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the European Union relating to their future trading relationship. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period. These developments, together with delays in negotiations caused by the COVID-19 pandemic, have created significant uncertainty about the future relationship between the U.K. and the European Union. Lack of clarity about future U.K. laws and regulations, as the U.K. determines which European Union-derived laws and regulations to replace or replicate as part of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could further decrease foreign direct investment in the U.K., increase costs, depress economic activity and restrict the Company's access to capital. These developments, or the perception that any of them could occur, have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Any of these factors could have a significant adverse effect on the Company's business, financial condition, results of operations and prospects.

Further, the U.K.'s withdrawal from the European Union has resulted in the relocation of the EMA from the U.K. to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the U.K. Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorisation or marketing authorisation, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorised formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorisation and commercialisation of products in the European Union and/or the U.K.

PART H. RISKS RELATED TO THE OWNERSHIP OF THE COMPANY'S SHARES

The Company has a number of outstanding warrants and options which, if exercised and/or converted could have a material dilutive effect on existing Shareholders.

The Company has outstanding 1,183,491 warrants over Ordinary Shares and 17,023,678 options over Ordinary Shares. These convertible instruments will have a material dilutive effect on Shareholders when and if they are exercised. If all outstanding warrants and options were exercised, the 18,207,169 Ordinary Shares to be issued would represent 8.6 per cent. of the total Existing Issued Share Capital (as so enlarged) of the Company.

The prices of the Company's ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for the Company's ordinary shareholders.

The market prices of the Company's ordinary shares on the Main Market of the London Stock Exchange may be volatile and fluctuate substantially. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, shareholders may not be able to sell their ordinary shares at or above the price at which they were purchased. The market price for the ordinary shares may be influenced by any of the factors discussed above.

PART III

IMPORTANT INFORMATION

The distribution of this prospectus may be restricted by law in certain jurisdictions and therefore persons into whose possession this prospectus comes should inform themselves about and observe any restrictions, including those set out below. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

General

No action has been or will be taken in any jurisdiction that would permit a public offering of the Ordinary Shares. Neither this prospectus nor any other offering material or advertisement in connection with the Ordinary Shares may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any and all applicable rules and regulations of any such country or jurisdiction. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. This prospectus does not constitute an offer to subscribe for any of the Ordinary Shares to any person in any jurisdiction.

This prospectus has been approved by the FCA as a prospectus which may be used to offer securities to the public for the purposes of section 85 of FSMA, and of the Prospectus Regulation. No arrangement has however been made with the competent authority in any other member states of the European Economic Area ("**EEA Member States**") (or any other jurisdiction) for the use of this prospectus as an approved prospectus in such jurisdiction and accordingly no public offer is to be made in such jurisdiction. Issue or circulation of this prospectus may be prohibited in Restricted Jurisdictions and in countries other than those in relation to which notices are given below.

For the attention of all investors

In deciding whether or not to invest in Ordinary Shares, prospective investors should rely only on the information contained in this prospectus. No person has been authorised to give any information or make any representations other than as contained in this prospectus and, if given or made, such information or representations must not be relied on as having been authorised by the Company, the Directors or Optiva. Without prejudice to the Company's obligations under the FSMA, the Prospectus Regulation Rules, the Listing Rules and the Disclosure Guidance and Transparency Rules, neither the delivery or this prospectus, shall not, under any circumstances, create any implication that there has been no change in the affairs of the Company since the date of this prospectus or that the information in this prospectus is correct as at any time after its date.

In making an investment decision, prospective investors must rely on their own examination of the Company. The contents of this prospectus are not to be construed as advice relating to legal, financial, taxation, accounting, regulatory, investment or any other matter.

Prospective investors must rely upon their own representatives, including their own legal and financial advisers and accountants, as to legal, tax, financial, investment or any other related matters concerning the Company and an investment therein.

An investment in the Company should be regarded as a long-term investment. There can be no assurance that the Company's objectives and acquisition, financing and business strategies will be achieved.

It should be remembered that the price of the Ordinary Shares and any income from such Ordinary Shares can go down as well as up.

This prospectus should be read in its entirety before making any investment in the Ordinary Shares. All Shareholders are entitled to the benefit of, are bound by, and are deemed to have notice of, the provisions of the Company's articles of association, which prospective investors should review.

European Economic Area

Pursuant to the Prospectus Regulation, an offer to the public of the Ordinary Shares may only be made once the prospectus has been passported in an EEA Member State of in accordance with the Prospectus Regulation. For any other EEA Member State an offer to the public in that EEA Member State of any Ordinary Shares may only be made at any time under the following

exemptions under the Prospectus Regulation, if they have been implemented in that EEA Member State:

(a) to any legal entity which is a Qualified Investor, within the meaning of Article 2(e) of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than Qualified Investors, within the meaning of Article 2(e) of the Prospectus Regulation) in such EEA Member State subject to obtaining prior consent of the Company for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Ordinary Shares shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Regulation and each person who initially acquires Ordinary Shares or to whom any offer is made will be deemed to have represented, warranted and agreed with Optiva and the Company that it is a "**Qualified Investor**" within the meaning of Article 2(e) of the Prospectus Regulation.

For the purposes of this provision, the expression an 'offer to the public' in relation to any offer of Ordinary Shares in any EEA Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Ordinary Shares to be offered so as to enable an investor to decide to purchase or subscribe for the Ordinary Shares and the expression "**Prospectus Regulation**" means Regulation (EU) 2017/1129.

This prospectus may not be used for, or in connection with, and does not constitute, any offer of Ordinary Shares or an invitation to purchase or subscribe for any Ordinary Shares in any EEA Member State.

The distribution of this prospectus in other jurisdictions may be restricted by law and therefore persons into whose possession this prospectus comes should inform themselves about and observe any such restrictions.

United Kingdom

This prospectus comprises a prospectus relating to the Company prepared in accordance with the Prospectus Regulation Rules and approved by the FCA under section 87A of FSMA. This prospectus has been filed with the FCA and made available to the public in accordance with Rule 3.2 of the Prospectus Regulation Rules.

There will be no offer to the public of the Ordinary Shares in the United Kingdom. This prospectus has been produced for the sole purpose of the admission of the issued share capital of the Company to the Official List and not for any other purpose.

United States

The Ordinary Shares (other than those Ordinary Shares which underly the ADSs in issue) have not been and will not be registered under the US Securities Act, or the securities laws of any state or other jurisdiction of the United States. Subject to certain exceptions, the Ordinary Shares may not be, offered, sold, resold, transferred or distributed, directly or indirectly, within, into or in the United States or to or for the account or benefit of persons in the United States.

The Ordinary Shares may not be taken up, offered, sold, resold, transferred or distributed, directly or indirectly within, into or in the United States except pursuant to an exemption from, or in a transaction that is not subject to, the registration requirements of the US Securities Act. There will be no public offer in the United States.

The Ordinary Shares have not been approved or disapproved by the US Securities and Exchange Commission, any State securities commission in the United States or any other US regulatory authority, nor have any of the foregoing authorities passed comment upon or endorsed the merits of the Ordinary Shares or adequacy of this prospectus. Any representations to the contrary is a criminal offence in the United States.

Canada

The Ordinary Shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus

Exemptions or subsection 73.3(1) of the Securities Act of 1990 (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the Ordinary Shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), Optiva is not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with the Ordinary Shares.

Australia

This prospectus does not constitute a prospectus or other disclosure document under the Corporations Act 2001 (Cth) ("**Australian Corporations Act**") and does not purport to include the information required of a disclosure document under the Australian Corporations Act. This prospectus has not been, and will not be, lodged with the Australian Securities and Investments Commission (whether as a disclosure document under the Australian Corporations Act or otherwise). Any offer in Australia of the Ordinary Shares under this prospectus or otherwise may only be made to persons who are "sophisticated investors" (within the meaning of section 708(8) of the Australian Corporations Act), to "professional investors" (within the meaning of section 708(11) of the Australian Corporations Act) or otherwise pursuant to one or more exemptions under section 708 of the Australian Corporations Act so that it is lawful to offer the Ordinary Shares in Australia without disclosure to investors under Part 6D.2 of the Australian Corporations Act.

Any offer for on-sale of the Ordinary Shares that is received in Australia within 12 months after their issue by the Company is likely to need prospectus disclosure to investors under Part 6D.2 of the Australian Corporations Act, unless such offer for on-sale in Australia is conducted in reliance on a prospectus disclosure exemption under section 708 of the Australian Corporations Act or otherwise. Any persons acquiring Ordinary Shares should observe such Australian on-sale restrictions.

The Company is not licensed in Australia to provide financial product advice in relation to the Ordinary Shares. Any advice contained in this prospectus is general advice only. This prospectus has been prepared without taking account of any investor's objectives, financial situation or needs, and before making an investment decision on the basis of this prospectus, investors should consider the appropriateness of the information in this prospectus, having regard to their own objectives, financial situation and needs. No cooling off period applies to an acquisition of the Ordinary Shares.

Japan

The Ordinary Shares have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended (the "**FIEA**")). Neither the Ordinary Shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or entity organised under the laws of Japan), or to others for reoffering or resale, directly or indirectly, in Japan or to, or for the benefit of, a resident of Japan except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEA and any other applicable laws, regulations and ministerial guidelines of Japan.

South Africa

This prospectus will not be registered as a prospectus in terms of the Companies Act 1973 in South Africa and as such, any offer of Ordinary Shares in South Africa may only be made if it shall not be capable of being construed as an offer to the public as envisaged by section 144 of such

Act. Furthermore, any offer or sale of the Ordinary Shares shall be subject to compliance with South African exchange control regulations.

General

No action has been or will be taken in any jurisdiction that would permit a public offering of the Ordinary Shares, or possession or distribution of this prospectus or any other offering material, in any country or jurisdiction where action for that purpose is required. Accordingly, the Ordinary Shares may not be offered or sold, directly or indirectly, and neither this prospectus nor any other offering material or advertisement in connection with the Ordinary Shares may be distributed or published in or from any Restricted Jurisdiction.

Persons into whose possession this prospectus comes should inform themselves about and observe any restrictions on the distribution of this prospectus and the offer of Ordinary Shares, including those in the paragraphs above. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. This prospectus does not constitute an offer to subscribe for or purchase any of the Ordinary Shares offered hereby to any person in any Restricted Jurisdiction.

Information to distributors

Solely for the purposes of the product governance requirements contained within: (a) MiFID II; (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; (c) and local implementing measures (together, the "**MiFID II Product Governance Requirements**"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any "manufacturer" (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the Ordinary Shares have been subject to a product approval process, which has determined that such Ordinary Shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "**Target Market Assessment**"). Notwithstanding the Target Market Assessment, distributors should note that: the price of the Ordinary Shares may decline and investors could lose all or part of their investment; the Ordinary Shares offer no guaranteed income and no capital protection; and an investment in the Ordinary Shares is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Ordinary Shares. Furthermore, it is noted that, notwithstanding the Target Market Assessment, Optiva will only procure investors who meet the criteria of professional clients and eligible counterparties.

For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the Ordinary Shares.

Optiva is responsible for undertaking its own target market assessment in respect of the Ordinary Shares and determining appropriate distribution channels.

Rounding

Percentages in tables have been rounded and accordingly may not add up to 100 per cent. Certain financial data have also been rounded. As a result of this rounding, the totals of data presented in this prospectus may vary slightly from the actual arithmetic totals of such data.

Data protection

The Company may delegate certain administrative functions to third parties and will require such third parties to comply with data protection and regulatory requirements of any jurisdiction in which data processing occurs. Such information will be held and processed by the Company (or any third party, functionary or agent appointed by the Company) for the following purposes:

(a) verifying the identity of the prospective investor to comply with statutory and regulatory requirements in relation to anti-money laundering procedures;

(b) carrying out the business of the Company and the administering of interests in the Company;

(c) meeting the legal, regulatory, reporting and/or financial obligations of the Company in the UK or elsewhere; and

(d) disclosing personal data to other functionaries of, or advisers to, the Company to operate and/or administer the Company.

Where appropriate it may be necessary for the Company (or any third party, functionary or agent appointed by the Company) to:

(a) disclose personal data to third party service providers, agents or functionaries appointed by the Company to provide services to prospective investors; and

(b) transfer personal data outside of the European Economic Area to countries or territories which do not offer the same level of protection for the rights and freedoms of prospective investors as the UK.

If the Company (or any third party, functionary or agent appointed by the Company) discloses personal data to such a third party, agent or functionary and/or makes such a transfer of personal data it will use reasonable endeavours to ensure that any third party, agent or functionary to whom the relevant personal data is disclosed or transferred is contractually bound to provide an adequate level of protection in respect of such personal data.

In providing such personal data, investors will be deemed to have agreed to the processing of such personal data in the manner described above. Prospective investors are responsible for informing any third-party individual to whom the personal data relates of the disclosure and use of such data in accordance with these provisions.

Presentation of financial information

Prospective investors should consult their own professional advisers to gain an understanding of the financial information contained in this prospectus. An overview of the basis for presentation of financial information in this prospectus is set out below. Part X – *Selected Historical Financial Information on the Company* of this prospectus presents selected financial information extracted without material adjustment from (i) the unaudited interim historical financial information of the Company for the six months ended 30 June 2019, 30 June 2020, and (ii) the audited historical financial information of the Company for the 12 month periods ended 31 December 2017, 31 December 2018; and 31 December 2019, both of which are incorporated by reference in Part XVI – *Documents Incorporated by Reference* of this prospectus.

The financial and volume information in this prospectus, including in a number of tables, has been rounded to the nearest whole number or the nearest decimal place. The sum of the numbers in a column in a table may not conform exactly to the total figure given for that column. In addition, certain percentages presented in the tables in this prospectus reflect calculations based on the underlying information prior to rounding, and, accordingly, may not conform exactly to the percentages that would be derived if the relevant calculations were based upon the rounded numbers.

Market data

Where information contained in this prospectus has been sourced from a third party, the Company and the Directors confirm that such information has been accurately reproduced and, so far as they are aware and have been able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

CREST

CREST is a paperless settlement procedure enabling securities to be evidenced otherwise than by a certificate and transferred otherwise than by written instrument. The Articles permit the holding of Ordinary Shares under the CREST system. The Ordinary Shares are admitted to CREST and accordingly, settlement of transactions in the Ordinary Shares following Admission may take place within the CREST system if any investor so wishes.

CREST is a voluntary system and Shareholders who wish to receive and retain certificates for their Ordinary Shares will be able to do so. Shareholders may elect to receive Ordinary Shares in uncertificated form if such Shareholder is a system-member (as defined in the CREST Regulations) in relation to CREST.

Transferability

The Ordinary Shares are freely transferable and tradable and there are no restrictions on transfer.

International Financial Reporting Standards

As required by the Companies Act and Article 4 of the European Union ("**EU**") International Accounting Standards Regulation, the financial statements of the Company are prepared in accordance with International Financial Reporting Standards as adopted by the EU ("**IFRS**") issued by the International Accounting Standards Board ("**IASB**") and interpretations issued by the International Financial Reporting Interpretations Committee of the IASB as adopted by the EU.

Incorporation of information by reference

The contents of the Company's website (www.tizianalifesciences.com), unless specifically incorporated by reference, any website mentioned in this prospectus or any website directly or indirectly linked to these websites have not been verified and do not form part of this prospectus, and prospective investors should not rely on them.

Forward-looking statements

This prospectus includes statements that are, or may be deemed to be, 'forward-looking statements'. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms 'targets', 'believes', 'estimates', 'anticipates', 'expects', 'intends', 'may', 'will', 'should' or, in each case, their negative or other variations or comparable terminology. They appear in a number of places throughout the document and include statements regarding the intentions, beliefs or current expectations of the Company and the Board concerning, *inter alia*: (i) the Company's objective, acquisition and financing strategies, results of operations, financial condition, capital resources, prospects, capital appreciation of the Ordinary Shares and dividends; and (ii) future deal flow and implementation of active management strategies. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. The Company's actual performance, results of operations, financial condition, distributions to Shareholders and the development of its financing strategies may differ materially from the forward- looking statements contained in this prospectus. In addition, even if the Company's actual performance, results of operations, financial condition, distributions to Shareholders and the development of its financing strategies are consistent with the forward-looking statements contained in this prospectus, those results or developments may not be indicative of results or developments in subsequent periods.

Prospective investors should carefully review Part II – *Risk Factors* of this prospectus for a discussion of additional factors that could cause the Company's actual results to differ materially, before making an investment decision. For the avoidance of doubt, nothing appearing under the heading "Forward-looking statements" constitutes a qualification of the working capital statement set out in paragraph 10 of Part XIV – *Additional Information* of this prospectus.

Forward looking statements contained in this prospectus apply only as at the date of this prospectus. Subject to any obligations under the Listing Rules, the Market Abuse Regulation (EU 596/2014)(the "**Market Abuse Regulation**"), the Disclosure Guidance and Transparency Rules and the Prospectus Regulation Rules, the Company undertakes no obligation publicly to

update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

Currency

Unless otherwise indicated, all references in this prospectus to:

- "UK Pounds Sterling", "Pounds Sterling", "pound", "pence", "GBP", "£" or "p" is to the lawful currency of the United Kingdom; and
- "US Dollars", "US$", "$" or "cents" is to the lawful currency of the United States.

PART IV

EXPECTED TIMETABLE

Publication of this prospectus	**18 December 2020**
Ordinary Shares cease to be traded on AIM	7.00 a.m. on 21 January 2021
Admission and commencement of dealings in Ordinary Shares	8.00 a.m. on 21 January 2021

All references to time in this prospectus are to London time, unless otherwise stated. Any changes to the expected timetable will be notified by the Company through an RIS.

ADMISSION STATISTICS

Number of Existing Ordinary Shares in issue	194,612,289
Number of warrants in issue prior to and at Admission	1,183,491
Number of options in issue prior to and at Admission	17,023,678
Market capitalisation at Admission [(1)]	£163,474,322.84
Ordinary Shares represented by ADSs as a percentage of Issued Share Capital	34.49%

(1) The market capitalisation of the Company at any given time will depend on the market price of the Ordinary Shares at that time and is based on the mid-market closing price of the Ordinary Shares as traded on AIM on 17 December 2020, being the last practical date prior to the publication of this Prospectus. There can be no assurance that the market price of an Ordinary Share will trade at the same price as they previously traded in AIM.

DEALING CODES

The dealing codes for the Ordinary Shares will be as follows:

ISIN	GB00BKWNZY55
SEDOL code	BKWNZY5
TIDM	TILS
LEI	213800CED47HI8PIOB36

PART V

DIRECTORS, AGENTS AND ADVISERS

Directors	Gabriele Cerrone (*Executive Chairman*) Kunwar Shailubhai PhD (*Executive Director*) Willy Simon (*Non-Executive Director*) John Brancaccio (*Non-Executive Director*)
Registered Office and Company Secretary	Accomplish Secretaries Limited 3rd Floor, 11-12 St James's Square London SW1Y 4LB
Sole Broker and Co-ordinator	Optiva Securities Limited 49 Berkeley Square Mayfair London W1J 5AZ
Auditors and Reporting Accountants	Mazars LLP Tower Bridge House St Katharine's Way London, E1W 1DD
Solicitors to the Company	Orrick Herrington & Sutcliffe (UK) LLP 107 Cheapside London EC2V 6DN
Registrar	Link Market Services 65 Gresham Street London EC2V 7NQ

PART VI

THE COMPANY'S STRATEGY

1. Introduction

Tiziana Life Sciences plc is a biotechnology company that focuses on the discovery and development of novel molecules that treat human disease in oncology and immunology.

Since its incorporation in 1998, the Company strove to generate revenue from Colostrinin, which was initially developed as a pharmaceutical compound to treat Alzheimer's disease. Whilst efficacy had been shown in a number of trials, it became apparent that, as a consequence of its complex nature, Colostrinin could not be characterised and therefore produced to the exacting standards demanded for a pharmaceutical product. As a consequence, the Company set out in 2003 to develop a nutraceutical business based on convincing clinical data. The first licensing deal was signed in 2006 and the product was first marketed in Australia in July 2007, the US in October 2007 and since then in Cyprus, Poland, the UK, Turkey and India. However, sales of the products did not reach the levels anticipated by the Company.

In the period from December 2010 to February 2011, the Company decided that Shareholders' interests would be better served by establishing a different business model. Accordingly, the Company decided to change the business of the Company to that of an investing company. In order to do this the Company demerged its business in respect of Colostrinin into a newly incorporated company with shares in that business being transferred to the then shareholders of the Company. Following the demerger, the Company adopted an investing policy pursuant to which the Company targeted small cap and special opportunities with a bias towards basic resources and oil and gas companies, predominantly on AIM. The Company continued its business as an investing company and sought to identify investments that ultimately increase shareholder value.

On 24 April 2014, the Company acquired Tiziana Pharma Limited ("**TPL**") via a reverse takeover (as defined in the AIM Rules). TPL was formed in November 2013 as a vehicle to acquire and exploit certain intellectual property in biotechnology. The acquisition of TPL had the effect of changing the status of the Company from an investing company under the AIM Rules to an operating company with a material trading activity. Since the acquisition of TPL, the Group's operations have thereafter constituted exclusively those of TPL.

On 22 December 2014, the Company in-licensed the molecule Foralumab, the only fully human engineered anti-human CD3 antibody in clinical development, from Novimmune SA. Foralumab targets the CD3 epsilon (CD3ε) receptor, which is a recognised approach for modulating T-Cell response and achieving immunosuppression. Foralumab is a Phase 2 asset with potential application in a wide range of autoimmune and inflammatory disease, such as multiple sclerosis, type-1 diabetes, inflammatory bowel disease, psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

On 20 January 2015, the Company in-licensed Milciclib from Nerviano Medical Sciences. The compound blocks the action of a specific set of enzymes known as cyclin-dependent kinases (CDKs), which are involved in the process of cell division, as well as a number of other protein kinases. Milciclib has an unusual kinase inhibitory profile making it active against other receptors such as, tyrosine kinase, src family and splicing kinases. Milciclib completed phase2 clinical trials for thymic carcinoma in patients previously treated with chemotherapy and has orphan drug designation for this indication is US and EU.

To date, Milciclib has been studied in a total of eight Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumour action.

The Company initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in Sorafenib-resistant patients with HCC in the first half of 2017.

The Phase 2a trial was completed in June 2019 with clinical safety and efficacy result reported in July 2019. A Phase 1 dose-escalation study of Milciclib in combination with gemcitabine in patients with refractory solid tumors exhibited clinical activity in patients including those refractory to gemcitabine. We plan to explore a combination drug treatment approach in patients with HCC.

TZLS-501 (formerly NI-1201), a fully human anti-interleukin-6 receptor (anti-IL6R) monoclonal antibody (mAb) was acquired from Novimmune, a Swiss biotechnology company, in 2017. In March 2020, the Company announced that it is expediting development of TZLS-501for treatment of inflammation and lung damage in patients infected with coronavirus COVID-19 (SARS-CoV-2). The Company plans to administer TZLS-501 as an aerosol directly to the site of inflammation using a nebulizer or metered inhaler.

In April 2020 the Company acquired all intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D; a.k.a. Dactinomycin), from Rasna Therapeutics, Inc. ("**Rasna**") to expand its pipeline.

Act D, an antibiotic drug, approved initially for infectious diseases in the United States in 1964. Subsequently, this antibiotic was shown to exhibit anti-cancer activity in 1974. Since then the drug has been used to treat various types of cancer. Since Act D is a potent inhibitor of RNA synthesis, may have potential for treatment of COVID-19 patients either alone or in combination with TZLS-501 inhalation treatment.

2. Company strategy

Objectives

The Company is a dual-listed clinical stage biotechnology company that specializes in the developing transformative therapies for autoimmune and inflammatory diseases, degenerative diseases and cancer related to the liver. The Company's clinical pipeline includes drug assets for Crohn's Disease, COVID-19 and Progressive Multiple Sclerosis and Hepatocellular Carcinoma. The Company is led by a team of highly qualified executives with extensive drug development and commercialization experience.

Mission

The Company's mission is to bring breakthrough therapies with the aim of treating Crohn's Disease, COVID-19, Pro-MS and HCC and optimizing health outcomes.

Vision

The Company envisions becoming a leader in advancing innovative, best-in-class medicines for patients with life threatening diseases.

Foralumab mAb

Foralumab is a fully human anti-CD3 monoclonal antibody (mAb) that the Company is using for the treatment of Crohn' sdisease, neurodegenerative diseases and treatment of COVID-19-induced inflammation. The Company has recently completed two Phase 1 clinical trials: one for progressive MS indication with nasal administration and the other for Crohn's disease indication, with enteric coated capsules administered orally. Clinical protocol for Phase 2 nasal clinical trial for progressive MS indication is finalized. The briefing package and protocol were submitted to FDA on 22 July 2020 requesting type C meeting and FDA response expected by mid-October, 2020. The trial is anticipated to begin in Q4 2020. Additionally, the Company plans to evaluate the use of foralumab to treat lung inflammation in COVID-19 patients in an investigator initiated trial in Brazil in Q4 2020. Foralumab has demonstrated ability to activate regulatory T cells that systemically circulate to elicit targeted immunomodulation providing therapeutic benefit to patients.

The Company has recently submitted a patent application on potential use of Foralumab, to improve success of chimeric antigen receptor T cells (CAR-T) therapy for cancer and other human diseases. The patent application covers inventions related to improving CAR-T expansion and/or survival. Foralumab administered alone or co-administered in combination with co-stimulatory molecules, such as an anti-IL-6 receptor monoclonal antibody, an anti-CD28 monoclonal antibody or specific inhibitors of signaling pathways of phosphatidylinositol 3-kinase (PI3K), protein kinase B (AKT), or mammalian target to improve success of CAR-T therapy.

Anti IL-6R mAb

Anti IL-6R is a fully human mAb, which binds to both the membrane-bound and soluble forms of the IL6R and depletes circulating levels of the IL-6 in the blood. The Company is accelerating development in Anti IL-6R mAb as a treatment of COVID-19. The treatment utilizes a novel mode of

administration using hand-held nebulizer to deliver aerosolized anti-IL6R mAb solution to inflamed tissue of deep lung. On 9 April 2020, the Company announced filing of patent application in support of treatment of COVID-19 utilizing Anti-IL6R via inhaled delivery (Kunwar Shailubhai, inventor).

Initial work on CMO selection, technology transfer and transfer of lead cell line candidate from Novimmune to CMO initiated in April 2020. STC Biologics is expanding the cell line, establishing monoclonality, screening for cell line stability and antibody titer and expanding the monoclonal cell line to larger scale for development and cGMP manufacturing. Concurrently they are purifying a batch of monoclonal antibody from the 70L Novimmune pilot batch, manufactured using the lead, non-clonal cell line. STC's generic downstream process is being used for the purification of test article for Inhalation Safety Toxicology studies using Cynomolgus monkeys at ITR Laboratories Canada in December 2020.

Work at Sciarra Laboratories in Hicksville, NY was initiated in May 2020 to evaluate two hand-held nebulizer devices for use in the study and characterizing physical/performance characteristics of the aerosol. Sciarra will execute cGMP manufacturing of drug product solution, packaging and ICH stability studies in Q1 2021.

In July 2020, the Company engaged FHI Clinical as CRO to conduct phase1/2 clinical trials of TZLS-501 in for the COVID-19 indication. Phase1/2 adaptive trial with sites located mostly ex-US in COVID-19 hot spots to speed enrollment to start in Q1 2021.

Milciclib

Milciclib is the Company's Phase 2 clinical candidate for the treatment of multiple cancer indications such as hepatocellular carcinoma, thymic cancer and thymoma. Milciclib, a pan cyclin-dependent kinases (CDK) inhibitor, has demonstrated potent anti-tumour activity as a monotherapy as well as combination therapy. To date, Milciclib has been studied in eight Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumour action. Milciclib has been granted orphan designation by the European Commission and by the FDA for the treatment of malignant thymoma and an aggressive form of thymic carcinoma in patients previously treated with chemotherapy. Milciclib is also being used for treatment of recurrent HCC in liver transplant patients in an investigator-initiated clinical trial. The safety and clinical activity of combination treatment of Milciclib with Regorafenib in liver transplant patients with recurrent HCC has been evaluated showing combination treatment was well tolerated with manageable toxicities. Safety and clinical activity data was presented at Virtual ASCO 2020 conference.

3. Short-term objectives

The Company's goal is to become a leading biotechnology company focused on developing and delivering therapies and related diagnostics in both oncology and immunology. The key elements of the Company's strategy to achieve this goal are to:

- Advance the clinical development of orally administered Foralumab for the treatment of Crohn's disease using a novel and proprietary oral formulation by initiating a Phase 2 trial in the second quarter of 2021. In addition, a Phase 1 trial for the first-in-human evaluation of the intranasal administration of Foralumab in healthy volunteers, for neurodegenerative disease indications such as progressive MS, was initiated in November 2018. The study was completed in September 2019 and a Phase 2 study in progressive MS patients is planned to start in Q4 2020 with results anticipated in Q2 2021.
- Evaluate the safety and clinical utility of nasally-administered Foralumab for treatment of cytokine-storm induced lung inflammation in COVID-19 patients in an investigator-driven clinical trial to be conducted in Brazil in Q4 2020. The collaborative clinical study will investigate nasally administered Foralumab either alone or in combination with orally administered dexamethasone in COVID-19 patients. In view of the importance and urgency, scientific teams at the Harvard Medical School, Santa Casa de Misericórdia de Santos Hospital (Jabaquara, Santos, Brazil) and at the Company are closely collaborating to facilitate initiation of this study in expedited time frames. This clinical trial will be coordinated by the team at INTRIALS, a leading, full-service Latin America Clinical Research Organisation, (CRO) based in Sao Paulo City, Brazil. The clinical data from this trial is expected to be available by the end of 2020.

- Accelerate development and cGMP manufacturing of its product candidate, TZLS-501, a fully human mAb targeting the IL-6 receptor (a biological mAb which may control the proteins involved in cell signaling relevant to many inflammatory diseases and cancers), for treatment of inflammatory and oncology indications such as COVID-19 and multiple myeloma, respectively. cGMP manufacturing has commenced and the Company is simultaneously developing inhalation delivery directly to the lungs using a nebulizer and conducting the inhalation safety toxicology studies in Cynomolgus monkeys. Completion of these studies will enable the Company to file an IND and initiate a clinical trial in COVID-19 patients by Q1 2021.
- Continue to advance the clinical development and obtain regulatory approval for the Company's lead oncology product candidate, Milciclib, as a monotherapy in HCC and as a combination therapy for the treatment of refractory solid tumors (being cancers which are non-responsive or become resistant to treatment) by initiating a planned Phase 2b trial in combination with a tyrosine kinase inhibitor such as Sorafenib or Regorafenib.
- Continue development of platform drug delivery technologies that provide competitive advantage over existing approved products, e.g. inhalation delivery and enteric delivery of monoclonal antibodies (mAbs).
- Continue to evaluate alternative, non-parenteral routes of mAb administration, namely oral, nasal and inhalation routes, to facilitate topical or local therapeutic action.
- Continue to leverage relationships with key opinion leaders to promote clinical trial success and enhance future commercialisation.
- Opportunistically identify and acquire or in-license complimentary product and technology candidates.
- Seek orphan drug, fast track or breakthrough designation for its product candidates where warranted.

4. Market background

Crohn's disease is an inflammatory bowel disease (IBD) that refers to a chronic inflammatory condition of the gastrointestinal tract causing inflammation in the digestive tract. The global inflammatory bowel disease treatment market size was valued at USD 15.9 billion in 2018 and is expected to register a compound annual growth rate of 4.4 per cent. from 2018 to 2026 (source: Grand View Research, Inc., "Inflammatory Bowel Disease Treatment Market Size, Share & Trends Analysis Report By Type (Ulcerative Colitis, Crohn's Disease), By Route of Administration, By Distribution Channel, And Segment Forecasts, 2019 – 2026, published June 2019). Market participants include Shire; AbbViee Inc.; Celgene, Eli Lilly and Company; Pfizer Inc.; and Gilead Sciences. These participants are involved in research and development to introduce and commercialize better versions of existing products.

The global COVID-19 current therapy market is expected to grow from $10.83 billion in 2019 to $16.51 billion in 2020 at a compound annual growth of 52.5 per cent. (source: The Business Research Company, "Coronavirus (COVID-19) Current Therapy Global Market Report 2020: COVID 19 Growth and Change, published July 2020). The COVID-19 pandemic and the global focus to treat the widespread cases is a key market driver.

The compounds and medications that are under investigation to treat Covid-19 can be grouped into three broad categories – antivirals, immune-system based and vaccines. The anti-virals including Darunavir, Favipiravir, Hydroxychloroquine and chloroquine, Lopinavir, and Remdesivir (GS-5734), immune system-related therapies including Tocilizumab, Tocilizumab, and Vitamin C, and other medications are currently being evaluated as therapies. Three key drugs are currently in phase III, of which are two small molecule-based drugs, Remdesivir by Gilead Sciences Inc. and Favipiravir by Fujifilm Toyama Chemical Co Ltd, and Sarilumab, a monoclonal antibody by Regeneron Pharmaceutical. With regards to the prophylactic vaccine pipeline, more than 90 per cent. are in early-stage development (discovery and preclinical), and only three in Phase II. These three COVID-19 vaccines are being developed by Sinovac Biotech Ltd, the University of Oxford, and the third vaccine, named CIGB-2020, is being developed by the Center for Genetic Engineering and Biotechnology.

Globally the size of liver cancer therapeutics market was worth USD $680.84 million in 2019 with an estimated compound annual growth rate of 9.1 per cent., to reach USD $1,052.3 million by 2024

(source: Market Data Forecast, "Global Liver Cancer Therapeutics Size & Growth (2019 – 2024), published February 2020). Malignant tumors of the liver are primarily adenocarcinomas, with two major cell types: hepatocellular carcinoma (HCC), and cholangiocarcinoma. Liver cancer is the third-leading cause of cancer-related deaths, and HCC accounts for 85 per cent. of all primary liver cancers. It occurs mainly due to hepatitis C infection, and to a lesser extent hepatitis B and alcohol. While surgical resection and liver transplantation are potentially curative therapies for early-stage HCC, the majority of diagnoses take place at a disease stage that is too advanced for these treatments. Technological advancements and the routine liver function tests are now resulting in the early detection of hepatocellular carcinoma. The increase in incidences of hepatocellular carcinoma associated with hepatitis C virus are expected to grow the hepatocellular carcinoma treatment market during 2016-2026.

Bayer AG is one of the leading provider of hepatocellular carcinoma (HCC) treatment drugs. Some of the key players in hepatocellular carcinoma treatment market are Novartis Pharmaceuticals, Merck & Co., Inc., Bristol-Myers Squibb Company, AbbVie Inc., Johnson & Johnson Pvt. Ltd., Celgen Corporation, Amgen Inc., Teva pharmaceutical Industries Ltd., Pfizer Inc., and Takeda Pharmaceutical Co. Ltd. These companies focuses on the priority areas of the antiviral and oncology in order to address unmet medical needs.

The global Multiple Sclerosis (MS) Therapeutics market was valued at USD $21.92 billion in 2019 and is expected to reach USD $26.69 billion by year 2027, at a compound annual growth rate of 2.5 per cent. (source: Reports and Data, "Multiple Sclerosis Therapeutics Market Analysis, By Product Type (Immuno-modulators, Immunosuppressant), By Mode of Administration Type (Injectable, Intravenous), By Distribution Channel (Healthcare Providers, Online Pharmacies), Forecast To 2017-2027", published July 2020). Multiple Sclerosis is a disabling condition of the central nervous system that impairs the flow of information within the brain and between the body and the brain. The MS therapeutics market covers the drugs that are being used for the treatment of this disease or to reduce the complications associated with the same. Key participants include Biogen Idec; Pfizer Inc.; Teva Pharmaceutical Industries Ltd.; Sanofi Aventis; Bayer Healthcare AG; Merck; Novartis AG; and AbbVie Inc.

5. Dividend policy

The Company intends to pay dividends on the Ordinary Shares at such times (if any) and in such amounts (if any) as the Board determines appropriate in its absolute discretion. The Company's current intention is to retain any earnings for use in its business operations, and the Company does not anticipate declaring any dividends until the Company is generating significant revenue. The Company will only pay dividends to the extent that to do so is in accordance with all applicable laws.

6. Corporate governance

The Company has adopted a corporate governance structure more fully outlined in Part VII – *The Board of Directors and Senior Members of Management* of this prospectus. The key features of its structure are:

- The Directors recognise the importance of sound corporate governance and the Company will comply with the provisions of the Corporate Governance Code for Small and Mid-Size Quoted Companies ("**QCA Code**"), as published by the Quoted Companies Alliance. The Company has also established a remuneration committee, an audit committee and an AIM Rules compliance committee with formally delegated duties and responsibilities.
- The Remuneration Committee will meet not less than twice each year. The committee will be responsible for the review and recommendation of the scale and structure of remuneration for senior management, including any bonus arrangements or the award of share options with due regard to the interests of the Shareholders and the Company's performance.
- The Audit, Risk and Disclosure Committee will meet not less than three times a year. The committee will be responsible for making recommendations to the Board on the appointment of auditors and the audit fee and for ensuring that the Company's financial performance is properly monitored and reported. In addition, the Audit Committee will receive and review reports from management and the auditors relating to the interim report, the annual report and accounts and the Company's internal control systems.

- The Nomination Committee will meet not less than two times a year. The committee will lead the process for Board appointments and make recommendations to the Board.

The Company recognises that it no longer complies with the QCA Code in relation to independent non-executive directors requirement but will seek to rectify this situation as soon as possible.

PART VII

THE BOARD OF DIRECTORS AND SENIOR MEMBERS OF MANAGEMENT

The Directors

The Board, collectively, has significant experience in the pharmaceutical sector.

The Directors of the Company have all been selected for their extensive experience in their specialised fields, making the Board well rounded and balanced. The Board has a strong track record of developing and bringing pharmaceutical products to market. The composition of the Board is regularly reviewed through the nomination committee. The wide range of skills among the Directors helps to further the business and strategic development of the Company as well as address any anticipated issued in the foreseeable future.

All Directors are expected to provide a sufficient amount of time to the Company to fully exhibit and fulfil their duties. Each Director's time spent is reviewed annually prior to recommending their re-election to the shareholders.

Details of the Directors are listed below.

Gabriele Cerrone (age 48, date of birth: 2 February 1972)

Mr. Cerrone has a successful track record and extensive experience in the financing and restructuring of micro-cap biotechnology companies. He has founded nine biotechnology companies in oncology, infectious diseases and molecular diagnostics, and has taken six of these companies to the NASDAQ Market and one to the AIM Market in London. Mr. Cerrone Co-Founded Trovagene, Inc. (NASDAQ: TROV), a molecular diagnostic company and served as its Co-Chairman; he was a Co-Founder and served as Chairman of both Synergy Pharmaceuticals, Inc. (NASDAQ: SGYP) and Callisto Pharmaceuticals, Inc. (OTCMKTS: CLSP), and was a Director of and led the restructuring of Siga Technologies, Inc. (NASDAQ: SIGA). Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc. and served as Chairman of the board until its merger in September 2007 with Inhibitex, Inc. Mr. Cerrone served as a Director of Inhibitex, Inc. until its US$2.5bn sale to Bristol Myers Squibb Co in 2012.

Mr Cerrone is the Executive Chairman and Co-Founder of Gensignia Life Sciences, Inc., a molecular diagnostics company focused on oncology using microRNA technology; Chairman and Co-Founder of Rasna Therapeutics Limited, a company focused on the development of therapeutics for leukaemias; Co-Founder of ContraVir Pharmaceuticals, Inc. (Nasdaq: CTRV); and Founder of BioVitas Capital Ltd.

Dr Kunwar Shailubhai (age 63, date of birth: 2 September 1957)

Kunwar Shailubhai, Ph.D., M.B.A. serves as Chief Executive Officer and Chief Scientific Officer of the Company, and is also an Executive Director of the Company. Dr. Shailubhai brings more than 25 years of experience within the life science industry, combined with a distinguished track record of success in translating drugs from concept through commercialisation to market. He also currently serves as CEO of Rasna Therapeutics, Inc., a developer of therapeutics to address the high unmet need that exists for Acute myeloid leukaemia and other forms of leukemia.

Dr. Shailubhai has been serving as a member of board of the Company since 2015. He actively played key roles in development of growth strategies through several key licensings of technologies and drug candidates. Dr. Shailubhai steered the company through prioritisation of projects to focus on novel drug candidates for treatment of autoimmune and inflammatory diseases and cancer.

As Co-Founder, EVP and CSO of Synergy Pharmaceuticals, Inc. (NASDAQ: SGYP) he led the non-clinical, CMC and clinical development of Trulance™ from inception to approval by the FDA, having co-invented and pioneered Synergy's platform technology for functional GI disorders, inflammatory bowel disease, GI cancer and other human diseases. Dr. Shailubhai as the Chief Architect of the IP estate, directed all aspects of IP management, including timely submission of patent applications, directing office actions and coordinating with IP attorneys.

Earlier, from 2003 until 2008, Dr. Shailubhai served as senior vice president, Drug Discovery and from 2001 to 2003, he held the position of Vice President, Drug Discovery at Synergy, where he

pioneered therapeutic applications of GC-C agonists in a variety of human diseases such as asthma, chronic obstructive pulmonary diseaseand cholesterol lowering.

Prior to Synergy, he was with Monsanto Company, serving as Group Leader, Cancer Prevention and previously served as a Senior Staff Fellow at the National Institutes of Health, and as an Assistant Professor at the University of Maryland.

Dr. Shailubhai received his Ph.D. in microbiology from the University of Baroda, India, and his MBA from the University of Missouri, St. Louis. He has more than 20 issued patents and over 50 peer-reviewed publications.

Willy Simon (age 69, date of birth: 11 May 1951)

Willy Jules Simon is a banker and worked at Kredietbank N.V. and Citibank London before serving as an executive member of the board of Generale Bank NL from 1997 to 1999 and as the Chief Executive of Fortis Investment Management from 1999 to 2002. He acted as Chairman of Bank Oyens & van Eeghen from 2002 to 2004. From 2004 until 2012, he served as a Non-Executive Director of Redi & Partners Ltd., a fund of funds. He was previously Chairman of AIM-traded Velox3 plc (formerly 24/7 Gaming Group Holdings plc) until 2015 and had been a director of Playlogic Entertainment Inc., a NASDAQ OTC listed company.

John Brancaccio (age 72, date of birth: 8 March 1948)

Mr. Brancaccio, retired CPA, is a financial executive with extensive international and domestic experience in pharmaceutical and biotechnology for privately and publicly held companies. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies.

Mr. Brancaccio is currently a director of Cardiff Oncology, Inc., Rasna Therapeutics, Inc., OKYO Pharma LTD and Hepion Pharmaceuticals, Inc.

Senior Management Team

The Company's current senior management team (the "**Senior Managers**"), in addition to the Directors listed above, is as follows:

Jules S. Jacob (age 68), Senior Director*, CMC & Non-Clinical Development

Mr. Jules Jacob has served as Senior Director of CMC and Non-Clinical Development of the Company and Rasna Therapeutics, Inc., respectively, since July 2017 and has over 25 years of drug development experience. Previously, Mr. Jacob was Senior Director of product development at Aprecia Pharmaceuticals Company, a drug delivery technology platform company, from March 2009 to July 2017, where he led the development of Spritam®, the first FDA-approved dosage form manufactured using 3-dimensional printing, and other 505(b)(2) pipeline products. Mr. Jacob was director of formulation development at Panacos Pharmaceuticals Inc., a drug company focused on human immunodeficiency virus, or HIV, and other major human viral diseases, from March 2007 to December 2008, where he worked on the development of first-in-class maturation inhibitors for the treatment of HIV. Mr. Jacob was a founding scientist, director of R&D and director of technology development at Spherics, Inc., a pharmaceutical company that engaged in developing and manufacturing oral pharmaceutical products for CNS conditions, GI disorders, and cancer, from February 2000 to February 2007. Mr. Jacob worked on the development of bioadhesive dosage forms for treatment of CNS disorders, through the 505(b)(2) regulatory pathway at Spherics Inc. Mr. Jacob completed his undergraduate degree and graduate education in biological and medical sciences at Brown University and has an active visiting faculty appointment in the Department of Molecular Pharmacology, Physiology and Biotechnology at Brown University.

Dr. Vaseem A. Palejwala (age 64) – Director*, Clinical Operations

Dr. Palejwala is currently the Director of Clinical Operations at the Company. From January 2017 to January 2019, he served as Director, Non-Clinical Studies of the company. He has over 20 years of experience in drug discovery and development. From January 2015 to January 2017, Dr. Palejwala

served as Director of Discovery and Preclinical Research, and from December 2012 to December 2014 served as Associate Director of Discovery and Preclinical Research, at Synergy Pharmaceuticals Inc. where he actively contributed to establishing GI tract-related preclinical animal models for testing the efficacy and validating the mechanism of action for both plecanatide and dolcanatide. Dr. Palejwala participated actively in preparation of the nonclinical pharmacology section of the NDA for Trulance®. From 2001 to 2012, Dr. Palejwala served as discovery scientist/ manager at Aventis/Sanofi-Aventis, a multinational pharmaceutical company, where he advanced both small molecule and biologic programs in immunology, inflammation, oncology, CNS and metabolic disorders and also contributed to establishing and managing high-throughput gene expression profiling platform capabilities. Dr. Palejwala holds a Bachelor's degree in microbiology and chemistry from Bombay University, as well as a Master of Science degree and a Ph.D. degree in microbiology from the Maharaja Sayajirao University of Baroda.

Keeren Shah (age 44) – Finance Director*

Keeren Shah serves as the Finance Director at the Company, having previously served as the Group Controller from June 2016 to July 2020. Prior to joining the Company, Ms. Shah spent 10 years at Visa, Inc. as a Senior Leader in its finance team where she was responsible for key financial controller activities, FP&A and core processes as well as leading and participating in key transformation programmes and Visa's IPO. Before joining Visa, Ms. Shah has also held a variety of finance positions at other leading companies including Arthur Andersen and BBC Worldwide.

She holds a Bachelor of arts with honours in Economics and is a member of the Chartered Institute of Management Accountants.

* Title of director but not a statutory director of the Company

Strategic decisions

Members and responsibility

The Directors are responsible for carrying out the Company's objectives, implementing its business strategy in relation to the development of its product candidates and conducting the Company's overall supervision. The Board will provide leadership within a framework of prudent and effective controls. The Board will establish the corporate governance values of the Company and will have overall responsibility for setting the Company's strategic aims, defining the business plan and strategy and managing the financial and operational resources of the Company.

Frequency of meetings

The Board will schedule quarterly meetings and will hold additional meetings as and when required. The expectation is that this will not result in more than four meetings of the Board each year.

Corporate governance

Audit Committee

The Audit Committee of the Board comprises of John Brancaccio and Willy Simon. It is chaired by John Brancaccio, and is responsible for:

(i) monitoring the quality of internal controls and ensuring the financial performance of the Group is properly measured and reported on;

(ii) consideration of the Directors' risk assessment and suggesting items for discussion at the full Board;

(iii) receipt and review of reports from the Company's management and auditors relating to the interim and annual accounts, including a review of accounting policies, accounting treatment and disclosures in the financial reports;

(iv) consideration of the accounting and internal control systems in use throughout the Company and its subsidiaries; and

(v) overseeing the Company's relationship with external auditors, including making recommendations to the Board as to the appointment or re-appointment of the external auditors, reviewing their terms of engagement, and monitoring the external auditors' independence, objectivity and effectiveness.

The Audit Committee meets not less than twice in each financial year and has unrestricted access to the Company's auditors.

Nomination Committee

The Nomination Committee of the Board comprises of Gabriele Cerrone and Willy Simon. It is chaired by Gabriele Cerrone, and is responsible for:

(i) drawing up selection criteria and appointment procedures for directors;

(ii) recommending nominees for election to our board of directors and its corresponding committees;

(iii) assessing the functioning of individual members of our board of directors and executive officers and reporting the results of such assessment to the board of directors; and

(iv) developing corporate governance guidelines.

Remuneration Committee

The Remuneration Committee of the Board comprises of Willy Simon and John Brancaccio. It is chaired by Willy Simon, and is responsible for:

(i) the review of the performance of the executive directors;

(ii) recommendations to the Board on matters relating to the remuneration and terms of service of the executive directors; and

(iii) recommendations to the Board on proposals for the granting of share options and other equity incentives pursuant to any share option scheme or equity incentive scheme in operation from time to time.

In making their recommendations the Remuneration Committee will have due regard to the interests of the Shareholders and the performance of the Company.

The Company has adopted and will operate a share dealing code governing the share dealings of the Directors of the Company and applicable employees with a view to ensuring compliance with the Market Abuse Regulation.

The Company has adopted a share dealing policy regulating trading and confidentiality of inside information for the Directors and other persons discharging managerial responsibilities (and their persons closely associated) which contains provisions appropriate for a company whose shares are admitted to trading on the Official List (particularly relating to dealing during closed periods which will be in line with the Market Abuse Regulation). The Company will take all reasonable steps to ensure compliance by the Directors and any relevant employees with the terms of that share dealing policy.

Scientific advisory board

The Board is assisted in its approach to its scientific strategy. The members of the Scientific Advisory Board are as follows:

Howard Weiner MD – Harvard Medical School

Dr. Howard Weiner is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis (MS) Center and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham & Women's Hospital in Boston. The Partners MS Center is the first integrated MS Center that combines clinical care, MRI imaging and immune monitoring to the MS patient as part of the 2000 patient CLIMB cohort study. He has pioneered immunotherapy in MS and has investigated immune mechanisms in nervous system diseases including MS, Alzheimer's disease, amyotrophic lateral sclerosis, stroke and brain tumours. He has also pioneered the investigation of the mucosal immune system for the treatment of autoimmune and other diseases and the use of anti-CD3 to induce regulatory T cells for the treatment of these diseases.

Kevan Herold MD – Yale University

Dr. Kevan Herold is Professor of Immunobiology and of Medicine (Endocrinology) as well as Deputy Director, Yale Center for Clinical Investigation, Director of the Yale Diabetes Center and Director of the TrialNet Center at Yale. His investigative work has focused on developing new ways to prevent and treat autoimmune diseases, using novel translational immunologic and metabolic approaches to prevent progression, in particular anti-CD3 monoclonal antibody therapy. His clinical interests are in the management of endocrine diseases, and he is involved in a number of national and international clinical studies of new treatments.

Arun Sanyal MD – Virginia Commonwealth University

Charles Caravati Distinguished Professor and Chair, Division of Gastroenterology, Hepatology and Nutrition at Virginia Commonwealth University School of Medicine. Dr Sanyal is a world leader in the field of liver disease.

Professor Napoleone Ferrara, MD – University of California's Moores Cancer Center in San Diego

Dr Ferrara is Senior Deputy Director for Basic Sciences at University of California's Moores Cancer Center in San Diego; and Distinguished Professor of Pathology at the University of California's School of Medicine, also in San Diego. Dr Ferrara's research led to the development of the anti-VEGF monoclonal antibody bevacizumab (Avastin®) which was initially approved for the treatment of colorectal cancers, now one of the top ten selling global pharmaceutical products and won the 2010 Lasker Award for his work on VEGF.

PART VIII

THE BUSINESS

Crohn's Disease

Crohn's disease is a relapsing, transmural inflammatory disease of the gastrointestinal mucosa that can affect all parts of the intestinal tract as well as extra-intestinal organs. Crohn's disease affects between 400,000 and 600,000 people in North America. Current estimates for Northern Europe have ranged from 27–48 people per 100,000.

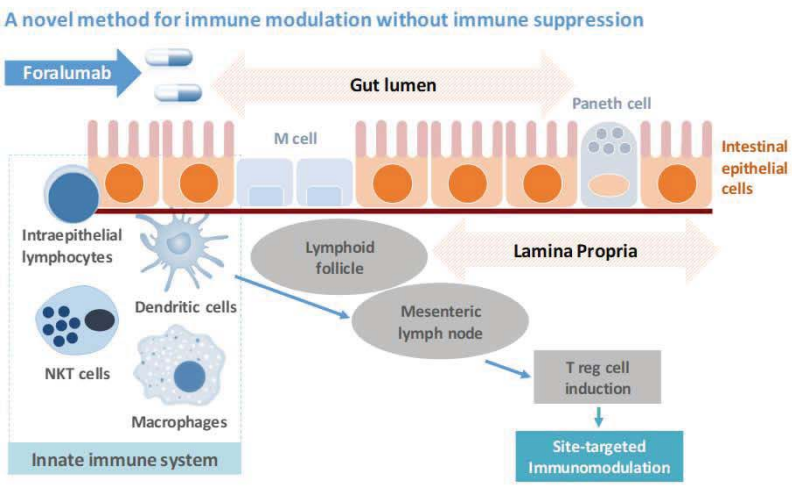
Although the exact etiology remains unknown, the occurrence of Crohn's disease is strongly associated with mutations of a receptor for microbial pathogens (nucleotide-binding oligomerization domain containing protein 2 – NOD2) that recognizes microbial pathogens leading to increased activation of antigen presenting cells. As a result of this altered balance of immune homeostasis, exposure to commensal bacterial antigens causes increased stimulation and proliferation of mucosal T-lymphocytes, leading to inflammatory responses.

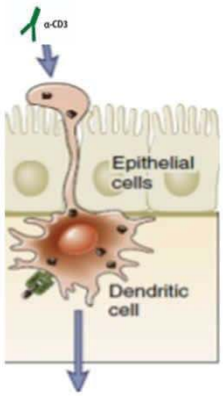
The pharmacological management of Crohn's disease is based on the control of the inflammatory process. The current leading biologic immunotherapies, Humira® (adalimumab) and Remicade® (infliximab) are administered parenterally to target Tumor Necrosis Factora(TNFa) to induce and maintain disease remission.

The Company intends to orally administer Foralumab to the small and large intestine via an enteric-coated capsule formulation. Foralumab binds locally to dendritic cells (antigen-presenting cells) lining the GI tract, inducing regulatory T cells supporting immunomodulation locally as well as systemically, it also has the ability to act topically to produce anti-inflammatory effects. The Company has completed a Phase 1 trial, conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA. The trial was a single-site, double-blind, placebo-controlled, single ascending dose study in healthy subjects in which Foralumab was orally administered at 1.25, 2.5 and 5.0 mg per dose as enteric-coated capsules. Each cohort comprised of 4 subjects, of whom 3 received Foralumab treatment and 1 received a placebo capsule. All subjects completed the trial without any safety concerns at any of the doses.

The Company has been granted the first-ever patent on the transformational technology for Oral Delivery of all Anti-CD3 monoclonal antibodies for treatment of human diseases.

Crohn's immune modulation

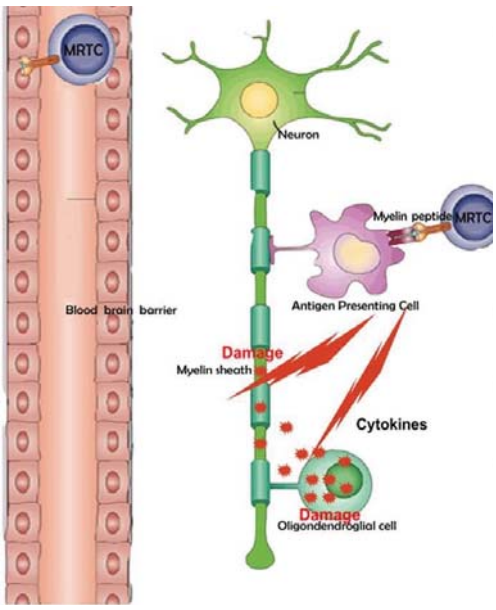




Presentation of Foralumab to T-cells in mucosa associated lymphoid tissue or mesenteric lymph nodes

Progressive Multiple Sclerosis

MS is an inflammatory-mediated demyelinating disease of the human central nervous system (CNS). The disease develops in young adults with a predisposing genetic trait and most likely involves an environmental insult such as a viral infection to trigger the disease.



The innate immune system plays a central role in the chronic central nervous system inflammation that drives neurological disability in progressive forms of multiple sclerosis, for which there are no effective treatments. The mucosal immune system is a unique tolerogenic organ that provides a physiological approach for the induction of regulatory T cells. Nasal administration of CD3-specific antibody ameliorates disease via an IL-10-dependent effect that is mediated by the induction of regulatory T cells that share a similar transcriptional profile to Tr1 regulatory cells and that suppress the astrocyte inflammatory transcriptional program. Treatment results in an attenuated inflammatory milieu in the central nervous system, decreased microglia activation, reduced recruitment of peripheral monocytes, stabilization of the blood–brain barrier and less neurodegeneration.

The Company conducted a Phase 1 trial, at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA. The trial was a single-site, double-blind, placebo-controlled, dose-ranging study with nasally administered Foralumab at 10, 50 and 250 µg per day, consecutively for 5 days in healthy volunteers for the treatment of progressive multiple sclerosis (pMS). 18 subjects received Foralumab treatment and 9 patients received placebo. All nasal doses were well tolerated. Biomarker analysis showed significant positive immune effects, that were most prominent in the 50 mg cohort with minimal immunomodulatory effects at the 10 µg and 250 µg doses.

COVID-19

Coronavirus disease 2019 (COVID-19) is a highly contagious disease attributed to transmission of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). The disease originated in Wuhan China, in December 2019, and has spread globally, creating an ongoing pandemic. As of 28 April 2020, 3 million cases have been tracked in 185 countries. More than 200,000 deaths have been recorded and greater than 900,000 people have recovered after infection.

The lungs are target organs for COVID-19 infection, owing in large part to virus entering alveolar cells via the enzyme angiotensin-converting enzyme 2 (ACE2). As the disease progresses, respiratory failure and death may follow.

Certain patients infected with COVID-19 develop an uncontrolled immune response ("cytokine storm") resulting in severe damage to lung tissue which could lead to respiratory failure. Early clinical studies conducted by doctors in China suggest that anti-IL6R mAbs may be used in clinical practice for treatment of COVID-19. Consequently, China's National Health Commission has recommended the use of Roche's blockbuster drug, Actemra® for treatment of patients infected with COVID-19, with serious lung damage and elevated IL-6 levels. Actemra was first approved by the FDA in 2010 for rheumatoid arthritis. Besides Actemra®, Sanofi and Regeneron are currently exploring Kevzara®, an FDA-approved anti-IL-6 receptor mAb therapy for rheumatoid arthritis, for treatment of severe COVID-19.

The Company intends to accelerate the development of hand-held nebulizer inhalation technology to deliver stable aerosols of TZLS-501 (anti-IL-6R mAb) and potentially other antiviral drugs such as remdesivir directly to lungs to treat COVID-19 by Q2 2021. The Company believes TZLS-501 (anti-IL6R mAb) combined with this newly introduced inhalation technology may rapidly inhibit inflammation in lungs and in combination with intravenous administration may deplete circulating levels of IL-6 and potentially halt progression of COVID-19-mediated lung damage and death. The Company is also evaluating the utility of nasally-administered foralumab to reduce inflammation in lungs and improve respiratory function in COVID-19 patients in an investigator's trail in Brazil in Q4 2020.

Hepatocellular cancer

The Company is developing Milciclib for the treatment of HCC, the world's most common primary cancer and a leading cause of cancer-related death in the United States. The primary risk factor for HCC is hepatic cirrhosis. The American Cancer Society predicts approximately 42,810 new cases of live cancer will be diagnosed in 2020, of which approximately 30,160 will die.

The Company has completed a Phase 2a trial in sorafenib-resistant HCC patients where, 14 patients completed treatments as per the protocol, 9 were approved for compassionate use and no drug related deaths occurred. The Company presented the Phase 2a clinical data at the 2020 Virtual American Society of Clinical Oncology (ASCO) conference.

The Company anticipates initiating Phase 2b in HCC patients with Milciclib in combination with a tyrosine kinase inhibitor (regorafenib or sorafenib) in 2Q 2021.

Milciclib is also being used in combination with regorafenib for treatment of liver transplant patients with recurrent HCC in an investigator-initiated clinical trial, as reported in an abstract presented at the 2020 ASCO Virtual Meeting. The Company intends to conduct a larger trial in liver transplant patients with recurrent HCC using this drug combination.

Drug Pipeline

Foralumab

The Company's patented oral formulation of fully human anti-CD3 mAb, Foralumab is a game changer for the treatment of Crohn's Disease, autoimmune diseases and other inflammatory diseases by potentially improving efficacy and reduced toxicity. Foralumab modulates the immune response, reducing inflammation locally and systemically, through interaction with the mucosal immune system. The Company anticipates the initiation of a Phase 2 trial with nasally administered Foralumab in progressive multiple sclerosis (pro-MS) in Q4 2020. Phase 2 trial with orally administered Foralumab for Crohn's indication is anticipated to be initiated soon. An investigator's trial with nasally administered Foralumab for treatment of inflammation in lungs of COVID-19 patients is expected to begin in Brazil in Q4 2020.

Anti IL-6R mAb

The Company's Anti IL-6R, an mAb, binds to both membrane-bound and soluble forms of IL-6R, an inflammatory cytokine driving chronic inflammation associated with autoimmune disease and cancer,

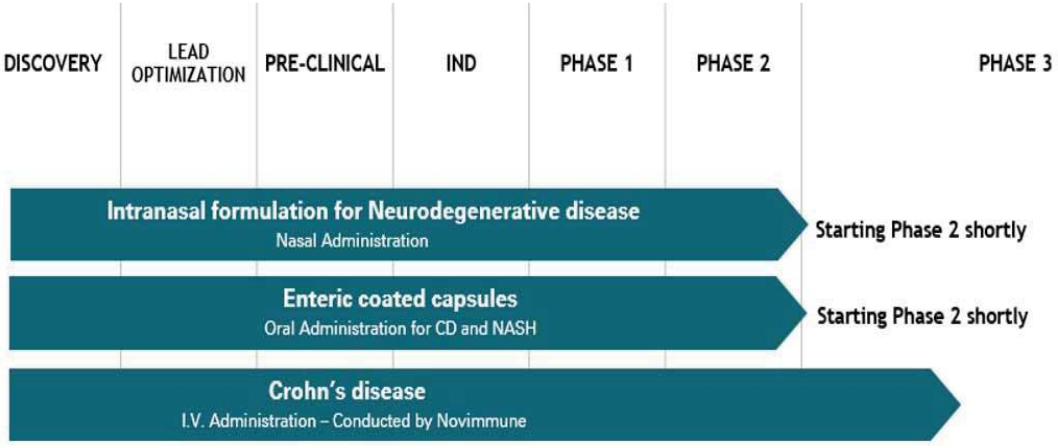
reducing circulating levels of the cytokine. Anti IL-6r antibody can potentially be used in combination with Foralumab or other anti-inflammatory and anti-infective agents as therapy for COVID-19, multiple myeloma, arthritis, lupus and oncology indications. Excessive production of IL-6 is regarded as a key driver of chronic inflammation and is believed to be associated with severe lung damage observed with COVID-19 infections and acute respiratory illness. China's National Health Commission has recommended the use of anti-IL6-R mAbs for treatment of inflammation and elevated cytokine levels ("cytokine storm") in COVID-19 patients. A recent study also reported that COVID-19 infection caused clusters of severe respiratory illness like ARDS. The Company aims to complete the development of inhalation technology to deliver stable aerosols directly into the lungs by Q2 2021.

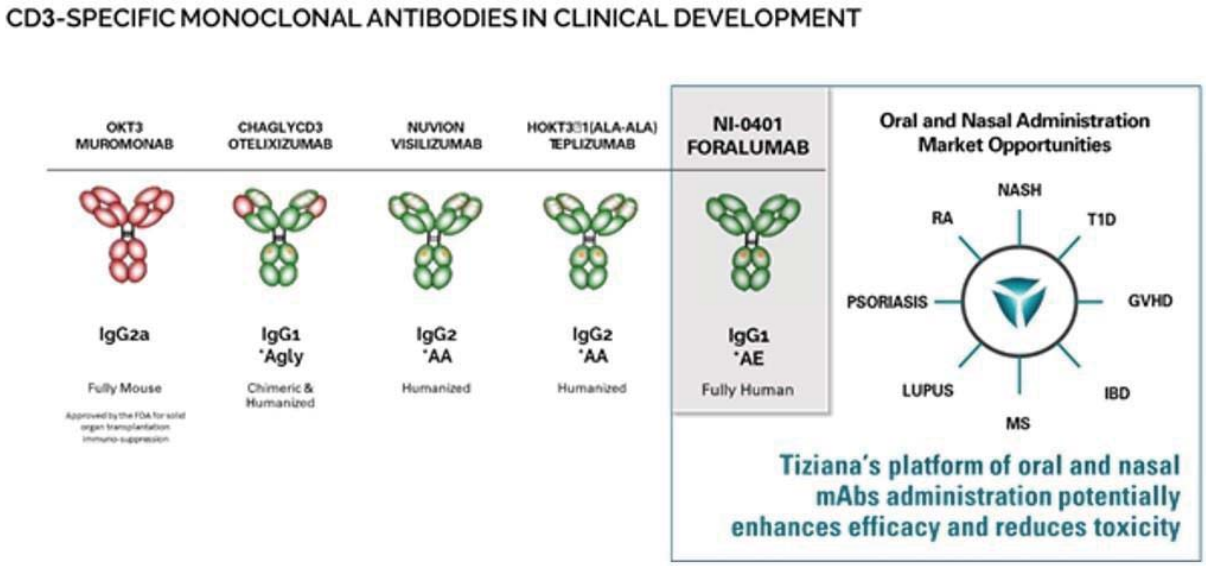
Milciclib

The Company's Milciclib is a potent, small molecule inhibitor of multiple cyclin-dependent kinases (CDKs), tropomycin receptor kinases and Src family kinases controlling cell growth and malignant progression of cancer. Milciclib has demonstrated safety in 316 patients with advanced solid cancers in Phase 1 and 2 studies and shown indications of efficacy. In two, completed, Phase 2 thymic cancer trials, Milciclib successfully increased overall survival and met both primary and secondary endpoints. While the current standard of care for hepatocellular carcinoma (HCC), the most common liver cancer, is only effective in a small percentage of patients, Milciclib has the potential to be broadly effective because it targets the underlying cause of disease. A unique feature of Milciclib is its ability to reduce microRNAs, miR-221 and miR-222, that promote the formation of blood vessels (angiogenesis) to facilitate the spread of cancer cells Levels of these microRNAs are consistently increased in HCC patients and may contribute towards resistance to treatment with Sorafenib. The Company intends to initiate Phase 2b in HCC patients with Milciclib in combination with a TKI in Q2 2021.

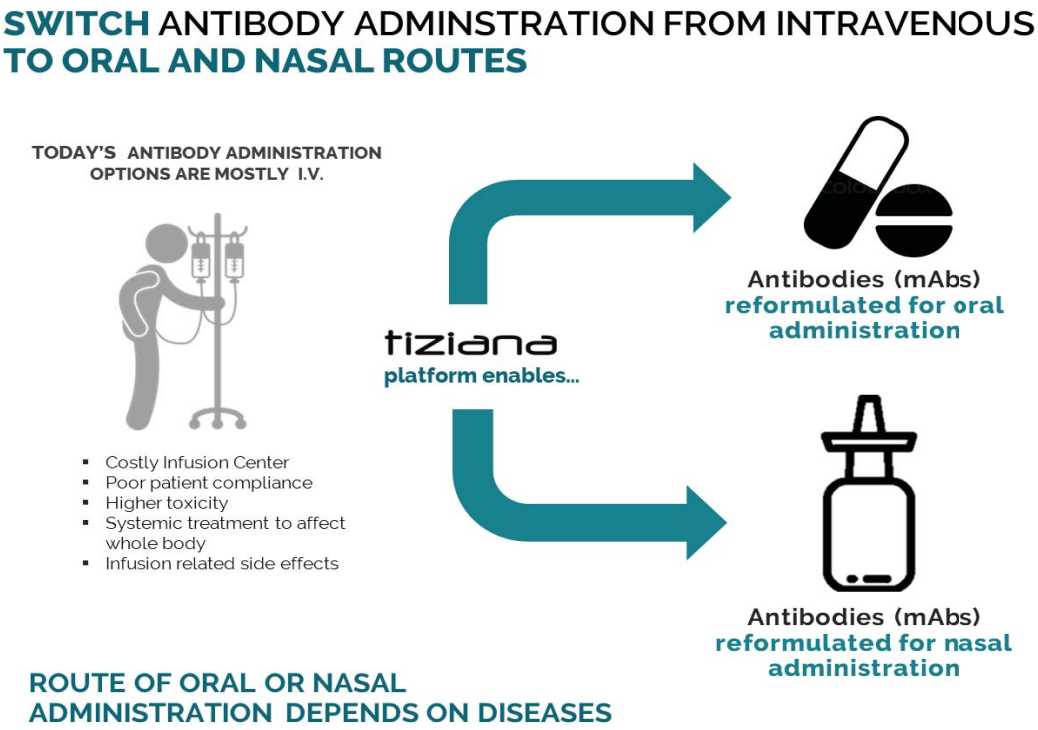
Foralumab

The Company's Foralumab is the world's first and only, fully human anti-CD3 antibody and can be delivered orally, making it a potential game changer in the treatment of Crohn's Disease and other autoimmune diseases through higher efficacy and reduced toxicity. The United States Patent and Trademark Office has granted a patent covering its proprietary formulation for oral administration. Additionally, the Company is employing another revolutionary approach to treat patients with neurodegenerative diseases such as progressive MS (pro-MS) by delivering Foralumab via nasal administration. Foralumab modulates the immune response, reducing inflammation locally and systemically, through interaction with the gastrointestinal and nasal mucosal immune system. The Company anticipates the initiation of a Phase 2 trial with nasally administered Foralumab in progressive multiple sclerosis (pro-MS) in Q2 2021. Phase 2 trial with orally administered Foralumab for Crohn's indication is anticipated to be initiated soon.





On 19 June 2020, the Company announced that patent 10,688,186 titled "Anti-CD3 formulations", Inventor: Kunwar Shailubhai, is the first-ever to be granted on anti-CD3 formulations and covers oral administration with lyophilized and stabilized free-flowing powder of Foralumab or any other anti-CD3 mAb, encapsulated in enteric-coated capsules, for treatment of human diseases. In addition, the stabilized liquid formulation of Foralumab and other anti-CD3 mAbs for nasal administration is also covered in this patent. These formulation technologies have the potential to transform immunotherapies, which currently can only be administered intravenously or subcutaneously.



Completed Phase 1 Clinical Trial: Nasal Administration of Foralumab for the Treatment of Multiple Sclerosis

The completed Phase 1 clinical trial of Foralumab in healthy volunteers was a single center, single arm, ascending dose study in which low doses (10, 50 and 250 µg/dose) of Foralumab and placebo were nasally administered for 5 consecutive days. Subjects were monitored for tolerance and immunological effects. The primary endpoint of the Phase 1 study is safety, tolerability and biomarkers of immunomodulation of clinical responses of intra nasally administered Foralumab.

Interim results have indicated no drug-related safety issues so far. Topline results were reported on 10 September 2019. All nasal doses were well tolerated. Biomarker analysis showed significant positive immune effects, that were most prominent in the 50 µg cohort with minimal immunomodulatory effects at the 10 µg and 250 µg doses. These results suggested stimulation of Tregs that are needed to provide clinical benefits. Phase 2a trials will be initiated in Q4 2020 for the treatment of MS.

Completed Phase 1 Clinical Trial: Oral Administration of Foralumab in Healthy Volunteers

An enteric-coated capsule formulation has been developed for oral administration of Foralumab. A single-center, ascending dose Phase 1 trial in healthy subjects administered, either enteric capsule formulation of Foralumab at 1.25, 2.5 and 5.0 mg/dose or placebo was initiated on 2 December 2019. The primary endpoint of the trial was safety and tolerability of oral Foralumab in humans. Results of the Phase 1 Trial were reported on 20 January 2020 The proprietary oral formulation, comprising the lyophilized and stabilized free-flowing powder of formulated Foralumab encapsulated in an enteric-coated capsule, was well-tolerated at all doses tested and there were no drug-related safety issues even at the highest dose of 5 mg in this trial. Based on the positive outcome of the Phase 1 trial, a Phase 2 trial in Crohn's Disease patients is expected to begin in Q2/Q3 2021.

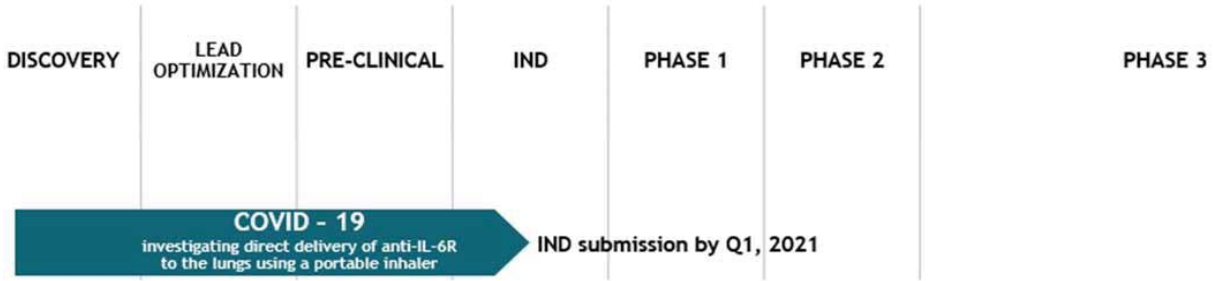
Prior Novimmune Clinical Trials using Intravenous Foralumab

Intravenous Foralumab has been studied in one Phase 1 and two Phase 2 clinical trials conducted by Novimmune. A total of 68 patients were administered Foralumab.

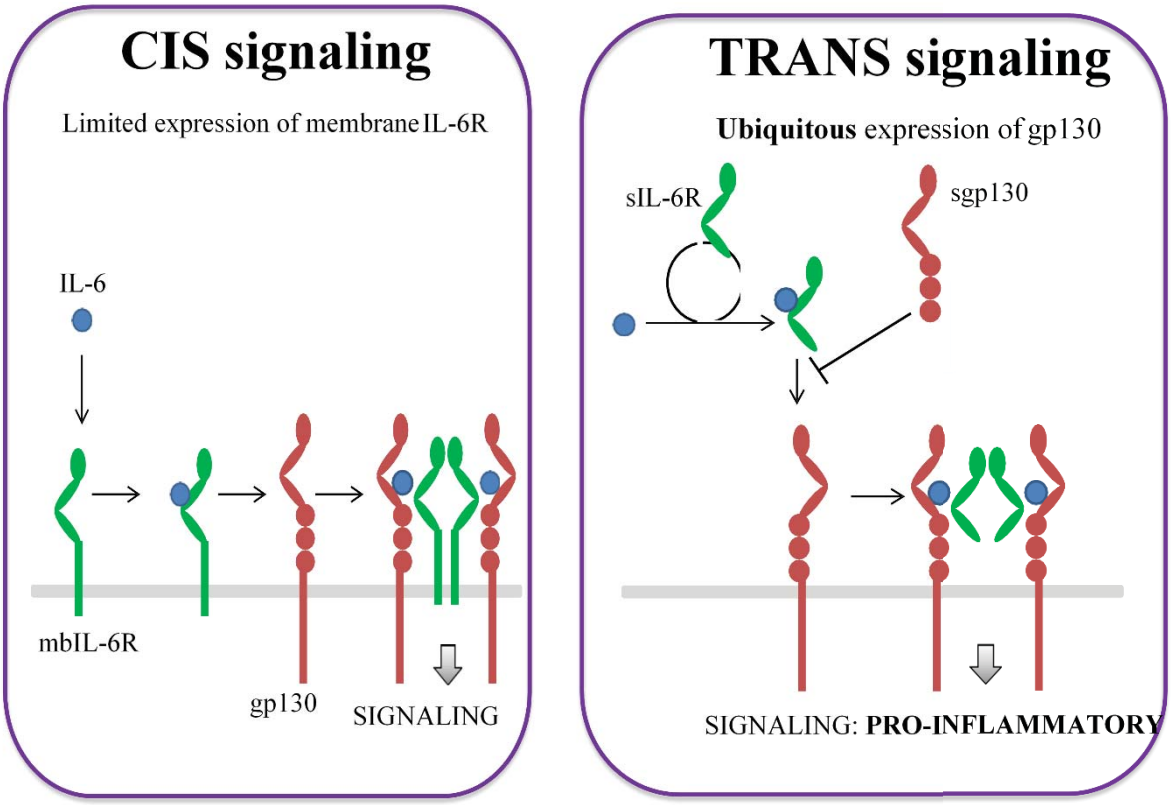
The short-term tolerability profile of Foralumab was very similar to those reported with other anti-CD3 antibodies and no new emerging concerns have been identified. Total daily doses of up to 1mg (~ 500 µg/m2) per patient were generally well tolerated without corticosteroid premedication with reduction in the Crohn's Disease Activity Index (CDAI) scores in patients. The most common adverse events following exposure to Foralumab were Infusion Related Reactions (IRRs).

The Company's Anti IL-6R mAb, binds to both membrane-bound and soluble forms of IL-6R, an inflammatory cytokine driving chronic inflammation associated with autoimmune disease and cancer, reducing circulating levels of the cytokine. Anti-IL-6R antibody can potentially be used in combination with Foralumab or other anti-inflammatory and anti-infective agents as therapy for COVID-19, multiple myeloma, arthritis, lupus and oncology indications. Excessive production of IL-6 is regarded as a key driver of chronic inflammation and is believed to be associated with severe lung damage observed with COVID-19 infections and acute respiratory illness. China's National Health Commission has recommended the use of anti-IL6-R mAbs for treatment of inflammation and elevated cytokine levels ("cytokine storm") in COVID-19 patients. A recent study also reported that COVID-19 infection caused clusters of severe respiratory illness like ARDS. The Company aims to complete the development of inhalation technology to deliver stable aerosols of TZLS-501 and potentially other antiviral drugs such as remdesivir directly into the lungs by Q2 2021.

In light of the coronavirus pandemic, the Company is accelerating GMP manufacturing of its anti-IL-6R mAb concurrently with developing an inhalation technology for direct delivery of the antibody into the lungs using a handheld inhaler or nebulizer for treatment of patients with COVID-19.



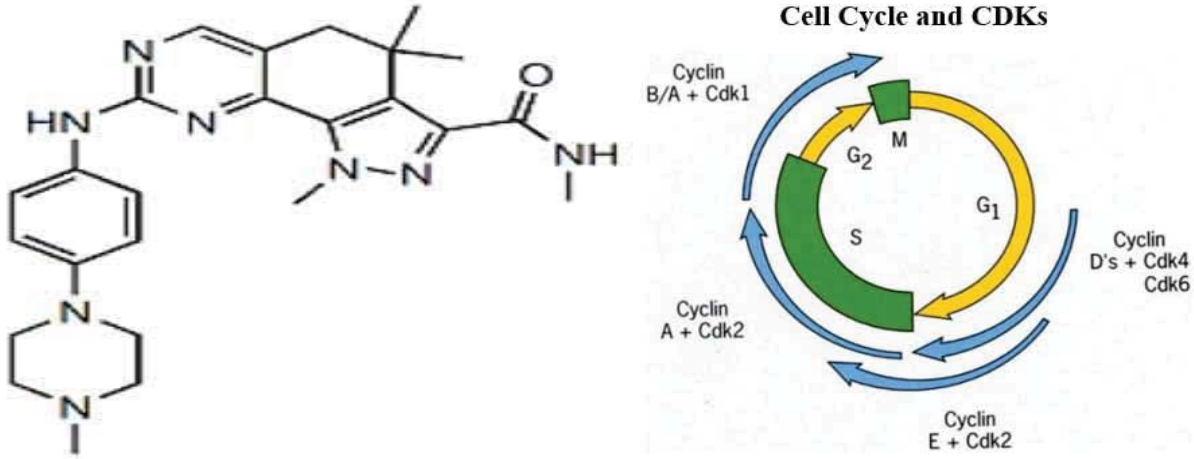
Manufacturing of clinical supplies for a Phase 1 study is anticipated to be complete the first quarter of 2021, at which time the Company plans to submit an application with the FDA for an Investigational New Drug ("**IND**") program, by which the Company intends to obtain permission to start human clinical trials.



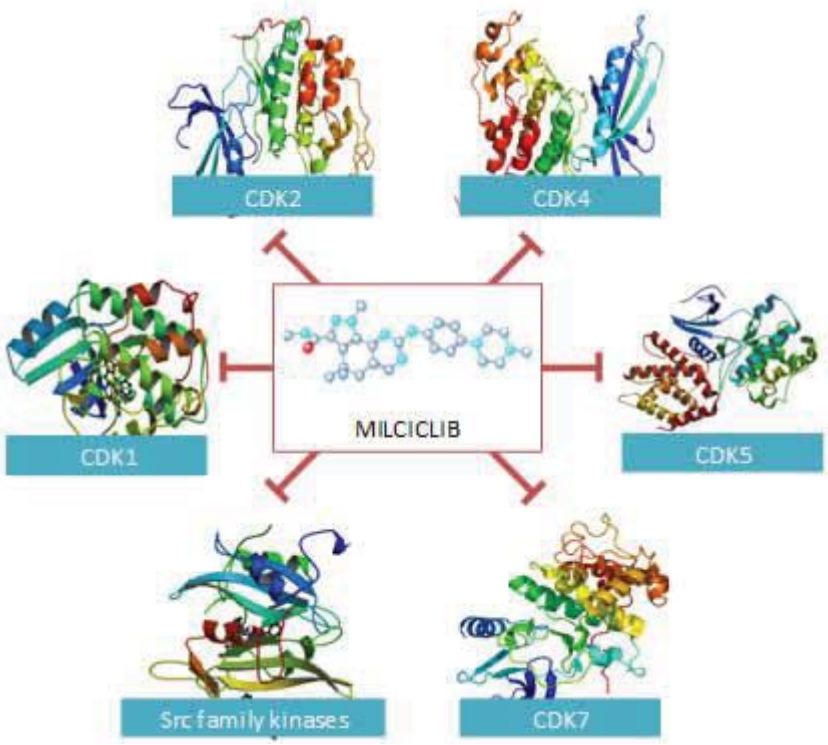
In inflammation, IL-6 levels increase 100-1000x favouring IL-6 TRANS-signaling conditions

The Company's Milciclib is a potent, small molecule inhibitor of multiple cyclin-dependent kinases (CDKs), tropomycin receptor kinases and Src family kinases controlling cell growth and malignant progression of cancer. Milciclib has demonstrated safety in 316 patients with advanced solid cancers in Phase 1 and 2 studies and shown indications of efficacy. In two, completed, Phase 2 thymic cancer trials, Milciclib successfully increased overall survival and met both primary and secondary endpoints. While the current standard of care for hepatocellular carcinoma (HCC), the most common liver cancer, is only effective in a small percentage of patients, Milciclib has the potential to be broadly effective because it targets the underlying cause of disease.

A unique feature of Milciclib is its ability to reduce microRNAs, miR-221 and miR-222, that promote the formation of blood vessels (angiogenesis) to facilitate the spread of cancer cells. Levels of these microRNAs are consistently increased in HCC patients and may contribute towards resistance to treatment with Sorafenib.



Safety and clinical activity of combination treatment of Milciclib with Regorafenib in liver transplant patients with recurrent HCC has also been evaluated in an investigator originated liver transplant patient recurrent HCC trial. Combination treatment was well tolerated with manageable toxicities. Safety and clinical activity data were presented at Virtual ASCO 2020 conference. The Company intends to initiate Phase 2b clinical trial in liver transplant recurrent HCC patients with Milciclib in combination with a Regorafenib in the second quarter of 2021.

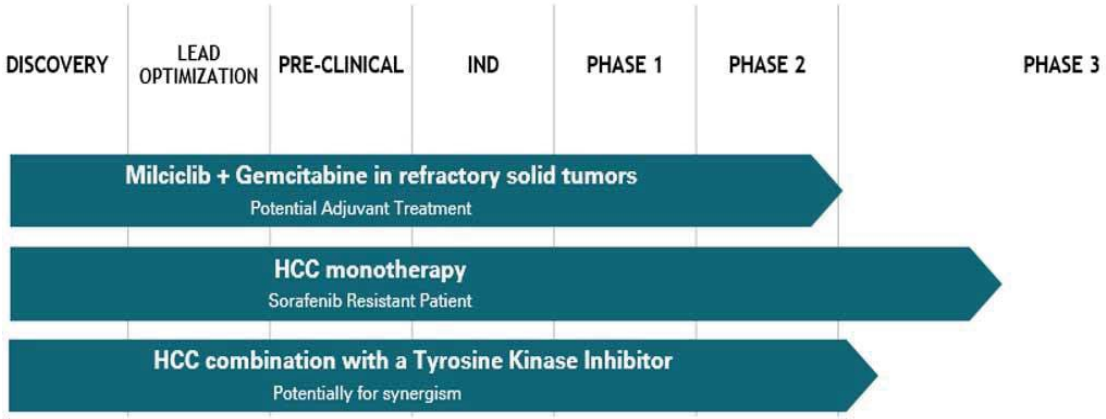


Phase 2a Clinical Trial (CDKO-125a-010) for Milciclib as a Monotherapy for the Treatment of HCC

The Company completed a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in sorafenib-resistant patients with HCC (https://clinicaltrials.gov/ct2/show/NCT01011439). 28 out of 31 treated patients were evaluable, 14 completed the 6-month duration study. Oral treatment with Milciclib was well-tolerated with manageable toxicities. No drug-related

deaths were recorded. The most frequent drug-related adverse events such as: diarrhoea, nausea, retinal haemorrhage, fatigue, asthenia, chills, ataxia, headache, rash. 64 per cent. of patients (9 patients) were approved for compassionate use treatment by their respective ethical committees. Seven of 9 patients on drug treatment between 9 and >16 months. As of 31 August 2020, 2 patients were in the 23rd month of treatment. Objective tumour assessments according to the mRECIST guideline and the conventional RECIST 1.1 criteria has been conducted by Independent Central Review and data is available.

The Company intends to initiate Phase 2b in HCC patients with Milciclib in combination with a Tyrosine-Kinase Inhibitor (TKI), such as Sorafenib or Regorafenib, in the second quarter of 2021.



Milciclib was granted orphan designation by the European Commission and by the FDA for the treatment of thymic carcinoma. In two Phase 2a trials, Milciclib exceeded efficacy endpoints, showed signs of slowing disease progression and acceptable safety.

Intellectual Property

Family	Subject	Priority	Status	Expires	Jurisdiction
Foralumab TZLS-401	Methods of Use (Autoimmune or inflammatory diseases and disorders)	2004	Issued	2025	Australia, Canada, China. Hong Kong, Israel, Japan, Mexico, Norway, Singapore, South Africa, Ukraine, Armenia, Austria, Azerbaijan, Belgium, Belarus, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, Kyrgyzstan, Kazakhstan, Luxembourg, Moldova, Netherlands, Portugal, Russian Federation, Sweden, Tajikistan, Turkmenistan
	Composition and methods of use	2004	Issued / Pending	2025	US, Armenia, Australia, Austria, Azerbaijan, Belarus, Brazil, Canada, China, Denmark, France, Germany, Hong Kong, India, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Mexico, Moldova, Netherlands, Norway, Republic of Korea, Russian Federation, Singapore, South Africa, Spain, Switzerland, Tajikistan, Turkmenistan and Ukraine Pending: Japan (divisional), Singapore (divisional), US (divisional)
	Methods of Use (in combination with anti-IL-6/IL-6R antibodies)	2011	Pending	2032	US
	Formulations and dosing regimen	2016	Pending	2037	US (allowed), Australia, Canada, China, Europe, Hong Kong, Israel, Japan
	Methods of Use (CNS disorders)	2017	Pending	2038	National
	Methods of Use (gastrointestinal / autoimmune / inflammatory)	2018	Pending	2039	PCT
Milciclib TZLS-201	Composition of matter, methods of use, process of manufacturing	2003	Issued / Pending	2024	US, Europe, Eurasia, Africa, Algeria, Argentina, Australia, Barbados, Bosnia & Herzegovina, Canada, Colombia, Costa Rica, Croatia, Cuba, Ecuador, Georgia, Iceland, India, Indonesia, Israel, Japan, Korea, Kosovo, Malaysia, Mexico, Mongolia, Montenegro, New Zealand, Nicaragua, Norway, Pakistan, Philippines, Serbia, Singapore, South Africa, Sri Lanka, Taiwan, Trinidad & Tobago, Tunisia, Ukraine, Uzbekistan, Vietnam Allowed: Brazil Pending: US, Brazil, Egypt, Thailand, Venezuela
	Methods of use (multiple indications)	2008; 2009	Issued	2029; 2030	US, EU, China, Hong Kong, Japan
	Methods of use (combination therapies with cytotoxics)	2008; 2009	Issued / Pending	2029; 2030	US, EU, China, Hong Kong, Japan Pending: EU
	Compositions of related entities, formulations and methods of treatment	2009	Issued	2030	US, EU, China, Hong Kong, Japan
	Methods of use (combination therapies	2006	Issued	2027	US, EU, China, Japan

Family	Subject	Priority	Status	Expires	Jurisdiction
	with therapeutic antibodies)				
	Formulations of milciclib and therapeutic combinations of the same for use in the treatment of cancer	2017	Pending	2038	US Pending: EU, Canada, Japan
Anti IL-6/IL – 6R Antibody TZLS-501	Composition of Matter and Methods of use	2009	Issued	2029	US, Austria, Australia, Belgium, Canada, China, Denmark, France, Germany, India, Ireland, Italy, Japan Luxembourg, Mexico, Netherland, Spain, Sweden, Switzerland and UK Pending: US (divisional), Japan (divisional)
StemPrinter	Methods and Kits Comprising Gene Signature for Stratifying Breast Cancer Patients	2016	Pending	2037	US, EU, Canada
Actinomycin D	Use of Actinomycin D in the Treatment of Acute Myeloid Leukemia	2015	Issued/ Pending	2036	US, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, and UK Pending: US (divisional), Australia, Canada, Japan
	Actinomycin D Compositions and Use of the Same in the Treatment of Myelodysplactic Syndrome and Acute Myeloid Leukemia	2016	Pending	2037	US, EU, Canada, Japan

The Company has rights to a patent family that discloses the Milciclib compound, methods of using the compound, and processes for making the compound under license from Nerviano (which is further described below). This patent family includes five granted U.S. patents, one granted European patent, and one granted Eurasian patent. This patent family also includes granted patents in Africa (African Intellectual Property Organization, African Regional Intellectual Property Organization), Algeria, Argentina, Australia, Barbados, Bosnia & Herzegovina, Canada, Colombia, Costa Rica, Croatia, Cuba, Ecuador, Georgia, Iceland, India, Indonesia, Israel, Japan, Korea, Kosovo, Malaysia, Mexico, Mongolia, Montenegro, New Zealand, Nicaragua, Norway, Pakistan, Philippines, Serbia, Singapore, South Africa, Sri Lanka, Taiwan, Tunisia, Ukraine, Uzbekistan, and Vietnam. Several applications are pending in the U.S. and other countries in this family. The patents in this family will expire in April 2024, excluding any patent term adjustment and patent term extension in the U.S. and similar regulatory extensions available in several other jurisdictions, such as Europe.

The Company also has rights to a second patent family which covers related entities, such as salts and crystal forms, of Milciclib, and methods of using the salts and crystal forms. This patent family comprises one granted U.S. patent and one granted patent in each of Europe, China, Japan, and Hong Kong. The patents in this family will expire in April 2030, excluding any patent term adjustment and patent term extension in the U.S. and several other jurisdictions, such as Europe.

In addition, the Company has rights to five patent families which cover methods of using Milciclib in the treatment of multiple indications. These patent families comprise five granted U.S. patents, and granted patents in Europe, China, Hong Kong, and Japan, and one pending patent application in Europe. The patents in these families will expire between February 2027 and March 2030, excluding any patent term adjustment and patent term extension in the U.S. and similar regulatory extensions available in several other jurisdictions, such as Europe.

Among the above five patent families, two families also cover combination therapies of Milciclib with cytotoxic agents. These families comprise two granted U.S. patents, and granted patents in Europe, China, Hong Kong, and Japan. The patents in these families will expire between November 2029

and March 2030, excluding any patent term adjustment and patent term extension in the U.S. and similar regulatory extensions available in several other jurisdictions, such as Europe.

One family of the above five patent families also covers combination therapies of Milciclib with therapeutic antibodies. This patent family includes one granted U.S. patent, and granted patents in Europe, China, and Japan. The patents in this family will expire in February 2027, excluding any patent term adjustment and patent term extension in the U.S. and similar regulatory extensions available in several other jurisdictions, such as Europe.

In addition, the Company has rights to a patent family which covers methods of using Milciclib together with a second anti-cancer agent in the treatment of cancer. This patent family includes one pending application in the U.S and one pending international application. The patent applications in this family, if issued as patents, will expire in December 2038, excluding any patent term adjustment and patent term extension in the U.S. and similar regulatory extensions available in several other jurisdictions, such as Europe.

The Company has rights to a first patent family that disclose methods of using Foralumab, licensed from Novimmune (which is further described below). This patent family includes, one granted European patent, and one granted Eurasian patent. This patent family also includes granted patents in Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Norway, Singapore, South Africa, Ukraine, and Portugal. The patents in this family will expire in April 2025, excluding any patent term extensions available in several jurisdictions, such as Europe.

The Company also has rights to a second patent family that discloses the Foralumab compound and methods of using the compound also licensed from Novimmune. This patent family comprises three granted U.S. patent one granted European patent, and one granted Eurasian patent. This patent family also includes granted patents in Australia, Canada, China, Hong Kong, India, Israel, Japan, Mexico, Norway, Republic of Korea, Singapore, South Africa, and Ukraine. Applications are pending in Brazil, Japan, Singapore and U.S. The patents in these families will expire in June 2025, excluding any patent term adjustment in the U.S. and patent term extensions available in the U.S. and several other jurisdictions, such as Europe.

In addition, the Company has rights to a third patent family that discloses combination therapies of Foralumab with Il-6 or IL-6R antibodies licensed from Novimmune. This patent family has one pending U.S. application. The patents in these families will expire in January 2032, excluding any patent term adjustment and patent term extensions available in the U.S.

The Company owns and has rights to a fourth patent family that discloses formulations of Foralumab and dosing regimens for treating various disorders. This patent family has applications pending in the U.S, Australia, Canada, China, Europe, Israel and Japan. The patents in these families will expire in August 2037, excluding any patent term adjustment and patent term extensions available in the U.S and several other jurisdictions.

The Company has rights to a patent family that discloses methods of using TZLS-501 to treat various disorders, licensed from Novimmune. This patent family includes, four granted U.S. patents and one granted European patent. This patent family also includes granted patents in Australia, Canada, China, Japan and Mexico. Applications are pending in U.S. and India. The patents in this family will expire in May 2029, excluding any patent term extensions available in several jurisdictions, such as Europe.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the USPTO delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability

of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

PART IX

REGULATORY AND OPERATING ENVIRONMENT

Overview

Government authorities in most jurisdictions extensively regulate the research, development, clinical testing, manufacture, distribution and marketing of pharmaceutical products such as those that the company is developing. Obtaining regulatory approvals and ensuring subsequent compliance with applicable laws and regulations requires the expenditure of substantial time and financial and managerial resources. Regulatory requirements in different jurisdictions vary, and the timing and success of efforts to obtain regulatory approvals can be highly uncertain. Development of a successful drug candidate, from identification of a candidate drug compound, through preclinical and clinical testing, to registration, typically takes more than ten years.

Drug development is a highly structured process divided into two major stages, preclinical and clinical. In the preclinical stage, the toxicology and mode of action of an active compound is evaluated. The clinical stage is designed to prove the safety of any new pharmaceutical, determine dosage requirements and, predominantly in the later phases, prove its therapeutic utility. This stage is carried out in three phases, which, as a developer moves through the phases, require increasingly large, complex, expensive and time-consuming clinical studies. During Phase 1, the product candidate is initially given to a small number of healthy human subjects or patients and tested for safety, tolerance, absorption, metabolism, distribution and excretion. During Phase 2, additional trials are conducted in a larger, but still relatively limited, patient population to verify that the product candidate has the desired effect and to identify optimal dosage levels. Furthermore, possible adverse effects and safety risks are identified. The therapeutic utility of the product candidate for specific targeted diseases is also studied in more depth. During Phase 3, trials are undertaken to further evaluate dosage, to provide statistically significant evidence of clinical effectiveness and to further study the safety in an expanded patient population at multiple clinical trial sites. Phase 3 trials may require several hundreds or thousands of patients and are therefore the most expensive and time-consuming to conduct. At any time during one of the phases, a trial may produce a negative result, in which case the developer may choose to end the development project.

Following completion of the Phase 3 trials, the developer submits all the preclinical and clinical trial documentation as well as extensive data characterizing the manufacturing process to the regulator to seek regulatory approval to market the formulation as a pharmaceutical product. The regulator reviews all the information related to the safety of the active compound, and whether the pharmacological effect claimed by the developer on the proposed label can be substantiated by the results of the clinical trials. The regulator has the option to decide to approve the application as requested, ask for changes to the claims made by the developer, ask for more information, require that further clinical trials are undertaken, or refuse to approve the formulation for sale.

Even after initial regulatory approval has been obtained, further studies, including Phase 4 post-approval safety studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. There are also 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, regulatory authorities require post-marketing reporting to monitor the adverse effects of the product. Results of post-approval programs may limit or expand the further marketing of the products. Further, if there are any modifications to the product, including changes in indication, manufacturing process or labeling, or a change in the manufacturing facility, an application seeking approval of such changes or, as the case may be, notification, must be submitted to the relevant regulatory authorities before the modified product can be commercialized. Moreover, an approved drug product may be subject to a REMS, which could impose a number of post-approval obligations, including (among other things) a communication plan for physicians regarding safe use of the drug, distribution and use restrictions, and/or periodic assessments of the effectiveness of the REMS. Finally, studies may be required as a contingency of regulatory approval (post-approval commitments), and completion of these studies within a regulator mandated time frame may be required.

European Union

The development, marketing and sale of medicinal products in the EU is subject to extensive pre and post marketing regulation by regulatory authorities at both the EU and national levels. The requirements, regulatory approvals and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, although there is some degree of EU wide harmonization.

Clinical Trials

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy and, in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the relevant regulatory authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the regulatory authority in each Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which has been delayed and now is not currently expected to take effect until mid-2021, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP.

Marketing Approval

In the EU medicinal products can only be commercialized after obtaining a marketing approval. There are three procedures for obtaining marketing approvals: the centralised procedure, the decentralised procedure and the mutual recognition procedure/national procedure.

The Community marketing authorization, which is issued by the European Commission through the centralized procedure, based on the opinion of the CHMP of the EMA, is valid throughout the entire territory of the EU. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Marketing approvals obtained using the decentralized procedure are available for products not falling within the mandatory scope of the Centralized Procedure. An identical dossier is submitted to the regulatory authorities of each of the Member States in which the marketing approval is sought, one of which is selected by the applicant as the Reference Member State ("**RMS**"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics and a draft of the labelling and package leaflet, which are sent to the other the concerned Member States, or CMSs, for their approval. A CMS can raise an objection, based on the assessment report, the summary of product characteristics, the labelling and the package leaflet on the grounds of potential serious risk to public health. If no such objections are raised the product will be granted a national marketing authorization in the RMS and all of the selected CMSs. Where a product has already been authorized for marketing in a Member State, this decentralized procedure approval can be recognized in other Member States through the mutual recognition procedure.

Marketing approvals obtained using the national procedure are issued by a single regulatory authority of one of the Member States and only apply to the territory covered by the relevant regulatory authority. They are available for products not falling within the mandatory scope of the

centralized procedure. Once a product has been authorized for marketing in a Member State through the national procedure, any application in another Member State must be by the mutual recognition procedure whereby the marketing approval can also be recognized in other Member States through the mutual recognition procedure.

Under the procedures described above, before granting the marketing approval, the EMA or the relevant regulatory authority of the Member States of the EU makes an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and therapeutic utility.

The holder of a marketing authorization in any Member State of the EU is subject to various obligations under applicable EU regulations, such as pharmacovigilance obligations, requiring it to, among other things, report and maintain detailed records of adverse reactions, and to submit periodic safety update reports to the regulatory authorities. The holder must also ensure that the manufacturing and batch release of its product is in compliance with the applicable requirements. The marketing approval holder is further obligated to ensure that the advertising and promotion of its products complies with applicable laws, which can differ from Member State to Member State of the EU.

Data Exclusivity

A Marketing Authorisation Application ("**MAA**") is an application submitted by a drug manufacturer seeking permission to bring a medicinal product (for example, a new medicine or generic medicine) to the market. MAAs for generic medicinal products in the EU do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the marketing approval of a reference product for which regulatory data exclusivity has expired. If a marketing approval is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic MAAs referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The EMA's Committee for Orphan Medicinal Products ("**COMP**"), may recommend orphan medicinal product designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan medicinal product designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication. Following a positive opinion by the COMP, the European Commission adopts a decision granting orphan status. The COMP will reassess orphan status in parallel with EMA review of a marketing authorization application and orphan status may be withdrawn at that stage if it no longer fulfils the orphan criteria (for instance because in the meantime a new product was approved for the indication and no convincing data are available to demonstrate a significant benefit over that product). Orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing authorization. During this period, the competent authorities may not accept or approve any similar medicinal product, unless it offers a significant clinical benefit. This period may be redacted to six

years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

United States

Standard Procedure

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act of 1938 and its implementing regulations. In order to request approval for marketing a new drug in the United States, a company must submit to the FDA a new drug application ("**NDA**") or a biologics license application ("**BLA**"). BLAs relate to biological products while NDAs generally pertain to traditional small molecule drugs. Both an NDA and a BLA are comprehensive documents describing a drug or biological product that has already passed through several clinical trials. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory studies, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by the institutional review board at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as GCPs to establish the safety and clinical utility of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA or an NDA;
- satisfactory completion of an FDA pre-approval inspection of the production facility or facilities where the product is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the product in the United States.

  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. 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 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.

Clinical Trials

Clinical trials involve the administration of the IND to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research patients provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, 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. In addition, an institutional review board at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their website. Regulatory authorities, institutional review boards or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls ("**CMC**"), and proposed labelling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of ten months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a filing decision.

In addition, under the Pediatric Research Equity Act of 2003, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant paediatric subpopulations, and to support dosing and administration for each paediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all paediatric data until after approval of the product for use in adults, or full or partial waivers from the paediatric data requirements.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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 reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. 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.

Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. 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 may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CR letter. A CR letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the

application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labelling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a 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-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labelling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an "orphan drug" if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, orphan drug designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

The designation as an orphan product does not guarantee that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as the Company's product candidates prior to the Company's product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before the Company do (regardless of the Company's orphan drug designation), the Company will be precluded from receiving marketing approval for the Company's product for the applicable exclusivity period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if the Company obtains orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the

latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, marketing authorisation may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Post-Approval Requirements for the EU and United States

The FDA and the relevant regulatory authorities in the EU strictly regulate marketing, labelling, advertising and promotion of products that are placed on the market in their respective territories. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The regulatory authorities 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, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the relevant regulatory authorities and are subject to periodic unannounced inspections by them to confirm compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior approval of the relevant regulatory authorities before being implemented. Regulations laid down by the FDA and the regulatory authorities in the EU also require investigation and correction of any deviations from the requirements of cGMP and impose reporting and documentation requirements upon the marketing approval holder and any third party manufacturers that the marketing approval holder may decide to use.

Some of the Company's product candidates are classified as biologics in the United States, and therefore, can only be sold if the Company obtain a BLA from the FDA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labelling or manufacturing process. In addition, the holder of a BLA must comply with the FDA's advertising and promotion requirements, such as those related to the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labelling (known as "off-label use"). Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If the Company, or a regulatory authority, discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labelling of that product (in addition to the Company's being obligated as holder of a BLA to monitor and report adverse events and any failure of a product to meet the BLA specifications), a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If the Company fails to comply with applicable regulatory requirements following approval of the Company's product candidates, a regulatory or enforcement authority may:

- issue a warning letter asserting that the Company is in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or the Company's strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of the product; or
- refuse to allow it to enter into supply contracts, including government contracts.

Other Healthcare Laws in the EU and United States

The Company will also be subject to healthcare regulation and enforcement by the U.S. federal government and the states and governments in the EU and any other countries in which the company conducts its business, including its research, and the marketing and distribution of its product candidates and products once they have obtained an MAA. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, exclusion from participating in health care programs, additional reporting requirements and oversight if the company becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and other sanctions. The healthcare laws and regulations that may affect the company's ability to operate in the United States include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. Many US states have similar laws and regulations that may differ from each other and federal law in significant ways. Moreover, several US states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. Rules and legislation covering more or less the same subject matter as those in the United States apply to in countries in the EU and to other countries. These can differ between jurisdictions and can sometimes result in lower or higher exposure in those countries than in the United States. Where a product is sold in a number of countries compliance efforts can therefore be complicated.

The related U.S. laws that will affect the Company's operations include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and wilfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for either the referral of an individual, or the purchase, leasing, furnishing or arranging for the purchase, lease or order of a good, facility, item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amended the intent requirement of the federal Anti-Kickback Statute, such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.
- Federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act of 1863.
- The federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economic and Clinical Health Act of 2009) ("**HIPAA**"), which created new federal criminal statutes that prohibit, among other things, a person from knowingly and wilfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private).

  HIPAA and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care

clearinghouses and health care providers, and their respective business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf.

- Federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- State and foreign law equivalents of each of the above federal laws, state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Coverage and Reimbursement in the United States and the EU

Sales of products developed from the Company's product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third party payors, such as government health care authorities, government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors develop their coverage and reimbursement policies. However, no uniform policy of coverage and reimbursement exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement. It is difficult to predict what the Centers for Medicare and Medicaid Services ("**CMS**") will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these types of products. Moreover, reimbursement agencies in the European Union may be more conservative than the CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union member states. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for the Company's product candidates.

Also, the containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010) (PPACA), contains provisions that may reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to product pricing, contain the cost of drugs, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

Governments influence the price of medicinal products in the EU through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other Member States allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general in the EU governments influence the price of medicinal products through their pricing and reimbursement.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that the Company are able to charge for the Company's product candidates. Accordingly, in markets outside the United States, the reimbursement for the Company's product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. 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 distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. To obtain reimbursement or pricing approval in some countries, the Company may be required to conduct a clinical trial that compares the cost-effectiveness of the Company's product candidates to other available therapies. If reimbursement of the Company's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the Company's business could be harmed.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for the Company's product candidates.

Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover product candidates that the Company or the Company's partners are able to commercialise. The Company expect to experience pricing pressures in connection with the sale of any of the Company's product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

Potential Changes to Healthcare Legislation

In the United States and elsewhere, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of the Company's product candidates, restrict or regulate post-approval activities and affect the Company's ability to profitably sell any product candidates for which the Company obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("**MMA**"), changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by adding a new Medicare Part D program and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class in their formularies. The MMA's cost reduction initiatives and other provisions could decrease the coverage and price that the Company receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets, which could similarly impact the Company's business.

More recently, in March 2010, the PPACA (as amended by the Health Care and Education Reconciliation Act of 2010) was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 per cent. point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic products that are demonstrated to be biosimilar or "interchangeable" with an FDA-approved biologic product. This new pathway could allow competitors to reference data from biologic products already approved after 12 years from the time of approval. This could expose us to potential competition by lower-cost biosimilars even if the Company commercialise a product candidate faster than the Company's competitors. Moreover, the creation of this abbreviated approval pathway does not preclude or delay a third party from pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical trial data.

Additional changes that may affect the Company's business include those governing enrolments in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the PPACA and the passage of additional laws and regulations may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

For each state that does not choose to expand its Medicaid program, there likely will be fewer insured patients overall, which could impact the sales, business and financial condition of manufacturers of branded prescription drugs. Where patients receive insurance coverage under any of the new options made available through the PPACA, manufacturers may be required to pay Medicaid rebates on that resulting drug utilization. The U.S. federal government also has announced delays in the implementation of key provisions of the PPACA. The implications of these delays for the Company's and the Company's potential partners' business and financial condition, if any, are not yet clear.

In addition, there have been judicial and congressional challenges to certain aspects of the PPACA, and the Company expect the current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, and Senate Republicans have released a draft bill known as the Better Care Reconciliation Act of 2017, each of which would repeal certain aspects of the PPACA if ultimately enacted. The prospects for enactment of these legislative initiatives remain uncertain. Further, Congress also could consider other legislation to replace elements of the PPACA. The Company cannot know how efforts to repeal and replace the PPACA or any future healthcare reform legislation will impact the Company's business.

The Company expects that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that the Company receives for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the Company from being able to generate revenue, attain profitability, or commercialise its products.

The Company expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for the Company's product candidates or additional pricing pressures.

Privacy and Data Protection Laws in Europe

The Company is subject to European laws relating to its and its suppliers', partners' and subcontractors' collection, control, processing and other use of personal data (i.e. any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). The Company is subject to the supervision of local data protection authorities in those jurisdictions where it is established, where it offer goods or services to EU residents and where it monitor the behaviour of individuals in the EU (i.e. undertaking clinical trials). The Company and its suppliers, partners and subcontractors process personal data including in relation to its employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation, or GDPR, the e-Privacy Directive (2002/58/EC) and the e-Privacy Regulation (once in force) and the national laws and regulations implementing or supplementing each of them.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner consistent with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the European Economic Area, (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organisational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which it can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of a data protection officer where sensitive personal data (i.e. health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when it are contracting with service providers.

In addition, to the extent a company processes, controls or otherwise uses "special category" personal data (including patients' health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which

a company is legally permitted to process that data. Finally, the GDPR provides a broad right for EEA Member States to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit its ability to use and share such data or could cause its costs to increase, and harm its business and financial condition.

The Company depends on a number of third parties in relation to the provision of its services, a number of which process personal data on its behalf. With each such provider it enters into contractual arrangements to ensure that they only process personal data according to its instructions, and that they have sufficient technical and organizational security measures in place. Where it transfers personal data outside the EU, it does so in compliance with the relevant data export requirements from time to time. The Company take its data protection obligations seriously, as any improper, unlawful or accidental disclosure, loss, alteration or access to, personal data, particularly sensitive personal data (i.e. special category), could negatively impact its business and/or its reputation.

The Company is also subject to EU laws on personal data export, as it may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer adequate protection of personal data. Such transfers need to be legitimised by a valid transfer mechanism under the GDPR. There is currently ongoing litigation challenging the commonly used transfer mechanisms, the EU Commission approved model clauses. In addition, the U.S. Privacy Shield was recently ruled invalid. As such, it is uncertain how the Privacy Shield framework and/or model clauses will be addressed. These changes may require the Company to find alternative bases for the compliant transfer of personal data from the EU to the United States and it is monitoring developments in this area. Invalidation of any mechanism on which it relies could require operational changes and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on its business.

The EU is in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each Member State, without the need for further enactment. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications and alters rules on third-party cookies, web beacons and similar technology. Regulation of cookies and web beacons may lead to broader restrictions on online research activities, including efforts to understand users' internet usage. The current draft also significantly increases fining powers to the same levels as GDPR (i.e. the greater of 20 million Euros or 4 per cent. of total global annual revenue). While no official timeframe has been provided, commentators have stated that the e-Privacy Regulation is likely to be agreed in 2019 and to come into force during the second half of 2020 or during 2021 following a transition period.

There are costs and administrative burdens associated with compliance with the GDPR and the resultant changes in the EU and EEA Member States' national laws and the introduction of the e-Privacy Regulation once it takes effect. Any failure or perceived failure to comply with global privacy laws carries with it the risk of significant penalties and sanctions of up to €20 million or 4 per cent. of global turnover. These laws or new interpretations, enactments or supplementary forms of these laws, could create liability for us, could impose additional operational requirements on its business, could affect the manner in which it use and transmit patient information and could increase its cost of doing business. Claims of violations of privacy rights or contractual breaches, even if it is not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm its business.

PART X

SELECTED FINANCIAL INFORMATION ON THE COMPANY

The selected financial information set out below has been extracted without material adjustment from the unaudited historical information of the Company for the six month period ended 30 June 2020 and the audited historical financial information of the Company for the 12 month period ended 31 December 2019, which is incorporated by reference in Part XVI – *Documents Incorporated by Reference* of this prospectus.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Continuing Operations	6 months to 30 June 2020 (unaudited)	Restated 6 months to 30 June 2019 (unaudited)	12 months to 31 December 2019 (audited) £'000	12 months to 31 December 2018 (audited) £'000	12 months to 31 December 2017 (audited) £'000
Research and development costs					
Operating expenses	760	(1,507)	(2,910)	(4,132)	(4,672)
Operating costs	(3,169)	(2,138)	(4,864)	(3,268)	(3,574)
Operating loss	(3,929)	(3,645)	(7,774)	(7,400)	(8,246)
Finance costs	(5)	(5)	(72)	(9)	(9)
Loss before taxation	(3,934)	(3,650)	(7,846)	(7,409)	(8,255)
Taxation	—	27	540	(1,459)	1,485
Loss for the year attributable to equity owners	(3,934)	(3,623)	(7,306)	(5,950)	(6,770)
Other comprehensive income that may be classified to profit and loss in subsequent periods					
Exchange differences on translation of foreign operations	23	52	129	(113)	—
Total comprehensive loss for the year attributable to equity owners	(3,911)	(3,571)	(7,177)	(6,063)	(4,770)
Loss per share					
Basic and diluted (loss) per share on continuing operations	(2.6p)	(2.6p)	(5.4p)	(4.7p)	(6.4p)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	6 months to 30 June 2020 (unaudited)	Restated 6 months to 30 June 2019 (unaudited)	12 months to 31 December 2019 (audited) £'000	12 months to 31 December 2018 (audited) £'000	12 months to 31 December 2017 (audited) £'000
ASSETS					
Non-Current assets					
Property, plant and equipment	5	5	5	6	**18**
Finance lease receivables	236	—	113	—	**—**
Right of use asset	308	358	329	—	**—**
Other non-current assets	217	217	217	217	**217**
Total non-current assets	766	580	664	223	235
Current assets					
Finance lease receivable	—	—	109	—	—
Related party receivable	—	—	245	20	20
Other receivables	2,013	245	124	228	94
Taxation receivable	513	827	513	800	1,434
Cash and cash equivalents	7,200	445	153	4,165	48
Total current assets	9,726	1,517	1,144	5,213	1,596
TOTAL ASSETS	10,492	2,097	1,808	5,436	1,831
EQUITY AND LIABILITIES					
Equity					
Capital and reserves attributable to equity holders of the company					
Called up share capital	4,992	4,094	4,099	4,094	3,752
Share premium	38,390	25,120	25,194	25,117	18,113
Capital reduction reserve	31,183	31,183	31,183	31,183	31,183
Shares to be issued reserve (convertible notes)	1,265	1,398	1,099	—	—
Share based payment reserve (options)	4,806	3,021	3,850	2,857	2,354
Share based payment reserve (warrants)	—	—	1,812	1,399	1,076
Other reserve	(28,286)	(28,286)	(28,286)	(28,286)	(28,286)
Translation reserve	(90)	(61)	15	(113)	—
Retained earnings	(47,318)	(39,463)	(43,146)	(35,840)	(29,874)
Total equity	4,942	(2,994)	4,180	411	(1,683)
Liabilities					
Non-Current liabilities					
Lease Liability	308	277	411	—	—
Current liabilities					
Trade and other payables	4,597	4,727	4,851	4,673	3,270
Lease liability	322	87	212	—	—
Related party payable	323	—	451	352	244
Other liabilities	—	—	63	—	—
Total current and non-current labilities	5,550	5,091	5,988	5,025	3514
TOTAL EQUITY AND LIABILITIES	10,492	2,097	1,808	5,436	1,831

Set out below are details of the significant changes in the financial position of the Company during, and subsequent to, the period ended 31 December 2019 and up to the date of this prospectus:

(i) On 16 March 2020, the Company announced the closing of its underwritten follow-on public offering of ADSs on the NASDAQ Global Market. The Company issued 3,333,333 ADSs (representing 16,666,665 new ordinary shares of nominal value £0.03 each in the capital of

the Company) at a price to the public of $3.00 per ADS raising gross proceeds of approximately $10 million (£8m) (before deducting underwriting discount, commissions and offering expenses);

(ii) On 15 April 2020, the Company raised £90,500 in connection with the exercise of options by a former director granted under the Company's 2014 share option scheme;

(iii) On 24 April 2020, the Company raised £599,435 due to the exercise of 1,712,672 warrants at a price of 35 pence per share;

(iv) On 18 May 2020, the Company raised £132,143 due to the exercise of 264,286 warrants at a price of 50 pence per share;

(v) On 2 June 2020, the Company raised £578,700 in respect of the exercise of 1,234,399 warrants at a price of 39 pence and 50 pence per share, The Company also announced that during the calendar month of May, the Company issued a total of 1,743,445 ordinary shares under the Company's ATM sales agreement announced on 15 April 2020 to meet sales of a total of 348,689 ADSs under the ATM sales agreement, totaling gross proceeds of $1,985,004;

(vi) On 24 July 2020, the Company raised £82,379 in cash through the exercise of warrants;

(vii) On 31 July 2020 – the Company announced that during the calendar month of July, it had issued a total of 2,043,000 ordinary shares under the Company's ATM sales agreement (announced on 15 April 2020) to meet sales of a total of 408,600 ADSs under the ATM sales agreement, totalling gross proceeds of $4,371,289;

(viii) On 5 August 2020, the Company announced the closing of its registered direct offering of ADSs on the NASDAQ Global Market. As of 3 August 2020, the Company issued 11,009,615 ADSs (representing 22,019,230 new ordinary shares of nominal value £0.03 each in the capital of the Company at a price of $5.20 per ADS raising gross proceeds of approximately $57.25 million (before deducting placement agent fees and offering expenses);

(xi) On 27 August 2020, the Company, raised £300,000 in cash through the exercise of warrants;

(x) On 16 September 2020, the Company entered into the Demerger Agreement with Accustem Sciences Limited pursuant to the terms of which the Tiziana declared a dividend in specie on the Ordinary Shares equal to the book value (of approximately £3.07m) of Tiziana's shareholding in StemPrintER Sciences Limited, the entity within the Group which holds all of the assets and intellectual property relating to StemPrintER and SPARE and £1.0 million in cash;

(xi) On 21 September 2020, the Company allotted 281,250 Ordinary Shares, credited as fully paid at a price of £1.28 per share in respect of agreements reached with certain members of the scientific advisory board concerning the commuting of cash fees into equity;

(xii) On 2 October 2020, resolutions were passed by Shareholders to approve the Demerger and to reduce the amount standing to the share premium account of the Company by £4,000,000 to facilitate the Demerger (the "**Capital Reduction**"). The Court sanctioned the Capital Reduction on 27 October 2020 and the Demerger became effective on 30 October 2020;

(xiii) On 20 October 2020, the Company issued 35,714 Ordinary Shares credited as fully paid on the exercise of certain warrants held by the Company's broker, Optiva;

(xiv) On 21 October 2020, the Company issued 1,750,000 Ordinary Shares of which 1,200,000 Ordinary Shares were issued credited as fully paid at a price of £0.15 per share and 550,000 shares were issued credited as fully paid at a price of £0.35 per share, both in respect of the exercise of share options by Gabriele Cerrone;

(xv) On 22 October 2020, the Company issued 285,714 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of warrants;

(xvi) On 26 October 2020, the Company issued 329,225 shares credited as fully paid at a price of £0.35 per share on the exercise of share options held by, inter alia, Gabriele Cerrone and Keeren Shah;

(xvii) On 28 October 2020, the Company issued 344,063 Ordinary Shares credited as fully paid at prices between £0.66 and £0.80 per share on the exercise of warrants; and

(xviii) On 29 October 2020, the Company issued 426,500 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of share options by, inter alia, Dr. Kunwar Shailubhai, Vaseem Palejwala and Jules Jacob.

PART XI

SHARE CAPITAL, LIQUIDITY AND CAPITAL RESOURCES

Share capital

The Company was incorporated as in England and Wales on 11 February 1998 as a private company with limited liability under the Companies Act with an indefinite life; re-registered as a public limited company on 8 June 1998 under the name Alexander David Investments Plc; and changed its name to Tiziana Life Sciences plc on 23 April 2014 when it acquired TPL via a reverse takeover (as defined in the AIM Rules). TPL was formed in November 2013.

Details of the Company's Existing Issued Share Capital are set out in paragraph 3 of Part XIV – *Additional Information* of this prospectus. As at Admission, there is expected to be £5,838,368.67 in nominal value of Ordinary Shares, divided into 194,612,289 issued Ordinary Shares of nominal value 3 pence each, all of which will be fully paid up.

All of the issued Ordinary Shares will be in registered form, and capable of being held in certificated or uncertificated form. The Registrar will be responsible for maintaining the share register. Temporary documents of title will not be issued. The ISIN of the Ordinary Shares is GB00BKWNZY55. The SEDOL code of the Ordinary Shares is BKWNZY5.

Fully diluted Existing Issued Share Capital

The following table sets out the fully diluted Existing Issued Share Capital as at the date of this prospectus and as at Admission:

	As of the date of this prospectus	As of the date of Admission	As a percentage of the Company's fully diluted Existing Issued Share Capital at Admission
Existing Issued Share Capital	194,612,289	194,612,289	91.4%
Existing Options	17,023,678	17,023,678	8.0%
Existing Warrants	1,183,491	1,183,491	0.6%

Accordingly, at Admission the share capital of the Company will be 194,612,289 Ordinary Shares with a total of 18,207,169 warrants and options outstanding. If all the warrants were to be exercised the Company would receive approximately £2,206,892 in cash and the options and warrants would represent 8.6 per cent. of the fully diluted Existing Issued Share Capital (as so enlarged).

Financial position

The financial information in respect of the Company upon which Mazars LLP has provided the accountant's report as at 31 December 2019, is set out in– Historical Financial Information on the Company.

Liquidity and capital resources

Sources of cash and liquidity

On 16 March 2020, the Company announced the closing of its underwritten follow-on public offering of ADSs on the NASDAQ Global Market. The Company issued 3,333,333 ADSs (representing 16,666,665 new ordinary shares of nominal value £0.03 each in the capital of the Company) at a price to the public of $3.00 per ADS raising gross proceeds of approximately $10 million (£8 million) (before deducting underwriting discount, commissions and offering expenses).

On 15 April 2020, the Company raised £90,500 in connection with the exercise of options by a former director granted under the Company's 2014 share option scheme.

On 24 April 2020, the Company raised £599,435 due to the exercise of 1,712,672 warrants at a price of 35 pence per share.

On 18 May 2020, the Company raised £132,143 due to the exercise of 264,286 warrants at a price of 50 pence per share.

On 2 June 2020, the Company raised £578,700 in respect of the exercise of 1,234,399 warrants at a price of 39 pence and 50 pence per share. The Company also announced that during the calendar month of May, the Company issued a total of 1,743,445 ordinary shares under the Company's ATM sales agreement announced on 15 April 2020 to meet sales of a total of 348,689 ADSs under the ATM sales agreement, totalling gross proceeds of $1,985,004.

On 24 July 2020, the Company raised £82,379 in cash through the exercise of warrants.

On 31 July 2020, the Company announced that during the calendar month of July, it had issued a total of 2,043,000 ordinary shares under the Company's ATM sales agreement (announced on 15 April 2020) to meet sales of a total of 408,600 ADSs under the ATM sales agreement, totalling gross proceeds of $4,371,289.

On 5 August 2020, the Company announced the closing of its registered direct offering of ADSs on the NASDAQ Global Market. As of 3 August 2020, the Company issued 11,009,615 ADSs (representing 22,019,230 new ordinary shares of nominal value £0.03 each in the capital of the Company at a price of $5.20 per ADS raising gross proceeds of approximately $57.25 million (before deducting placement agent fees and offering expenses).

On 27 August 2020, the Company, raised £300,000 in cash through the exercise of warrants.

On 21 September 2020, the Company allotted 281,250 Ordinary Shares, credited as fully paid at a price of £1.28 per share in respect of agreements reached with certain members of the scientific advisory board concerning the commuting of cash fees into equity.

On 20 October 2020, the Company issued 35,714 Ordinary Shares credited as fully paid on the exercise of certain warrants held by the Company's broker, Optiva.

On 21 October 2020, the Company issued 1,750,000 Ordinary Shares of which 1,200,000 Ordinary Shares were issued credited as fully paid at a price of £0.15 per share and 550,000 shares were issued credited as fully paid at a price of £0.35 per share, both in respect of the exercise of share options by Gabriele Cerrone.

On 22 October 2020, the Company issued 285,714 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of warrants.

On 26 October 2020, the Company issued 329,225 shares credited as fully paid at a price of £0.35 per share on the exercise of share options held by, *inter alia*, Gabriele Cerrone and Keeren Shah.

On 28 October 2020, the Company issued 344,063 Ordinary Shares credited as fully paid at prices between £0.66 and £0.80 per share on the exercise of warrants.

On 29 October 2020, the Company issued 426,500 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of share options by, inter alia, Dr. Kunwar Shailubhai, Vaseem Palejwala and Jules Jacob.

Following the Company's raise of $57.25 million raise on 5 August 2020, the Group has sufficient resources to fund its activities (including all clinical trials and programmes and operating expenditure) for at least the next 24 months. The Company's liquidity sufficiently covers the Group's short-term objectives and the clinical studies and trials due to start in 2020 and 2021 (as set out in paragraph 3 of Part VI – *The Company's Strategy*).

Current Liquidity

The Company's cash balances at 31 October 2020 were approximately £50.6 million, which the Company holds on deposit and in short-dated money market instruments.

Hedging arrangements and risk management

The Company may use forward contracts, options, swaps, caps, collars and floors or other strategies or forms of derivative instruments to limit its exposure to changes in the relative values of investments that may result from market developments, including changes in prevailing interest rates

and currency exchange rates, as previously described. It is expected that the extent of risk management activities by the Company will vary based on the level of exposure and consideration of risk across the business.

The success of any hedging or other derivative transaction generally will depend on the Company's ability to correctly predict market changes. As a result, while the Company may enter into such a transaction to reduce exposure to market risks, unanticipated market changes may result in poorer overall investment performance than if the transaction had not been executed. In addition, the degree of correlation between price movements of the instruments used in connection with hedging activities and price movements in a position being hedged may vary. Moreover, for a variety of reasons, the Company may not seek, or be successful in establishing, an exact correlation between the instruments used in a hedging or other derivative transactions and the position being hedged and could create new risks of loss. In addition, it may not be possible to fully or perfectly limit the Company's exposure against all changes in the values of its assets, because the values of its assets are likely to fluctuate as a result of a number of factors, some of which will be beyond the Company's control.

PART XII

TAXATION

UK Taxation

The following summary is intended only as a general guide and relates solely to UK tax. It is based on current UK law and published practice of H.M. Revenue & Customs as at the date of this prospectus, each of which may be subject to change, possibly with retrospective effect.

The following paragraphs are not intended to be exhaustive and relate only to certain limited aspects of the UK taxation consequences of acquiring, holding and disposing of the Ordinary Shares and do not constitute legal or tax advice. Except to the extent expressly stated, they apply only to holders of Ordinary Shares who are resident, and in the case of individuals, domiciled, solely in the United Kingdom for UK tax purposes, and who are the absolute beneficial owners of their Ordinary Shares and who do not hold their Ordinary Shares through an individual savings account or a self-invested personal pension ("**UK Holders**"). The information may not apply to certain classes of UK Holders such as tax exempt entities, collective investment schemes, pension schemes, insurance companies, financial institutions, dealers, professional investors, persons who hold Ordinary Shares in connection with a trade, profession or vocation, persons connected with the Company and persons who have acquired (or been deemed to have acquired) their Ordinary Shares by reason of their (or another person's) office or employment, to whom special rules may apply.

IT IS RECOMMENDED THAT ALL PROSPECTIVE HOLDERS OF ORDINARY SHARES OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ORDINARY SHARES IN THEIR OWN SPECIFIC CIRCUMSTANCES FROM THEIR OWN TAX ADVISERS. IN PARTICULAR, PROSPECTIVE SHAREHOLDERS WHO MAY BE SUBJECT TO TAX IN A JURISDICTION OTHER THAN THE UNITED KINGDOM ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

Dividends

Withholding Tax

Dividends paid by the Company will not be subject to any withholding or deduction for or on account of UK tax, irrespective of the residence or particular circumstances of the holders of Ordinary Shares.

Income Tax

An individual UK Holder may, depending on his or her particular circumstances, be subject to UK tax on dividends received from the Company.

All dividends received by an individual UK Holder from the Company (or from other sources, except to the extent within an individual savings account, self-invested pension plan or other regime which exempts dividends from tax) will form part of that UK Holder's total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the individual UK Holder in a tax year. Income within this nil-rate band will be taken into account in determining whether income in excess of the £2,000 nil-rate band falls within the basic rate, higher rate or additional rate tax bands. Dividend income in excess of the nil-rate band will (subject to the availability of any income tax personal allowance) be taxed at 7.5 per cent. to the extent that the excess amount falls within the basic rate tax band, 32.5 per cent. to the extent that the excess amount falls within the higher rate tax band and 38.1 per cent. to the extent that the excess amount falls within the additional rate tax band.

An individual holder of Ordinary Shares who is not resident for tax purposes in the United Kingdom should not be chargeable to UK income tax on dividends received from the Company unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency to which the Ordinary Shares are attributable. There are certain exceptions for trading in the United Kingdom through independent agents, such as some brokers and investment managers.

Corporation Tax

Corporate UK Holders should not be subject to UK corporation tax on any dividend received from the Company so long as the dividends qualify for exemption, which should generally be the case, provided certain conditions (including under anti-avoidance rules) are met. If the conditions for the exemption are not satisfied, or such UK Holder elects for an otherwise exempt dividend to be taxable, UK corporation tax will be chargeable on the amount of any dividends (currently at the rate of 19 per cent.).

A corporate holder of Ordinary Shares who is not resident for tax purposes in the United Kingdom should not be within the scope of UK corporation tax in respect of dividends received from the Company unless it carries on (whether solely or in partnership) a trade in the United Kingdom through a permanent establishment to which the Ordinary Shares are attributable.

Chargeable Gains

If a UK Holder disposes (or is treated as disposing) of some or all of its Ordinary Shares, a liability to tax on chargeable gains may arise, depending on the UK Holder's circumstances and any exemptions or reliefs which may be available.

Individual UK Holders

For an individual UK Holder, a disposal (or deemed disposal) of Ordinary Shares may give rise to a chargeable gain or allowable loss for the purposes of UK capital gains tax. For an individual UK Holder who is subject to UK income tax at either the higher or the additional rate, the current applicable rate of capital gains tax is 20 per cent. For an individual UK Holder who is subject to UK income tax at the basic rate, the current applicable rate would be 10 per cent., save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate currently applicable to the excess would be 20 per cent. An individual UK Holder is entitled to realise an annual exempt amount of gains (£12,300 for the year to 5 April 2021) without being liable to UK capital gains tax.

Corporate UK Holders

For a UK Holder within the charge to UK corporation tax, a disposal (or deemed disposal) of Ordinary Shares may give rise to a chargeable gain or to an allowable loss for the purposes of UK corporation tax. The current rate of UK corporation tax is 19 per cent. Indexation allowance is not available in respect of disposals of Ordinary Shares acquired on or after 1 January 2018 (and only covers the movement in the retail prices index up until 31 December 2017, in respect of assets acquired prior to that date).

Shareholders who are not UK Resident

A holder of Ordinary Shares who is not resident for tax purposes in the United Kingdom should not normally be liable to UK capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of Ordinary Shares unless (i) the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency (or, in the case of a corporate holder of Ordinary Shares, through a permanent establishment) to which the Ordinary Shares are attributable or (ii) in respect of disposals made on or after 6 April 2019, the Company directly or indirectly derives 75 per cent. or more of its qualifying asset value from UK land, in which case a holder may, depending on its circumstances, be liable for non-resident capital gains tax. However, an individual holder of Ordinary Shares who has ceased to be resident for tax purposes in the United Kingdom (including where an individual is treated as resident outside the United Kingdom for the purposes of a double tax treaty) for a period of five years or less and who disposes of Ordinary Shares during that period may be liable on his or her return to the United Kingdom to UK tax on any capital gain realised (subject to any available exemption or relief).

Stamp Duty and Stamp Duty Reserve Tax

The discussion below relates to holders of Ordinary Shares, wherever resident. However, special rules may apply where Ordinary Shares are issued or transferred to, or to a nominee or agent for, a depositary receipt issuer or clearance service provider, which are briefly summarised below, or persons such as market makers, brokers, dealers or intermediaries.

Issue of Shares

No UK stamp duty or stamp duty reserve tax ("**SDRT**") should ordinarily be payable on an issue of Ordinary Shares.

Transfers of certificated Ordinary Shares

Stamp duty at the rate of 0.5 per cent. (rounded up to the next multiple of £5) of the amount or value of the consideration given is generally payable on an instrument transferring Ordinary Shares. An exemption from stamp duty is available on an instrument transferring Ordinary Shares where the amount or value of the consideration is £1,000 or less, and it is certificated on the instrument that the transaction effected by the instrument does not form part of a larger transaction or series of transactions for which the aggregate consideration exceeds £1,000. A charge to SDRT will also arise on an unconditional agreement to transfer Ordinary Shares (at the rate of 0.5 per cent. of the amount or value of the consideration payable). However, if within six years of the date of the agreement becoming unconditional an instrument of transfer is executed pursuant to the agreement, and stamp duty is paid on that instrument, or the instrument is otherwise exempt, any SDRT already paid will be refunded (generally, but not necessarily, with interest) provided that a claim for repayment is made, and any outstanding liability to SDRT will be cancelled. The purchaser or transferee of Ordinary Shares will generally be accountable for the SDRT. In the absence of contractual agreement no party is legally responsible for the payment of stamp duty as it is not an assessable tax, however, in practice the purchaser or transferee will usually pay stamp duty to ensure that the Company's register of members can be updated by the registrar to show the new ownership.

Ordinary Shares transferred through paperless means including CREST

Paperless transfers of Ordinary Shares, such as those occurring within CREST, are generally liable to SDRT rather than stamp duty, at the rate of 0.5 per cent. of the amount or value of the consideration. CREST is obliged to collect SDRT on relevant transactions settled within the system and to pay this to HMRC. The SDRT charge is generally borne by the purchaser. Under the CREST System, no stamp duty or SDRT will arise on a transfer of Ordinary Shares into the CREST System unless such a transfer is made for consideration in money or money's worth, in which case a liability to SDRT (usually at a rate of 0.5 per cent.) will arise.

Ordinary Shares held through Clearance Systems or Depositary Receipt Arrangements

Special rules apply where Ordinary Shares are issued or transferred to, or to a nominee or agent for, either a person whose business is or includes issuing depositary receipts within Section 67 or Section 93 of the Finance Act 1986 or a person providing a clearance service within Section 70 or Section 96 of the Finance Act 1986, under which SDRT or stamp duty may be charged at a rate of 1.5 per cent. Following litigation, HMRC confirmed that they will no longer seek to apply the 1.5 per cent. SDRT charge on an issue of shares into a clearance service or depositary receipt arrangement on the basis that the charge is not compatible with EU law. It was announced on 22 November 2017 that the government will not seek to reintroduce this charge following the departure of the UK from the European Union.

Based on current published HMRC practice and recent case law, no SDRT is generally payable where the transfer of shares to a clearance service or depositary receipt system is an integral part of an issue of share capital. Any liability for stamp duty or SDRT in respect of such a transfer that is not integral to an issue of share capital will generally be accountable by the clearance service or depositary 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 depositary receipt system.

Transfers of Ordinary Shares within a depositary receipt system or a clearance service that has not made and maintained an election under section 97A of the Finance Act 1986 (a "**section 97A election**") will be exempt from SDRT and, provided no instrument of transfer is entered into, will not be subject to stamp duty.

Where a clearance service has made and maintained a section 97A election the 1.5 per cent. charge will not apply. Rather, stamp duty or SDRT will be charged at the normal rate of 0.5 per cent. on the transfer of existing shares into and within the clearance service.

Accordingly, specific professional advice should be sought before incurring a 1.5 per cent. stamp duty or stamp duty reserve tax charge in any circumstances.

Inheritance tax

The Ordinary Shares will be assets situated in the UK for the purposes of UK inheritance tax. A gift of such assets by, or the death of, an individual holder of such assets may (subject to certain exemptions and reliefs) give rise to a liability to UK inheritance tax even if the holder is neither domiciled in the UK nor deemed to be domiciled there under certain rules relating to long residence or previous domicile. For inheritance tax purposes, a transfer of assets at less than full market value may be treated as a gift and particular rules apply to gifts where the donor reserves or retains some benefit.

Special rules also apply to close companies and to trustees of settlements who hold Ordinary Shares, bringing them within the charge to inheritance tax. Shareholders should consult an appropriate tax adviser if they make a gift or transfer at less than market value or intend to hold any Ordinary Shares through trust arrangements. They should also seek professional advice in a situation where there is potential for a double charge to UK inheritance tax and an equivalent tax in another country or if they are in any doubt about their UK inheritance tax position.

PART XIII

CONSEQUENCES OF A STANDARD LISTING

An application will be required to be made for the immediate admission of the Issued Share Capital to a Standard Listing (pursuant to Chapter 14 of the Listing Rules) and to trading on the Main Market of the London Stock Exchange. The Company intends to comply with the Listing Principles set out in Chapter 7 of the Listing Rules at Listing Rule 7.2.1 which apply to all companies with their securities admitted to the Official List. Premium Listing Principles 1 to 6 as set out in Listing Rule 7.2.1AR of the Listing Rules do not apply to the Company.

However, while the Company has a Standard Listing, it is not required to comply with the provisions of, *inter alia*:

- Chapter 8 of the Listing Rules regarding the appointment of a sponsor to guide the Company in understanding and meeting its responsibilities under the Listing Rules in connection with certain matters. The Company has not and does not intend to appoint such a sponsor in connection with the Admission;
- Chapter 9 of the Listing Rules relating to the ongoing obligations for companies admitted to the Premium List and therefore does not apply to the Company.
- Chapter 10 of the Listing Rules relating to significant transactions. It should be noted therefore that an acquisition will not require Shareholder consent, even if Ordinary Shares are being issued as consideration for such acquisition;
- Chapter 11 of the Listing Rules regarding related party transactions. Nevertheless, the Company will not enter into any transaction which would constitute a 'related party transaction' as defined in Chapter 11 of the Listing Rules without the specific prior approval of the Directors;
- Chapter 12 of the Listing Rules regarding purchases by the Company of its Ordinary Shares. In particular, the Company has not adopted a policy consistent with the provisions of Listing Rules 12.4.1 and 12.4.2; and
- Chapter 13 of the Listing Rules regarding the form and content of circulars to be sent to Shareholders.

It should be noted that the FCA will not have the authority to (and will not) monitor the Company's compliance with any of the Listing Rules which the Company has indicated herein that it intends to comply with on a voluntary basis, nor to impose sanctions in respect of any failure by the Company so to comply. However, the FCA would be able to impose sanctions for non-compliance where the statements regarding compliance in this prospectus are themselves misleading, false or deceptive.

PART XIV

ADDITIONAL INFORMATION

1. RESPONSIBILITY

The Directors, whose names appear on page 46, and the Company accepts responsibility for the information contained in this prospectus. To the best of the knowledge of the Directors and the Company, the information contained in this prospectus is in accordance with the facts and the prospectus makes no omission likely to affect its import.

2. THE COMPANY

2.1 The Company was incorporated as in England and Wales on 11 February 1998 as a private company with limited liability under the Companies Act with an indefinite life; re-registered as a public limited company on 8 June 1998 under the name Alexander David Investments Plc; and changed its name to Tiziana Life Sciences plc on 23 April 2014 when it acquired TPL via a reverse takeover (as defined in the AIM Rules). TPL was formed in November 2013. On 20 November 2018, the Company's ADSs were listed for trading on NASDAQ

2.2 The Company is not regulated by the FCA or any financial services or other regulator. The Company is subject to the Listing Rules and the Disclosure Guidance and Transparency Rules (and the resulting jurisdiction of the FCA), to the extent such rules apply to companies with a Standard Listing pursuant to Chapter 14 of the Listing Rules.

2.3 As at the date of this prospectus, the Company has three, wholly-owned subsidiaries: TPL (England and Wales); Tiziana Therapeutics, Inc. (Delaware, USA); Longevia Genomics SRL (Italy); and StemPrintER Sciences Limited (England and Wales).

2.4 The principal legislation under which the Company operates, and pursuant to which the Ordinary Shares have been created, is the Companies Act and the regulations made thereunder. The Company operates in conformity with its constitution.

2.5 The Company's registered office is at 3rd Floor, 11-12 St James's Square, London SW1Y 4LB. The Company's telephone number is +44 20 7495 2379.

2.6 On incorporation of the Company, Hallmark Secretaries Limited subscribed for 1 Ordinary Share of nominal value £1.00 in the capital of the Company at par and Hallmark Registrars Limited subscribed for 1 Ordinary Share of nominal value £1.00 in the capital of the Company at par.

2.7 On 5 March 2018, the Company allotted a total 1,682,813 Ordinary Shares of £0.03 each for a total of £1,466,250.40.

2.8 On 27 April 2018, the Company allotted a total of 23,014 Ordinary Shares of £0.03 each for a total of £16,109.80.

2.9 On 19 November 2018, the Company allotted a total of 1,515,150 Ordinary Shares of £0.03 each for a total of £1,136,362.50.

2.10 On 20th November 2018, the Company allotted a total of 3,538,269 Ordinary Shares of £0.03 each for a total of £2,372,715.20.

2.11 On 23rd November 2018, the Company allotted a total of 4,429,100 Ordinary Shares of £0.03 each for a total of £3,321,825.00.

2.12 On 11 December 2018, the Company allotted a total of 54,000 Ordinary Shares of £0.03 each for a total amount of £41,566.68.

2.13 On 19 November 2019, the Company allotted a total of 190,698 Ordinary Shares of £0.03 each for a total amount of £82,000.14.

2.14 On 16 March 2020, the Company allotted 16,666,665 Ordinary Shares of £0.03 each for a total of £7,999,999.20.

2.15 On 15 April 2020, the Company allotted 670,950 Ordinary Shares of £0.03 each for a total of £233,541.50.

2.16 On 17 April 2020, the Company allotted 150,000 Ordinary Shares of £0.03 each for a total of £82,500.00.

2.17 On 20 April 2020, the Company allotted 205,955 Ordinary Shares of £0.03 each for a total of £111,215.70.

2.18 On 22 April 2020, the Company allotted 50,000 Ordinary Shares of £0.03 each for a total of £26,000.00.

2.19 On 23 April 2020, the Company allotted a total of 6,118,797 Ordinary Shares of £0.03 each for a total of £2,450,007.70.

2.20 On 28 April 2020, the Company allotted a total of 250,000 Ordinary Shares of £0.03 each for a total of £135,000.00.

2.21 On 5 May 2020, the Company allotted a total of 200,000 Ordinary Shares of £0.03 each for a total of £100,000.00.

2.22 On 12 May 2020, the Company allotted a total of 5,180 Ordinary Shares of £0.03 each for a total of £3,522.40.

2.23 On 13 May 2020, the Company allotted a total of 14,315 Ordinary Shares of £0.03 each for a total of £9,447.90.

2.24 On 18 May 2020, the Company allotted a total of 228,950 Ordinary Shares of £0.03 each for a total of £212,923.50.

2.25 On 19 May 2020, the Company allotted a total of 370,000 Ordinary Shares of £0.03 each for a total of £358,900.00.

2.26 On 22 May 2020, the Company allotted a total of 264,286 Ordinary Shares of £0.03 each for a total of £132,143.00.

2.27 On 26 May 2020, the Company allotted a total of 250,000 Ordinary Shares of £0.03 each for a total of £222,500.00.

2.28 On 27 May 2020, the Company allotted a total of 500,000 Ordinary Shares of £0.03 each for a total of £515,000.00.

2.29 On 1 June 2020, the Company allotted a total of 175,000 Ordinary Shares of £0.03 each for a total of £189,000.00.

2.30 On 2 June 2020, the Company allotted a total of 300,000 Ordinary Shares of £0.03 each for a total of £330,000.00.

2.31 On 5 June 2020, the Company allotted a total of 50,000 Ordinary Shares of £0.03 each for a total of £52,500.00.

2.32 On 22 June 2020, the Company allotted a total of 250,000 Ordinary Shares of £0.03 each for a total of £267,500.00.

2.33 On 30 June 2020, the Company allotted a total of 77,500 Ordinary Shares of £0.03 each for a total of £82,150.00.

2.34 On 13 July 2020, the Company allotted a total of 25,000 Ordinary Shares of £0.03 each for a total of £30,250.00.

2.35 On 15 July 2020, the Company allotted a total of 375,500 Ordinary Shares of £0.03 each for a total of £554,810.00.

2.36 On 16 July 2020, the Company allotted a total of 80,000 Ordinary Shares of £0.03 each for a total of £120,800.00.

2.37 On 17 July 2020, the Company allotted a total of 85,000 Ordinary Shares of £0.03 each for a total of £133,450.00.

2.38 On 20 July 2020, the Company allotted a total of 550,000 Ordinary Shares of £0.03 each for a total of £940,500.00.

2.39 On 21 July 2020, the Company allotted a total of 850,000 Ordinary Shares of £0.03 each for a total of £1,623,500.00.

2.40 On 24 July 2020, the Company allotted a total of 88,580 Ordinary Shares of £0.03 each for a total of £82,379.

2.41 On 3 August 2020, a registered direct offering was made through the Company's ADS's which resulted in an issue for 22,019,230 Ordinary Shares of £0.03 each for a total of approximately $57.25 million.

2.42 On 29 August 2020, the Company allotted a total of 600,000 Ordinary Shares of £0.03 each for a total of £300,000.

2.43 On 21 September 2020, the Company allotted 281,250 Ordinary Shares, credited as fully paid at a price of £1.28 per share in respect of agreements reached with certain members of the scientific advisory board concerning the commuting of cash fees into equity.

2.44 On 2 October 2020, resolutions were passed by Shareholders to approve the Demerger and to reduce the amount standing to the share premium account of the Company by £4,000,000 to facilitate the Demerger (the "**Capital Reduction**"). The Court sanctioned the Capital Reduction on 27 October 2020 and the Demerger became effective on 30 October 2020.

2.45 On 20 October 2020, the Company issued 35,714 Ordinary Shares credited as fully paid on the exercise of certain warrants held by the Company's broker, Optiva.

2.46 On 21 October 2020, the Company issued 1,750,000 Ordinary Shares of which 1,200,000 Ordinary Shares were issued credited as fully paid at a price of £0.15 per share and 550,000 shares were issued credited as fully paid at a price of £0.35 per share, both in respect of the exercise of share options by Gabriele Cerrone.

2.47 On 22 October 2020, the Company issued 285,714 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of warrants.

2.48 On 26 October 2020, the Company issued 329,225 shares credited as fully paid at a price of £0.35 per share on the exercise of share options held by, inter alia, Gabriele Cerrone and Keeren Shah.

2.49 On 28 October 2020, the Company issued 344,063 Ordinary Shares credited as fully paid at prices between £0.66 and £0.80 per share on the exercise of warrants.

2.50 On 29 October 2020, the Company issued 426,500 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of share options by, *inter alia*, Dr. Kunwar Shailubhai, Vaseem Palejwala and Jules Jacob.

3. SHARE CAPITAL

3.1 The following table shows the issued and fully paid shares of the Company at the date of this prospectus:

Class	Number	Amount paid
Ordinary Shares	194,612,289	£5,838,368.67

3.2 Pursuant to an ordinary resolution of the Shareholders passed at the 2020 AGM of the Company held on 16 July 2020 the Directors, in accordance with section 551 of the Companies Act, were generally and unconditionally authorised to allot shares in the Company, or to grant rights to subscribe for or to convert any security into shares in the Company ("**Rights**"):

(i) up to an aggregate nominal amount of £1,623,690; and

(ii) comprising equity securities (as defined in section 560 of the Act) up to an aggregate nominal amount of £1,623,690 (such amount to be reduced by the aggregate nominal amount of any allotments or grants made under paragraph (i) of this resolution) in connection with an offer by way of rights issue:

A) to ordinary shareholders in proportion (as nearly as may be practicable) to their existing holdings; and

B) to holders of other equity securities as required by the rights of those securities or, subject to such rights, as the Directors otherwise consider necessary,

and so that the Directors may impose any limits or restrictions and make any arrangements which they consider necessary or appropriate to deal with treasury shares, fractional entitlements, record dates, legal, regulatory or practical problems in, or under the laws of any territory or any other matter, such authorities to expire at the conclusion of the Company's next AGM after this resolution is passed or, if earlier, 15 months after the passing of this Resolution, but, in each case, so that the Company may make offers or agreements before the authority expires which would or might require shares to be allotted or Rights to be granted after the authority expires, and so that the Directors may allot shares or grant Rights in pursuance of any such offer or agreement notwithstanding that the authority conferred by this resolution has expired.

3.3 Pursuant to a special resolution of the Shareholders passed at the 2020 AGM of the Company held on 16 July 2020:

(a) the Directors, in accordance with sections 570 and 573 of the Companies Act, were generally empowered to allot equity securities (as defined in section 560 of the Companies Act) for cash pursuant to the authorities granted by the resolution in paragraph 3.2 above, and/or sell ordinary shares held by the Company as if section 561 of the Companies Act did not apply to any such allotment or sale provided that this power shall be limited:

(i) to the allotment of equity securities in connection with an offer of equity securities (but in the case of an allotment pursuant to the authority granted under paragraph

(ii) of the resolution in paragraph 3.2 above, such power shall be limited to the allotment of equity securities in connection with an offer by way of rights issue only):

A) to ordinary shareholders in proportion (as nearly as may be practicable) to their existing holdings; and

B) to holders of other equity securities, as required by the rights of those securities or, subject to such rights, as the Directors otherwise consider necessary,

and so that the Directors may impose any limits or restrictions and make any arrangements which they consider necessary or appropriate to deal with treasury shares, fractional entitlements, record dates, legal, regulatory or practical problems in, or under the laws of any territory or any other matter; and

(iii) to the allotment (otherwise than in the circumstances set out in paragraph (i) of this resolution) of equity securities or sale of treasury shares pursuant to the authority granted by paragraph (i) of the resolution in paragraph 3.2 above, up to an aggregate nominal amount of £1,000,000, such power to expire at the conclusion of the Company's next AGM after this resolution is passed or, if earlier, 15 months after the passing of this resolution, but so that the Company may make offers or agreements before the power expires which would or might require equity securities to be allotted (and/or treasury shares to be sold) after the power expires and so that the Directors may allot equity securities (and/or sell treasury shares) in pursuance of any such offer or agreement notwithstanding that the power conferred by this authority has expired; and

(b) the Directors, in accordance with sections 570 and 573 of the Companies Act, were generally empowered to allot equity securities (as defined in section 560 of the Companies Act) for cash pursuant to the authorities granted by the resolution in paragraph 3.2 above, and/or sell ordinary shares held by the Company as if section 561 of the Companies Act did not apply to any such allotment or sale provided that this power shall be:

(i) limited to the allotment of equity securities or sale of treasury shares pursuant to the authority granted by paragraph (i) of Resolution 9 up to an aggregate nominal amount of £1,623,690; and

(ii) the allotment of equity securities for cash otherwise than pursuant to sub-paragraph up to an aggregate maximum nominal amount of £984,054.

such power to expire at the conclusion of the Company's next AGM after this resolution is passed or, if earlier, 15 months after the passing of this Resolution, but so that the Company may make offers or agreements before the power expires which would or might require equity securities (and/or treasury shares to be sold) to be allotted after the power expires and so that the Directors may allot equity securities (and/or sell treasury shares) in pursuance of any such offer or agreement notwithstanding that the power conferred by this authority has expired.

3.4 Save as disclosed in this prospectus:

(a) no Ordinary Share or loan capital of the Company has been issued or is proposed to be issued;

(b) no person has any preferential subscription rights for any Ordinary Shares in the Company;

(c) no Ordinary Share or loan capital of the Company is unconditionally to be put under option;

(d) no commissions, discounts, brokerages or other special terms have been granted by the Company since its incorporation in connection with the issue or sale of any share or loan capital of the Company;

3.5 Save as set out in: (i) paragraph 9 below with respect to the 1,183,491 Warrants; and (ii) paragraph 8 below with respect to the 17,023,678 options outstanding over Ordinary Shares under the terms of the two options plans, the Company does not have any convertible securities, exchangeable securities or securities with warrants currently in issue.

3.6 All Ordinary Shares in the capital of the Company are in registered form.

3.7 The Ordinary Shares are currently admitted to trading on AIM. An application will be made for the Ordinary Shares to be admitted to a Standard Listing on the Official List and traded on the Main Market for listed securities of the London Stock Exchange. ADSs, each representing 2 Ordinary Shares are traded on the Global Capital Market of NASDAQ. Save as set out above, the Ordinary Shares are not listed or traded on, and no application has been or is being made for the admission of the Ordinary Shares to listing or trading on, any other stock exchange or securities market.

3.8 The Company has only fully paid Ordinary Shares in issue and no shares which do not represent capital.

3.9 No Ordinary Shares are held by or on behalf of the Company or by any subsidiary of the Company.

4. ARTICLES OF ASSOCIATION OF THE COMPANY

4.1 The Articles of the Company were adopted by a special resolution of the Shareholders passed by written resolution on 6 May 2020. A summary of the terms of the Articles is set out below. The summary below is not a complete copy of the terms of the Articles.

4.2 The Articles contain no specific restrictions on the Company's objects and therefore, by virtue of section 31(1) of the Companies Act, the Company's objects are unrestricted.

4.3 The Articles contain, *inter alia*, provisions to the following effect:

(a) ***Share capital***

The Company's Issued Share Capital currently consists of Ordinary Shares. The Company may issue shares with such rights or restrictions as may be determined by ordinary resolution, including shares which are to be redeemed, or are liable to be

redeemed at the option of the Company or the holder of such shares. The Ordinary Shares are not convertible into any other security in the Company.

(b) ***Voting***

The Shareholders have the right to receive notice of, and to vote at, general meetings of the Company. Such notice shall specify whether the meeting shall be a physical or electronic meeting or a hybrid meeting. Any resolution put to the vote of a general meeting must be decided exclusively on a poll. Votes may be given in person or by proxy. A member entitled to more than one vote need not, if he votes, use all his votes or cast all the votes he uses in the same way. Every such holder who is present in person (or, being a corporation, by representative) or by proxy has one vote in respect of every share held by him.

(c) ***Variation of rights***

Whenever the share capital of the Company is divided into different classes of shares, the special rights attached to any class may be varied or abrogated either with the consent in writing of the holders of three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class and may be so varied and abrogated whilst the Company is a going concern or during or in contemplation of a winding up.

(d) ***Liquidation***

In the event of the liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to members shall be distributed amongst all holders of Ordinary Shares, in proportion to the number of Ordinary Shares held irrespective of the amount paid or credited as paid on any share.

(e) ***Dividends***

The Company may, subject to the provisions of the Companies Act and the Articles, by ordinary resolution from time to time declare dividends to be paid to members not exceeding the amount recommended by the Directors. Subject to the provisions of the Companies Act in so far as, in the Directors' opinions, the Company's profits justify such payments, the Directors may pay interim dividends on any class of shares.

Any dividend unclaimed after a period of 12 years from the date such dividend was declared or became payable shall, if the Directors resolve, be forfeited and shall revert to the Company. No dividend or other moneys payable on or in respect of a share shall bear interest as against the Company.

(f) ***Transfer of Ordinary Shares***

Each member may transfer all or any of his shares which are in certificated form by means of an instrument of transfer in any usual form or in any other form which the Directors may approve. Each member may transfer all or any of his shares which are in uncertificated form by means of a 'relevant system'.

The Board may, in its absolute discretion, refuse to register a transfer of certificated shares unless:

(i) it is for a share which is fully paid up;

(ii) it is for a share upon which the Company has no lien;

(iii) it is only for one class of share;

(iv) it is in favour of a single transferee or no more than four joint transferees;

(v) it is duly stamped or is duly certificated or otherwise shown to the satisfaction of the Board to be exempt from stamp duty; and

(vi) it is delivered for registration to the registered office of the Company (or such other place as the Board may determine), accompanied (except in the case of a transfer by a person to whom the Company is not required by law to issue a certificate and to whom a certificate has not been issued or in the case of a renunciation) by the certificate for the shares to which it relates and such other

evidence as the Board may reasonably require to prove the title of the transferor (or person renouncing) and the due execution of the transfer or renunciation by him or, if the transfer or renunciation is executed by some other person on his behalf, the authority of that person to do so.

The Directors may refuse to register a transfer of uncertificated shares in any circumstances that are allowed or required by the uncertificated securities rules and the relevant system.

(g) ***Allotment of shares and pre-emption rights***

Subject to the Companies Acts, the Articles and to any relevant authority of the Company in general meeting required by the Act, the Board may offer, allot (with or without conferring rights of renunciation), grant options over or otherwise deal with or dispose of shares or grant rights to subscribe for or convert any security into shares to such persons, at such times and upon such terms as the Board may decide. No share may be issued at a discount to the nominal value of such share.

Subject to the Companies Act and to any rights attached to existing shares, any share may be issued with or have attached to it such rights and restrictions as the Company may by ordinary resolution determine, or if no ordinary resolution has been passed or so far as the resolution does not make specific provision, as the Directors may determine (including shares which are to be redeemed, or are liable to be redeemed at the option of the Company or the holder of such shares).

In accordance with section 551 of the Companies Act, the Directors may be generally and unconditionally authorised to exercise all the powers of the Company to allot shares up to an aggregate nominal amount equal to the amount stated in the relevant ordinary resolution authorising such allotment. The authorities referred to in paragraph 3.3(a) and 3.3(b) above were included in the special resolution passed at the 2020 AGM and remain in force at the date of this prospectus.

The provisions of section 561 of the Companies Act (which confer on Shareholders rights of pre-emption in respect of the allotment of equity securities which are paid up in cash) apply to the Company except to the extent disapplied by special resolution of the Company. Such pre-emption rights have been disapplied to the extent referred to in paragraph 3.3(b) above pursuant to the special resolution passed at the 2020 AGM.

(h) ***Redeemable Shares***

Subject to the Companies Acts and to any rights attaching to existing shares, the Company may issue any share which can be redeemed or is liable to be redeemed at the option of the Company or the holder. The Board may determine the terms, conditions and manner of redemption of any redeemable shares which are issued. Such terms and conditions shall apply to the relevant shares as if the same were set out in these Articles. Currently, the Company has not issued any redeemable shares.

(i) ***Alteration of share capital***

The Company may by ordinary resolution consolidate or divide all of its share capital into shares of larger nominal value than its existing shares, or cancel any shares which, at the date of the ordinary resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the nominal amount of shares so cancelled or sub-divide its shares, or any of them, into shares of smaller nominal value.

The Company may, in accordance with the Companies Act, reduce or cancel its share capital or any capital redemption reserve or share premium account in any manner and with and subject to any conditions, authorities and consents required by law.

(j) ***Directors***

Unless otherwise determined by the Company by ordinary resolution, the number of Directors (other than any alternate Directors) shall be at least two and not more than fifteen (15).

Subject to the Articles and the Companies Acts, the Company may by ordinary resolution appoint a person who is willing to act to be a Director, either to fill a vacancy or as an addition to the existing Board but the total number of Directors shall not exceed any maximum number fixed in accordance with the Articles.

Subject to these Articles, the Board shall have power at any time to appoint any person who is willing to act as a Director, either to fill a vacancy or as an addition to the existing Board but the total number of Directors shall not exceed any maximum number fixed in accordance with these Articles.

At each annual general meeting of the Company all Directors shall retire from office except any Director appointed by the Board after the notice of that annual general meeting has been given and before that annual general meeting has been held.

Subject to the Companies Acts, these Articles and to any directions given by special resolution of the Company, the business of the Company will be managed by the Board, which may exercise all the powers of the Company, whether relating to the management of the business or not.

The quorum for a Directors' meeting shall be fixed from time to time by a decision of the Directors, but it must never be less than two and unless otherwise fixed, it is two.

Questions arising at any Board meeting shall be determined by a majority of votes. In the case of an equality of votes the chairman of that meeting shall have a second or casting vote (unless he is not entitled to vote on the resolution in question).

Each of the Directors may be paid a fee at such rate as may from time to time be determined by the Board. However, the aggregate of all fees payable to the Directors (other than amounts payable under any other provision of the Articles) must not exceed £2,000,000 a year or such higher amount as may from time to time be decided by ordinary resolution of the Company. Any fees payable under this provision shall be distinct from any salary, remuneration or other amounts payable to a Director under any other provisions of the Articles and shall accrue from day to day.

The Directors shall also be entitled to be paid all reasonable expenses properly incurred by them in connection with their attendance at meetings of Shareholders or class meetings, board or committee meetings or otherwise in connection with the exercise of their powers and the discharge of their responsibilities in relation to the Company.

The Board may, in accordance with the requirements in the Articles, authorise any matter proposed to them by any Director which would, if not authorised, involve a Director breaching his duty under the Companies Act to avoid conflicts of interests.

A Director seeking authorisation in respect of such conflict shall declare to the Board the nature and extent of their interest in a conflict as soon as is reasonably practicable.

The Director shall provide the Board with such details of the matter as are necessary for the Board to decide how to address the Conflict together with such additional information as may be requested by the Board.

Any authorisation by the Board will be effective only if:

(i) to the extent permitted by the Companies Act, the matter in question shall have been proposed by any Director for consideration in the same way that any other matter may be proposed to the Directors under the provisions of the Articles;

(ii) any requirement as to the quorum for consideration of the relevant matter is met without counting the conflicted Director and any other conflicted Director; and

(iii) the matter is agreed to without the conflicted Director voting or would be agreed to if the conflicted Director's and any other interested Director's vote is not counted.

Subject to the provisions of the Companies Act, every Director, secretary or other officer of the Company (other than an auditor) is entitled to be indemnified against all costs, charges, losses, damages and liabilities incurred by him in the actual purported

exercise or discharge of his duties or exercise of his powers or otherwise in relation to them.

(k) ***General meetings***

The Company must convene and hold AGMs in accordance with the Companies Act.

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the choice or appointment of a Chair of the meeting which shall not be treated as part of the business of the meeting. Save as otherwise provided by the articles, two Shareholders present in person or by proxy and entitled to vote shall be a quorum for all purposes.

(l) ***Borrowing powers***

Subject to the Articles and the Companies Act, the Board may exercise all of the powers of the Company to:

(i) borrow money;

(ii) indemnify and guarantee;

(iii) mortgage or charge all or any part of the undertaking, property and assets (present and future) and uncalled capital of the Company;

(iv) create and issue debentures and other securities; and

(v) give security either outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

(m) ***Capitalisation of profits***

The Directors may, if they are so authorised by an ordinary resolution of the Shareholders, decide to capitalise any undivided profits of the Company (whether or not they are available for distribution), or any sum standing to the credit of the Company's share premium account or capital redemption reserve. The Directors may also, subject to the aforementioned ordinary resolution, appropriate any sum which they so decide to capitalise to the persons who would have been entitled to it if it were distributed by way of dividend and in the same proportions.

(n) ***Uncertificated shares***

Subject to the Companies Act and the uncertificated securities rules, the Board may permit title to shares of any class to be evidenced otherwise than by certificate and title to shares of such a class to be transferred by means of a relevant system and may make arrangements for a class of shares (if all shares of that class are in all respects identical) to become a participating class. Title to shares of a particular class may only be evidenced otherwise than by a certificate where that class of shares is at the relevant time a participating class

The Board may also, subject to compliance with the uncertificated securities rules, determine at any time that title to any class of shares may from a date specified by the Board no longer be evidenced otherwise than by a certificate or that title to such a class shall cease to be transferred by means of any particular relevant system.

The Board may take such other action that the Board considers appropriate to achieve the sale, transfer, disposal, forfeiture, re-allotment or surrender of an uncertified share or otherwise to enforce a lien in respect of it.

5. OTHER RELEVANT LAWS AND REGULATIONS

5.1 ***Mandatory bid***

(a) The City Code on Takeovers and Mergers (the "**Takeover Code**") applies to the Company. Under the Takeover Code, where:

(i) any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares in which he is

already interested, and in which persons acting in concert with him are interested) carry 30 per cent. or more of the voting rights of a company; or

(ii) any person who, together with persons acting in concert with him, is interested in shares which in the aggregate carry not less than 30 per cent. of the voting rights of a company but does not hold shares carrying more than 50 per cent. of such voting rights and such person, or any person acting in concert with him, acquires an interest in any other shares which increases the percentage of shares carrying voting rights in which he is interested;

such person shall, except in limited circumstances, be obliged to extend offers, on the basis set out in Rules 9.3, 9.4 and 9.5 of the Takeover Code, to the holders of any class of equity share capital whether voting or non-voting and also to the holders of any other class of transferable securities carrying voting rights. Offers for different classes of equity share capital must be comparable; the Takeover Panel should be consulted in advance in such cases.

(b) An offer under Rule 9 of the Takeover Code must be in cash and at the highest price paid for any interest in the shares by the person required to make an offer or any person acting in concert with him during the 12 months prior to the announcement of the offer.

(c) Under the Takeover Code, a 'concert party' arises where persons acting together pursuant to an agreement or understanding (whether formal or informal and whether or not in writing) actively co-operate, through the acquisition by them of an interest in shares in a company, to obtain or consolidate control of the company. 'Control' means holding, or aggregate holdings, of an interest in shares carrying 30 per cent. or more of the voting rights of the company, irrespective of whether the holding or holdings give *de facto* control.

5.2 ***Squeeze-out***

(a) Under sections 979 to 982 of the Companies Act, if an offeror were to acquire 90 per cent. of the Ordinary Shares it could then compulsorily acquire the remaining 10 per cent. It would do so by sending a notice to outstanding Shareholders telling them that it will compulsorily acquire their shares, provided that no such notice may be served after the end of: (a) the period of three months beginning with the day after the last day on which the offer can be accepted; or (b) if earlier, and the offer is not one to which section 943(1) of the Companies Act applies, the period of six months beginning with the date of the offer.

(b) Six weeks following service of the notice, the offeror must send a copy of it to the Company together with the consideration for the Ordinary Shares to which the notice relates, and an instrument of transfer executed on behalf of the outstanding Shareholder(s) by a person appointed by the offeror.

(c) The Company will hold the consideration on trust for the outstanding Shareholders.

5.3 ***Sell-out***

(a) Sections 983 to 985 of the Companies Act also give minority Shareholders in the Company a right to be bought out in certain circumstances by an offeror who has made a takeover offer. If a takeover offer relating to all the Ordinary Shares is made at any time before the end of the period within which the offer could be accepted and the offeror held or had agreed to acquire not less than 90 per cent. of the Ordinary Shares, any holder of shares to which the offer related who had not accepted the offer could by a written communication to the offeror require it to acquire those shares. The offeror is required to give any Shareholder notice of his right to be bought out within one month of that right arising. The offeror may impose a time limit on the rights of minority Shareholders to be bought out, but that period cannot end less than three months after the end of the acceptance period, or, if longer a period of three months from the date of the notice.

(b) If a Shareholder exercises his/her rights, the offeror is bound to acquire those shares on the terms of the offer or on such other terms as may be agreed.

5.4 ***Shareholder notification and disclosure requirements***

(a) Shareholders are obliged to comply with the shareholding notification and disclosure requirements set out in Chapter 5 of the DTRs. A Shareholder is required pursuant to Rule 5 of the DTRs to notify the Company if, as a result of an acquisition or disposal of shares or financial instruments, the Shareholder's percentage of voting rights of the Company reaches, exceeds or falls below, 3 per cent. of the nominal value of the Company's share capital or any 1 per cent. threshold above that.

(b) The DTRs can be accessed and downloaded from the FCA's website at http://fshandbook.info/FS/html/FCA/DTR. Shareholders are urged to consider their notification and disclosure obligations carefully as a failure to make a required disclosure to the Company may result in disenfranchisement.

6. DIRECTORS' AND OTHER INTERESTS

6.1 Immediately following Admission, the Directors and Senior Managers will have the following interests in the shares of the Company:

Name	No. of Ordinary Shares
Gabriele Cerrone [(1)]	66,304,893
Dr Kunwar Shailubhai	405,000
Willy Jules Simon	16,500
John P Brancaccio	—
Jules S. Jacob	3,500
Dr. Vaseem A. Palejwala	20,000
Keeren Shah	5,000

(1) Mr Cerrone's interests in the ordinary shares of the Company are based on a holding of 63,297,647 ordinary shares held by Planwise Limited and voting rights in respect of 3,007,246 ordinary shares held by Panetta Partners Limited. Mr Cerrone is considered beneficially interested in the holdings of Panetta Partners Limited and Planwise Limited.

6.2 Neither the Directors nor the Senior Managers have held any directorships of any company (other than the Company and its subsidiaries) or partnerships within the last five years, except as set forth below:

Gabriele Cerrone

Current	*Past*
Gensignia IP Limited	N/A
11 Chelsea Embankment Management Company Limited	
Accustem Sciences plc	
Panetta Partners Limited	

Willy Jules Simon

Current	*Past*
StemPrintER Sciences Limited	N/A
Accustem Sciences plc	
African Metals Limited	
Frasia Holdings S.A.	
Bever Holding NV	
Ducat Maritime	
OKYO Pharma Ltd	
Rasna Therapeutics, Inc.	

Dr Kunwar Shailubhai

Current	*Past*
Rasna Therapeutics, Inc	N/A
Accustem Sciences plc	

John P Brancaccio

Current	*Past*
OKYO Pharma Ltd	N/A
Cardiff Oncology, Inc	
Rasna Therapeutics, Inc	
Hepion Pharmaceuticals	
Accustem Sciences plc	

Jules S. Jacob

Current	*Past*
N/A	

Dr. Vaseem A. Palejwala N/A

Current	*Past*
N/A	

Keeren Shah N/A

Current	*Past*
N/A	N/A

6.3 At the date of this prospectus, none of the Directors:

(a) has any convictions in relation to fraudulent offences for at least the previous five years;

(b) as been associated with any bankruptcy, receivership or liquidation while acting in the capacity of a member of the administrative, management or supervisory body or of senior manager of any company for at least the previous five years; or

(c) has been subject to any official public incrimination and/or sanction of him by any statutory or regulatory authority (including any designated professional bodies) or has ever been disqualified by a court from acting as a director of a company or from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer for at least the previous five years.

6.4 None of the Directors or the Senior Managers has any potential conflicts of interest between their duties to the Company and their private interests or other duties they may also have.

6.5 Save as set out below, the Directors are not aware of any person who, directly or indirectly, had an interest in 3 per cent. or more of the voting rights of the Company as at the date of publication of this prospectus and immediately following Admission; accordingly not less than 60.48 per cent. of the Ordinary Shares will be in public hands:

Shareholder	No. of Ordinary Shares prior to and at Admission	Percentage of Issued Share Capital
Planwise Group Limited[(1)]	63,297,647	32.52%
Emprey Asset Management, L.P	10,153,770	5.22%
Laura Fonda	7,971,966	4.10%
Morris Silverman	7,944,457	4.08%
Howard Freedberg	6,296,221	3.24%

(1) Mr Gabriel Cerrone, a director, is the ultimate beneficial owner of the entire issued share capital of Planwise Group Limited

6.6 As at 17 December 2020 (being the latest practicable date prior to the publication of this prospectus), the Company was not aware of any person or persons who, directly or indirectly, jointly or severally, exercise or could exercise control over the Company nor is it aware of any arrangements, the operation of which may at a subsequent date result in a change in control of the Company.

6.7 Those interested, directly or indirectly, in 3 per cent. or more of the issued Ordinary Shares of the Company (as set out in paragraph 6.5 above) do not now, and, following the Admission, will not, have different voting rights from other holders of Ordinary Shares.

7. RELATED PARTY TRANSACTIONS

7.1 ***Director and Senior Management Service Agreements, Appointment Letters and Consulting Agreements***

(a) **Dr. Kunwar Shailubhai**

The Company entered into an employment agreement with Dr. Kunwar Shailubhai in May 2017. This agreement entitles Dr. Shailubhai to receive an initial annual base salary of $600,000 per year. Dr. Shailubhai is eligible to receive an annual bonus of up to 35 per cent. of his base salary, such bonus amount to be determined in the Company's sole discretion. Dr. Shailubhai is also entitled to the same fringe benefits as the Company provides to its other executives from time to time and is eligible to receive employee share incentives. The vesting of any unvested employee share incentives held by Dr. Shailubhai will accelerate in the event his employment is terminated without cause (as such term is defined in his employment agreement), or if he resigns for good reason (as such term is defined in his employment agreement) and, in each case, such termination is upon the consummation of or within 12 months following a change of control of the Company. If Dr. Shailubhai's employment with the Company is terminated without cause, or if he resigns for good reason, Dr. Shailubhai will also be entitled to receive severance equal to continuation of his base salary as then currently in effect for 12 months following his date of termination and will be eligible for reimbursement for medical coverage premiums for up to the same period. Dr. Shailubhai, his spouse and eligible dependents are entitled to stay on the Company's health insurance plans for a period of 12 months following his termination for any reason. Dr. Shailubhai's severance benefits are conditioned on, among other things, his execution of the Company's standard separation agreement and a general release of claims in the Company's favor.

The agreement provides that Dr. Shailubhai's employment with the Company is at-will. If required by the Company, the agreement further provides that Dr. Shailubhai will resign from his position on the Company's board of directors effective as of the date of his termination for any reason. The agreement further contains a six-month non-competition covenant and a 12-month non-solicitation covenant by Dr. Shailubhai.

(b) **Gabriele Cerrone**

The Company entered into a Consultancy agreement with Gabriele Cerrone in June 2016, which was replaced by an agreement dated 9 October 2020. This agreement entitles Mr. Cerrone to receive a consultancy fee of £240,000 per year. Mr. Cerrone is also eligible to receive an annual bonus of up to 50 per cent. of his base salary, such bonus amount to be determined at the discretion of the Board of Directors.

Additionally, Mr Cerrone is also eligible to receive a realisation bonus in the event that, there is either: (i) a sale, in one or a series of transactions, of all or substantially all of the assets (calculated on the basis of book values) of the Group (or a licence of the same on an exclusive or non-exclusive basis), where the Enterprise Value equals or exceeds £300,000,000; or (ii) there is either a change of control where the Enterprise Value equals or exceeds £300,000,000, Mr. Cerrone will be entitled to receive a realisation bonus in the amount equal to the Enterprise Value multiplied by three and a half (3.5) per cent. The Enterprise Value means: (i) in the case of a change of control resulting in consideration payable to the Group (for example, on a sale of its assets or licensing transaction), the total cash and non-cash consideration received by the Group; or (ii) in the case of a change of control resulting in consideration payable to the shareholders of the ordinary shares in the issued share capital of the Group from time to time, the total cash and non-cash consideration payable to Shareholders. In the event of any demerger or spin out of any asset or assets to a new entity, the Company is required to ensure that am appropriate and commensurate realisation bonus obligation passes to any acquiring entity.

Mr. Cerrone accrued a bonus of 4,763,995 Ordinary Shares on the closing of the Company's registered direct offering of ADSs on the NASDAQ Global Market on August 2020, the bonus was performance based and the target set in June 2016. The balance of 4,763,955 Ordinary Shares will be issued at future dates dependent upon the level of Mr. Cerrone's interests in the share capital of the Company and the relevant periods elapsing allowing Mr. Cerrone to increase his interests without incurring any obligation under Rule 9 of the Takeover Code.

(c) **Willy Simon**

Willy Simon entered into a Director's non-executive letter of appointment dated 26 January 2016 with the Company in respect of his appointment as a Director of the Company.

Under the terms of the appointment letter, Mr. Simon is entitled to a fee of £38,000 per annum. Fees will accrue on a daily basis and will be payable in equal monthly instalments in arrears on the last Business Day of each month (or as otherwise agreed).

The appointment as a non-executive director of the Company, is (subject to limited exceptions) terminable by either party on six months' written notice, under which he is not entitled to any pension, benefits or bonuses.

(d) **John Brancaccio**

John Brancaccio entered into a Director's non-executive letter of appointment dated 15 July 2020 with the Company in respect of his appointment as a Director of the Company.

Under the terms of the appointment letter, Mr. Brancaccio is entitled to a fee of £38,000 per annum. Fees will accrue on a daily basis and will be payable in equal monthly instalments in arrears on the last Business Day of each month (or as otherwise agreed).

The appointment as a non-executive director of the Company, is (subject to limited exceptions) terminable by either party on three months' written notice, under which he is not entitled to any pension, benefits or bonuses.

(e) **Jules S. Jacob**

Tiziana Therapeutics, Inc. entered into an employment agreement with Jules S. Jacob on 1 September 2017 (as amended and restated on 14 January 2019. This agreement entitles Mr. Jacob to receive an annual base salary of $185,000 per year. Mr. Jacob is eligible to receive an annual bonus of up to 35 per cent. of his base salary, such bonus amount to be determined in the Company's sole discretion. Mr. Jacob is also entitled to the same fringe benefits as the Company provides to its other executives from time to time and is eligible to receive employee share incentives. The agreement constitutes employment at will under applicable law and accordingly notice periods are not applicable.

(f) **Dr. Vaseem A. Palejwala**

Tiziana Therapeutics, Inc. entered into an employment agreement with Dr. Vaseem A. Palejwala on 1 September 2017 (as amended and restated on 14 January 2019. This agreement entitles Dr. Palejwala to receive an annual base salary of $170,000 per year. Dr. Palejwala is eligible to receive an annual bonus of up to 35 per cent. of his base salary, such bonus amount to be determined in the Company's sole discretion. Dr. Palejwala is also entitled to the same fringe benefits as the Company provides to its other executives from time to time and is eligible to receive employee share incentives. The agreement constitutes employment at will under applicable law and accordingly notice periods are not applicable.

(g) **Keeren Shah**

The Company entered into an employment agreement with Kereen Shah in August 2020. This agreement entitles Ms. Shah to receive a base salary of £85,000 per year. Ms. Shah is eligible to receive an annual bonus of up to 20 per cent. of her base salary, such bonus amount to be determined in the Company's sole discretion. Ms. Shah is also entitled to the same fringe benefits as the Company provides to its other executives from time to time. If Ms. Shah's employment with the Company is terminated without cause, Ms. Shah will be entitled to a payment in lieu of notice to the equal to her basic salary for all or any remaining part of the relevant period of notice. The payment in lieu shall consist solely of her basic salary for the relevant period and shall exclude any other entitlements or benefits referable to the executive's employment and shall be subject to deductions for income tax and national insurance contributions as appropriate.

The agreement further contains a six-month non-competition covenant and non-solicitation covenant by Ms. Shah.

7.2 ***Director and Senior Manager Options***

The following table summarises: (i) the outstanding number of options and awards under the equity incentive plans; and (ii) the number of ordinary shares granted to the Directors and Senior Managers, as of 17 December 2020:

Holder	Date of Grant	Number of Options	Exercise Price	Vesting Conditions	Plan under which Granted
Gabriele Cerrone	25/06/2014	1,830,775	£0.35 per share	Fully vested	2014 Plan
Arun Sanyal	30/04/2018	200,000	£0.8175 per share	25 per cent. will vest on each of 30 April 2019, 2020, 2021 and 2022.	2016 Plan
Howard Weiner	30/04/2018	1,000,000	£0.8175 per share	Vesting per the deed of grant.	2016 Plan
Gary Jacob	30/04/2018	100,000	£0.8175 per share	25 per cent. will vest on each of 30 April 2019, 2020, 2021 and 2022	2016 Plan
Kunwar Shailubhai	06/05/2020	2,500,000	£0.35 per share	Fully vested	2016 Plan
Kunwar Shailubhai	06/05/2020	4,700,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan
Kunwar Shailubhai	06/05/2020	1,400,000	£0.35 per share	Fully vested	2016 Plan
Vaseem Palejwala	06/05/2020	20,000	£0.35 per share	Fully vested	2016 Plan
Vaseem Palejwala	06/05/2020	110,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan
Jules Jacob	06/05/2020	46,500	£0.35 per share	Fully vested	2016 Plan
Jules Jacob	06/05/2020	125,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan
Keeren Shah	06/05/2020	125,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan
Hana Malik	06/05/2020	75,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan

Holder	Date of Grant	Number of Options	Exercise Price	Vesting Conditions	Plan under which Granted
Maria Preiss	06/05/2020	2,000	£0.35 per share	Fully vested.	2016 Plan
Maria Preiss	06/05/2020	30,000	£0.35 per share	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	2016 Plan
Gabriele Cerrone	06/05/2020	3,259,403	£0.35 per share	Vesting conditions: weighted average of an ordinary share must be greater than £3 for 120 consecutive dealing days	2016 Plan
Howard Weiner	23/07/2020	1,000,000	£1.57 per share	Vesting per the deed of grant.	2016 Plan
Willy Simon	25/08/2020	250,000	£1.57 per share	25 per cent. of the options (i.e. options to subscribe for 62,500 new ordinary shares) vest on the each anniversary of the Grant Date PROVIDED THAT total shareholder return (as set out in the annual report and accounts for the Company) is equal to or greater than 10 per cent. for the financial year	2016 Plan
John Brancaccio	25/08/2020	250,000	£1.57 per share	25 per cent. of the options (i.e. options to subscribe for 62,500 new ordinary shares) vest on the each anniversary of the Grant Date PROVIDED THAT total shareholder return (as set out in the annual report and accounts for the Company) is equal to or greater than 10 per cent. for the financial year	2016 Plan

7.3 ***Other related party transactions***

Save as set out in paragraphs 7.1 above, from 18 December 2018 (being the date falling 2 years prior to the date of this prospectus) up to and including the date of this prospectus, the Company has not entered into any related party transactions.

8. SHARE OPTION PLANS

8.1 A total of 17,023,678 options are outstanding over Ordinary Shares under the terms of two options plans, The Tiziana Life Sciences plc 2014 Share Option Plan (the "**2014 Plan**") and The Tiziana Life Sciences plc 2016 Share Option Plan (the "**2016 Plan**").

8.2 The material terms of the 2014 Plan are summarised below.

Grant of Option and Exercise Price

The Company may grant an Option to any director, employee or consultant it chooses during (i) the period of 42 days immediately following a closed period (as defined in the Market Abuse Regulation) or (ii) any period which the Board deems to be exceptional circumstances. An Option must be granted using an option certificate (an "**Option Certificate**") executed as a deed in a form approved by the Board.

The Option Price of an Option shall be specified in each Option Certificate, although may not be less than the nominal value of an Ordinary Share.

Lapse of Options

Options (and any rights arising under them) may not be transferred or assigned, or have any charge or other security interest created over them. An Option shall lapse if the relevant Option holder attempts to do any of those things. However, the transfer of an Option to an Option holder's personal representatives on the death of the Option holder will not cause an Option to lapse.

Takeovers

If any person (the "**Offeror**"): (i) makes an offer to acquire the whole of the issued share capital of the Company which is made on a condition such that, if it is satisfied, the Offeror will have control of the Company; or (ii) makes an offer to acquire all the Ordinary Shares in the Company; or (iii) negotiates a share sale and purchase agreement with the shareholders of the Company which contemplates that the Offeror will obtain control of the Company upon completion (the "**Controller**"), then any Option may be exercised within three months after the time when the Controller has obtained control of the Company. Upon the Controller obtaining control of the Company, the Committee shall engage with the buyer to offer an Option exchange. Where the Board is unable to make such arrangements with the Buyer within thirty days of the change of control, the Optionholders will have three months to exercise their Options.

Variation of Share Capital

If there is any variation of the share capital of the Company (whether that variation is a capitalization issue (other than a scrip dividend), rights issue, consolidation, subdivision or reduction of capital or otherwise), which affects (or may affect) the value of Options to Option holders, the Board may adjust the number and description of Ordinary Shares subject to each Option and/or the Exercise Price of each Option in a manner which the Board, in its reasonable opinion, considers to be fair and appropriate.

8.3 The material terms of the 2016 Plan are summarised below:

The Company may grant an Option to any director or employee it chooses during (i) the period of 42 days immediately following a closed period (as defined in the Market Abuse Regulation) or (ii) any period which the Board deems to be exceptional circumstances. An Option must be granted using an option certificate (an "Option Certificate") executed as a deed in a form approved by the Board.

The Exercise Price of an Option shall be specified in each Option Certificate, although may not be less than the nominal value of an Ordinary Share.

Overall Limits on Grants

No Option shall be granted if that grant would result in the total number of Dilutive Shares exceeding 10 per cent. of the issued share capital of the Company.

Lapse of Options

Options (and any rights arising under them) may not be transferred or assigned, or have any charge or other security interest created over them. An Option shall lapse if the relevant Option holder attempts to do any of those things. However, the transfer of an Option to an Option holder's personal representatives on the death of the Option holder will not cause an Option to lapse.

Takeovers

If any person (the "**Offeror**"): (i) makes an offer to acquire the whole of the issued share capital of the Company which is made on a condition such that, if it is satisfied, the Offeror will have control of the Company; or (ii) makes an offer to acquire all the Ordinary Shares in the Company; or (iii) negotiates a share sale and purchase agreement with the shareholders of the Company which contemplates that the Offeror will obtain control of the Company upon completion, then any Option may be exercised within a reasonable period to be specified by the Board for that purpose and ending immediately before the Offeror obtains control of the Company as a result of the offer or the share sale and purchase agreement. If any person obtains control of the Company (the "Controller"), then any Option may be exercised within six weeks after the time when the Controller has obtained control of the Company.

Variation of Share Capital

If there is any variation of the share capital of the Company (whether that variation is a capitalization issue (other than a scrip dividend), rights issue, consolidation, subdivision or reduction of capital or otherwise), which affects (or may affect) the value of Options to Option holders, the Board may adjust the number and description of Ordinary Shares subject to each Option and/or the Exercise Price of each Option in a manner which the Board, in its reasonable opinion, considers to be fair and appropriate.

Non-Employee Sub-Plan

Under the Non-Employee Sub-Plan, options may be granted to advisers, consultants and non-executive directors on terms comparable to those described above.

US Sub-Plan

The US Sub-Plan permits the grant of options to employees, directors and consultants who are US residents and US taxpayers, including potentially tax efficient Incentive Stock Options (as defined in Section 422 of the Internal Revenue Code of 1986, as amended).

9. WARRANTS

9.1 The Company has entered into a series warrant instruments between 24 March 2015 and 18 April 2020. Each warrant instrument was executed as a deed poll pursuant to which the Company created and issued warrants each entitling the holder to acquire one Ordinary Share at a price of 1 pence (a summary of the terms being set out in paragraph 9.2 below) at various exercise prices set out below;

Tranche	Date of Warrant Instrument	Issue Date	Number of Warrants	Exercise Price	Expiry Date
D	24/03/2015	16/12/2015	20,000	£1.05 per share	31/12/2023
E	24/03/2015	16/12/2015	5,300	£2.50 per share	31/12/2023
E	24/03/2015	16/12/2015	92,803	£2.50 per share	31/12/2023
E	24/03/2015	16/12/2015	57,454	£2.50 per share	31/12/2023
E	24/03/2015	16/12/2015	79,544	£2.50 per share	31/12/2023
E	24/03/2015	16/12/2015	129,880	£2.50 per share	31/12/2023
E	24/03/2015	16/12/2015	26,665	£2.50 per share	31/12/2023
F	24/03/2015	12/01/2016	8,844	£2.50 per share	31/12/2023
G	20/11/2017	20/11/2017	100,000	£1.60 per share	31/12/2023
H	24/11/2017	24/11/2017	131,300	£1.60 per share	31/12/2023
H	24/11/2017	24/11/2017	28,700	£1.60 per share	31/12/2023
H	24/11/2017	24/11/2017	6,667	£1.60 per share	31/12/2023
H	24/11/2017	24/11/2017	5,000	£1.60 per share	31/12/2023
H	24/11/2017	24/11/2017	5,000	£1.60 per share	31/12/2023
I	13/12/2017	13/12/2017	133,333	£1.60 per share	31/12/2023
I	13/12/2017	13/12/2017	31,667	£1.60 per share	31/12/2023
I	13/12/2017	15/12/2017	31,667	£1.60 per share	31/12/2023
J	12/01/2018	12/01/2018	100,000	£1.60 per share	15/01/2024
J	12/01/2018	12/01/2018	31,667	£1.60 per share	15/01/2024
K	19/01/2018	19/01/2018	66,667	£1.60 per share	22/01/2024
K	19/01/2018	19/01/2018	13,333	£1.60 per share	22/01/2024
L	05/03/2018	05/03/2018	78,000	£1.00 per share	05/03/2023

9.2 The following summary is common to the terms of each class of the Warrants unless the context requires otherwise, each of the following expressions has the following meanings:

"Certificate"	in relation to a Warrant, a certificate evidencing a Warrantholder's entitlement to Warrants.
"Exercise Date"	(i) in relation to a Warrant which is in certificated form, the date of delivery to the registered office of the Company of the items specified in the Warrant Instrument (and the date of such delivery shall be the date on which such items are received at the Company's registered office) or if not a Business Day then the immediately following Business Day; and (ii) in relation to a Warrant which is in uncertificated form, the date of receipt of the properly authenticated dematerialised instruction and/or other instruction or notification.
"Final Subscription Date"	the dates set out in the table in paragraph 9.1 as applicable to the relevant class of the Warrants.
"Notice of Exercise"	in relation to a Warrant, the duly completed notice of exercise in the form, or substantially in the form, contained in the certificate for such Investor.
"Regulations"	the Uncertificated Securities Regulations 2001 (SI 2001 No.3755) (as amended from time to time).
"stock account"	an account within a member account in CREST to which a holding of a particular share or other security in CREST is credited.
"Subscription Price"	the exercise prices set out in the table in paragraph 9.1 as applicable to the relevant class of Warrant (as may be adjusted from time to time).
"Subscription Rights"	the rights of the Warrantholders to subscribe for Ordinary Shares pursuant to the Warrants on the terms and subject to the conditions of the Warrant instrument.
"Warrantholder(s)"	the person(s) in whose name(s) a Warrant is registered in the Register from time to time.

(a) *Subscription Rights*

Warrantholders are entitled in respect of every one Warrant held to subscribe for one Ordinary Share in the Company at a price per share equal to the Issue Price. The Warrants registered in a Warrantholder's name will be evidenced by a Certificate issued by the Company.

Each Warrant may be exercised by Warrantholders at any time after the date on which the Warrants are issued and before the Final Subscription Date.

In order to exercise the whole or any part of its holding of Warrants held in certificated form, a Warrantholder must deliver to the Company before the Final Subscription Date a Notice of Exercise together with the relevant Certificate and the remittance in cleared funds of an amount equal to the Subscription Price multiplied by the number of Ordinary Shares to be allotted and issued to the Warrantholder as a result of the exercise of the Warrants which are being exercised.

In order to exercise the whole or any part of its holding of Warrants in uncertificated form, a Warrantholder must deliver to the Company before the Final Subscription Date a properly authenticated dematerialised instruction and/or other instruction or notification together with the payment transfer for the aggregate amount equal to the Subscription Price multiplied by the number of Ordinary Shares to be allotted and issued to the Warrantholder as a result of the exercise of the Subscription Rights.

Once delivered to the Company a Notice of Exercise shall (save with the consent of the Company) be irrevocable.

To the extent that Ordinary Shares to be allotted and issued on the exercise of Warrants held in certificated form, the Company shall deliver a share certificate for the Ordinary Shares so allotted to the relevant Warrantholder by no later than 28 days after such Notice of Exercise was delivered to the Company.

To the extent that Ordinary Shares to be allotted and issued on the exercise of Warrants held in uncertificated form through CREST, the Company shall procure that Euroclear is instructed to credit to the stock account of the relevant Warrantholder entitlements to such Ordinary Shares.

Ordinary Shares allotted pursuant to the exercise of Warrants shall be allotted and issued credited as fully paid, shall have the rights set out in the Articles, shall be entitled in full to all dividends and distributions declared or paid on any date, or by reference to any date, on or after the date on which the relevant Notice of Exercise was delivered to the Company and shall otherwise rank *pari passu* in all respects from the date of allotment with the Ordinary Shares of the Company then in issue.

Warrants shall be deemed to be exercised on the Exercise Date.

(b) *Adjustment of Subscription Rights*

Upon the occurrence of a reorganisation or reclassification of the share capital of the Company, or an issue of new shares, capitalisation issue or offer by way of rights by the Company, or a sub-division, reduction or consolidation of the capital of the Company, or a merger or consolidation of the Company with or into another company or demerger, or the modification of rights attaching to the Ordinary Shares or a dividend in kind declared and/or made by the Company (each, an "**Adjustment Event**") after the date on which any Warrants are granted, the number of Ordinary Shares which are the subject of the Warrants and the Subscription Price payable on the exercise of Warrants shall be adjusted either in such manner as the Company agree in writing is appropriate or, failing agreement, in such manner as the auditors of the Company shall certify is appropriate.

The Company shall not implement an Adjustment Event if it would otherwise result in the Subscription Price payable per Ordinary Share on the exercise of the Warrants being less than the nominal value of an Ordinary Share.

No exercise of Warrants shall result in the issue of a fraction of an Ordinary Share. Any fractional entitlements to Ordinary Shares arising as a result of an adjustment shall be rounded down to the nearest whole Ordinary Share.

(c) *Winding-up of the Company*

If, at any time when any Subscription Rights are exercisable, an order is made or an effective resolution is passed for the winding-up or dissolution of the Company or if any other dissolution of the Company by operation of law is to be effected then:

(A) if such winding-up or dissolution is for the purpose of a reconstruction or amalgamation pursuant to a scheme of arrangement to which any Warrantholder has consented in writing, the terms of such scheme of arrangement will be binding on such Warrantholder; or

(B) in any other case, the Company shall forthwith notify the Warrantholder stating that such an order has been made or resolution has been passed or other dissolution is to be effected and the Warrantholder shall be entitled to receive out of the assets which would otherwise be available in the liquidation to the holders of Ordinary Shares, such a sum, if any, as it would have received had it been the holder of and paid for the Ordinary Shares to which it would have become entitled by virtue of such exercise, after deducting from such sum an amount equal to the amount which would have been payable by it in respect of such Ordinary Shares if it had exercised all its Warrants, but nothing contained in this paragraph shall have the effect of requiring the Warrantholder to make any actual payment to the Company.

The Warrants lapse on a dissolution or winding-up of the Company.

(d) *Undertakings*

Unless otherwise authorised in writing by the Warrant holder(s) holding the majority of the outstanding Warrants from time to time:

(A) the Company shall maintain all necessary authorisations pursuant to the Act to enable it to lawfully and fully perform its obligations under the Warrant instrument to allot and issue Ordinary Shares upon the exercise of all Warrants remaining exercisable from time to time;

(B) if at any time an offer is made to all holders of Ordinary Shares (or all such holders other than the offeror and/or any company controlled by the offeror and/or persons acting in concert with the offeror) to acquire the whole or any part of the share capital of the Company, the Company will as soon as possible give notice of such offer to the Warrantholders and use its best endeavours to procure that a full and adequate opportunity is given to the Warrantholders to exercise the Warrants and that a like offer, being one *pari passu* with the best terms offered to holders of Ordinary Shares, is extended in respect of any Ordinary Shares issued upon exercise of the Warrants. The publication of a scheme of arrangement providing for the acquisition by any person of the whole or any part of the share capital of the Company shall be deemed to be the making of an offer and references herein to such an offer shall be read and construed accordingly;

(C) if at any time an offer or invitation is made by the Company to the holders of Ordinary Shares for the purchase by the Company of any of the Ordinary Shares, the Company shall simultaneously give notice thereof to the Warrantholders who shall be entitled, at any time while such offer or invitation is open for acceptance, to exercise their Warrants on the terms (subject to any adjustments) on which the same could have been exercised and as if the same had been exercised on the day immediately preceding the record date for such offer or invitation;

(D) the Company shall supply to the Warrantholders copies of all notices of meetings, annual reports and accounts and all documents required by law to be annexed thereto and all statements, circulars and other communications to its Shareholders at the same time as they are despatched to its Shareholders.

(e) *Modification of Rights*

All or any of the rights for the time being attached to the Warrants may from time to time (whether or not the Company is being wound up) be altered, amended or abrogated only with the prior sanction of a Special Resolution of the Warrantholders and the agreement of the Company and shall be effected by an instrument by way of deed executed by the Company and expressed to be supplemental to the Warrant instrument.

All the provisions of the Articles for the time being of the Company relating to general meetings shall apply *mutatis mutandis* as though the Warrants were a class of shares forming part of the share capital of the Company except that:

(A) the necessary quorum shall be Warrantholders present (in person or by proxy) entitled to subscribe for 10 per cent. in nominal amount of the Ordinary Shares attributable to the outstanding Warrants;

(B) every Warrantholder present in person at any such meeting shall be entitled on a show of hands to one vote and every Warrantholder present in person or by proxy shall be entitled on a poll to one vote for every Ordinary Share for which he is entitled to subscribe pursuant to the Warrants held by him; and

(C) any Warrantholder present (in person or by proxy) may demand or join in demanding a poll.

(f) *Transfer*

The Warrants shall be in registered form and shall be transferable by instrument in writing in the usual common form (or in such other form as the Directors may reasonably approve). A Warrantholder's holding of Warrants may be transferred in whole

or in part, but no transfer of a right to subscribe for a fraction of an Ordinary Share shall be affected.

(g) *Purchase*

The Company and its subsidiaries shall have the right to purchase Warrants in the market, by tender or by private treaty or otherwise.

All Warrants purchased or surrendered shall forthwith be cancelled and shall not be available for reissue or resale.

(h) *Tradability*

The Warrants shall not be listed or traded on a recognised stock exchange.

(i) *Governing Law and Jurisdiction*

The provisions of the Warrant instrument and the Warrants shall be subject to and governed by English law and each of the parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute which may arise out of or in connection with the Warrant instrument.

10. WORKING CAPITAL

In the opinion of the Company, the working capital available to the Group is sufficient for the Group's present requirements, that is, for a least 12 months from the date of this prospectus.

11. CAPITALISATION AND INDEBTEDNESS

As at the date of this prospectus, the Company has no guaranteed, secured, unguaranteed or unsecured debt and no indirect or contingent indebtedness and the Company's Existing Issued Share Capital consists of 194,612,289 Ordinary Shares with no legal reserve or other reserves.

Total Current debt	**0**
Guaranteed	0
Secured	0
Unguaranteed/Unsecured	0
Total Non-Current debt	**0**
Guaranteed	0
Secured	0
Unguaranteed/Unsecured	0
Shareholder equity	
Share capital	5,838,368.67
Legal Reserve	0
Other Reserves	0

12. SIGNIFICANT CHANGE

Set out below are details of the significant changes in the financial position of the Company during, and subsequent to the period ended 30 June 2020 up to the date of this prospectus. There have been no significant changes to the financial performance of the Company.

12.1 on 24 July 2020, the Company raised £82,379 in cash through the exercise of warrants;

12.2 on 31 July 2020, the Company announced that during the calendar month of July, it had issued a total of 2,043,000 ordinary shares under the Company's ATM sales agreement (announced on 15 April 2020) to meet sales of a total of 408,600 ADSs under the ATM sales agreement, totalling gross proceeds of $4,371,289;

12.3 on 5 August 2020, the Company announced the closing of its registered direct offering of ADSs on the NASDAQ Global Market. As of 3 August 2020, the Company issued 11,009,615 ADSs (representing 22,019,230 new ordinary shares of nominal value £0.03 each in the capital of the Company at a price of $5.20 per ADS raising gross proceeds of approximately $57.25 million (before deducting placement agent fees and offering expenses);

12.4 on 27 August 2020, the Company, raised £300,000 in cash through the exercise of warrants;

12.5 on 16 September 2020, the Company entered into the Demerger Agreement with Accustem Sciences Limited pursuant to the terms of which the Tiziana declared a dividend in specie on the Ordinary Shares equal to the book value (of approximately £3.07m) of Tiziana's shareholding in StemPrintER Sciences Limited, the entity within the Group which holds all of the assets and intellectual property relating to StemPrintER and SPARE and £1.0 million in cash; and

12.6 on 21 September 2020, the Company allotted 281,250 Ordinary Shares, credited as fully paid at a price of £1.28 per share in respect of agreements reached with certain members of the scientific advisory board concerning the commuting of cash fees into equity;

12.7 on 2 October 2020, resolutions were passed by Shareholders to approve the Demerger and to reduce the amount standing to the share premium account of the Company by £4,000,000 to facilitate the Demerger (the "**Capital Reduction**"). The Court sanctioned the Capital Reduction on 27 October 2020 and the Demerger became effective on 30 October 2020;

12.8 on 20 October 2020, the Company issued 35,714 Ordinary Shares credited as fully paid on the exercise of certain warrants held by the Company's broker, Optiva;

12.9 on 21 October 2020, the Company issued 1,750,000 Ordinary Shares of which 1,200,000 Ordinary Shares were issued credited as fully paid at a price of £0.15 per share and 550,000 shares were issued credited as fully paid at a price of £0.35 per share, both in respect of the exercise of share options by Gabriele Cerrone;

12.10 on 22 October 2020, the Company issued 285,714 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of warrants;

12.11 on 26 October 2020, the Company issued 329,225 shares credited as fully paid at a price of £0.35 per share on the exercise of share options held by, *inter alia*, Gabriele Cerrone and Keeren Shah;

12.12 on 28 October 2020, the Company issued 344,063 Ordinary Shares credited as fully paid at prices between £0.66 and £0.80 per share on the exercise of warrants; and

12.13 on 29 October 2020, the Company issued 426,500 Ordinary Shares credited as fully paid at a price of £0.35 per share on the exercise of share options by, inter alia, Dr. Kunwar Shailubhai, Vaseem Palejwala and Jules Jacob.

Demerger of StemPrintER

All on-going research and development expenditure is currently expensed in the period in which it is incurred. Due to the regulatory environment inherent in the development of the Group's products, the criteria for development costs to be recognised as an asset, as set out in IAS 38 'Intangible Assets', are not met until a product has been granted regulatory approval and it is probable that future economic benefit will flow to the Group. The Group currently has no expenditure qualifying under IAS 38 to be treated as intangible assets. For the purposes of the Demerger, the assets relating to StemPrintER (primarily the benefit of a licence from IEO and the University of Milan and an outsourced research programme) were transferred to a new subsidiary, StemPrintER Sciences Limited together with £1 million in cash, prior to the sale of StemPrintER to Accustem Sciences Limited and Accustem Sciences Limited issuing shares to the Shareholders on a one-for-one basis by way of demerger. The accumulated spend on the transfer StemPrintER project (a research stream within the Group), which had previously been expensed as it was not capable of recognition as an asset pursuant to IAS 38 so the expenditure, was notionally written back as an asset at a book value of £2,073,930 (the sum of spend on the project since inception). In context, the accumulated R&D spend and expensed sums amount to some £23m over the same period. Including the £1m of cash (which on the date of the Demerger was approximately 2 per cent. of the Company's cash reserves), the "written back" book value of the assets demerged (including cash) represented 13.7 per cent. of expensed R&D costs or 4.2 per cent. of expensed R&D costs and current assets (primarily cash). In terms of quantum for the purposes of valuing the "distribution" (and NASDAQ reporting) the figure was 1.56 pence per share against a share price of £1.45 (on the record date of the Demerger), being 1.07 per cent. and, on a comparative market capitalisation to value of the distribution, being approximately 1 per cent. The Company considers the metrics of value of assets demerged (i.e. the cash plus the R&D expenditure) compared to total R&D

expenditure to be the primary test of whether the transaction constituted a significant gross change; secondary tests of value per share to share price and gross assets disposed of to market value all result in percentages of 3 per cent. or lower. On this basis, the Company concludes that the Demerger does not constitute a significant gross change.

Save as set out above in this paragraph 12, there has been no significant change in the financial position and financial performance of the Group since 30 June 2020 (being the end date of the period covered by the latest published unaudited historical financial information of the Group).

13. CURRENT INVESTMENTS

The Company currently has no investments.

14. INVESTMENTS IN PROGRESS

The Company has no investments in progress.

15. LITIGATION

There are currently no proceedings against the Group and there have been no governmental, legal or arbitration proceedings during the 12 months prior to the date of this prospectus, and neither the Company nor any member of the Group is aware of any governmental legal or arbitration proceedings pending or threatened, which may have, or have had in the recent past, a significant effect on the financial position or profitability of the Company or any member of the Group.

16. MATERIAL CONTRACTS

The following are all of the contracts (not being contracts entered into in the ordinary course of business) that have been entered into by the Company (including its wholly-owned subsidiaries) since the Company's incorporation which: (i) are, or may be, material to the Company (or its wholly-owned subsidiaries); or (ii) contain obligations or entitlements which are, or may be, material to the Company (or its wholly-owned subsidiaries) as at the date of this prospectus.

16.1 ***Broker agreement***

A broker agreement dated 30 January 2018 between the Company and Optiva, pursuant to which the Company appointed Optiva as the Company's broker as from Admission and for an initial period of 12 months and continuing thereafter until terminated by either party giving the other three months' notice. Pursuant to the broker agreement, the Company has agreed to pay to Optiva an annual retainer fee of £15,000 (together with any applicable VAT) payable quarterly in advance, the first payment being due on the day of Admission.

16.2 ***Warrant Instruments***

In connection with the IPO, on 9 November 2018, the Company entered into the Investor Warrant Instrument, and the Adviser Warrant Instrument. On 14 February 2018 the Company entered into the IPO Warrant Instrument. Each of the warrant instruments entitles the holder to subscribe for one Ordinary Share per warrant at a price of 2 pence per Ordinary Share, exercisable within two years after the date of the IPO. The terms of all of the warrant instruments are summarised in paragraph 9 above.

16.3 ***Nerviano Agreement***

In January 2015, the Company entered into an agreement with Nerviano, or the Nerviano Agreement, pursuant to which the Company obtained a worldwide, exclusive license to patents owned or controlled by Nerviano, or the Nerviano License to develop and commercialize products and services incorporating Milciclib as an active ingredient, and any product or service controlled or owned by Nerviano that is used to diagnose or assess responsiveness to Milciclib therapy or dosage. The Nerviano License confers the right on the Company to grant sub-licenses, and otherwise to employ third party manufacturers and distributors to produce and sell licensed products and services.

Each party to the Nerviano Agreement agreed to a development plan, or the Nerviano Development Plan, approved by a joint development committee, or the JDC. The JDC is comprised of at least two members of each party, meets at least twice a year and endeavors

to make decisions by consensus, save that where there is a disagreement with respect to any aspect of the licensed products or services the Company shall have a deciding vote.

Under the Nerviano Development Plan, the Company (or, as the case may be, the Company's sub-licensee(s)) are obliged to use commercially reasonable efforts to develop and commercialize a licensed product or service in at least one therapeutic indication that arises out of the Nerviano Development Plan, and Nerviano is obliged to use commercially reasonable efforts to manufacture such product(s) or service(s). Pursuant to the Nerviano Development Plan, the Company has sole responsibility for costs for further clinical development and Nerviano is obliged to perform Phase 2 studies of licensed products and services, save that the amounts to be invoiced by Nerviano to the Company for Phase 2 studies shall be commercially reasonable and not be greater than a low-double-digit percentage in excess than amounts estimated to be invoiced by another reputable clinical research organization.

During the term of the Nerviano Development Plan, or the Nerviano Exclusivity Period, the Company and its affiliates may not, directly or indirectly, develop, make, use, sell, offer for sale or import any small molecule compound or other biological or chemical molecule other than Milciclib that directly binds to, with an affinity indicated by an IC50 of 100nM or less, and modulates the following specified pharmacological targets hit by Milciclib: Cdk-2, Cdc-4 and Cdc6.

Upon entry into the Nerviano Agreement, the Company paid an upfront, non-refundable initial license fee of $3,500,000 to Nerviano. The Company issued 4,233,616 of ordinary shares, fully paid with a nominal value of three pence each, or the Consideration Shares, to Nerviano at an issue price of 50.5 pence (equivalent to an aggregate value of £2,137,976.08).

Nerviano granted the Company an option, or the Nerviano Option, to buy-back all the Consideration Shares for a de minimis aggregate consideration exercisable on written notice at any time after the earlier of:

(a) an unsuccessful Phase 2 trial for HCC or breast cancer with a licensed product or service and the concomitant decision of the Company, its affiliates or sub-licensees to discontinue development of a licensed product or service;

(b) the fifth anniversary of the Nerviano Agreement, (provided that if on such date a Phase 2 trial has commenced but has not been completed, the Company's ability to exercise the Nerviano Option shall be delayed until the outcome of the Phase 2 trial has become clear); or

(c) the Company's abandonment of any licensed product or service for *bona fide* scientific reasons.

The Nerviano Option cannot be exercised if any of the following events (each, a Release Event), occurs:

(a) a successful completion of a Phase 2 trial for HCC or breast cancer with a licensed product or service, where such successful conclusion renders the licensed product or service eligible for entry into a Phase 3 trial with no further clinical study; or

(b) the Company's abandonment of the development of, or failure to exercise commercially reasonable efforts develop any, licensed product or service, save for where the Company has *bona fide* scientific reasons.

The Nerviano Option effectively allows the Company to recover the Consideration Shares if it transpires that Milciclib proves to be unsuccessful in the indications for which the Company licensed it or the Company fails to see satisfactory results in a period of 5 years from the date of the license agreement.

Prior to a Release Event, Nerviano has agreed to not transfer, dispose of, or grant options or other rights over directly or indirectly any interests in the Consideration Shares nor to derive any financial benefit from the Shares, but is entitled to exercise all voting rights arising from the Consideration Shares.

Following a Release Event, Nerviano has agreed to a 12 month lock-up, or the Nerviano Lock-Up, in respect of the Consideration Shares, subject to customary exceptions, including

the prior written consent of the Company and the Company's nominated adviser from time to time (which consent may be approved, provided or provided subject to conditions as each may determine in its absolute discretion), acceptance of takeover bids, share buy-backs by the Company, or where required by law.

Following the lapse of the term of the Nerviano Lock-Up, Nerviano has agreed to not directly or indirectly, transfer, sell, mortgage, charge or otherwise dispose of more than 10 per cent. of the Consideration Shares (i.e. 423,362 ordinary shares) per calendar month, and to utilize the Company's broker from time to time to execute those transactions in respect of the legal and or beneficial ownership or any other interest in the Consideration Shares so as to ensure an orderly market.

The Company is obligated to pay Nerviano the following additional amounts in respect of the first licensed product or service which achieves the stated development milestones:

(a) $100,000 upon initiation, first patient dosed, or FPD, of the first Phase 3 registration trial in thymic carcinoma.

(b) $4,000,000 upon FPD of the first Phase 3 registration trial in HCC.

(c) $6,000,000 upon FPD of the first Phase 3 registration trial in breast cancer.

(d) Upon the first NDA equivalent in: thymic carcinoma, $900,000; HCC, $9,000,000; breast cancer, $15,000,000.

The Company is obliged to pay Nerviano a low-single-digit percentage royalty fee of the annual net sales of licensed products or services, subject to certain royalty off-sets on a country-by-country basis and, subject to certain exclusions, a low-double-digit percentage of sub-licensing revenues from the sale of licensed products or services for the life of the licensed patents.

During the Nerviano Exclusivity Period, the Company has the right to terminate activities and funding to Nerviano after 24 months from the beginning of the Nerviano Exclusivity Period but not prior thereto. If the Company exercises its termination right, the Company is obliged to transfer to Nerviano all relevant data, licensed products and services and an exclusive license pertaining to the licensed product or services, and Nerviano shall pay the Company a low-single-digit percentage royalty on annual net sales of licensed products and services, subject to certain exceptions.

Following the expiry of the Nerviano Exclusivity Period, the Company may terminate the Nerviano Agreement at any time on 90 days' written notice, and either party may terminate the Nerviano Agreement for material breach by the other party of any material obligation or condition of the Nerviano Agreement by written notice, subject to a 45 day cure period for a payment breach, and a 120 day cure period for any other breach.

Absent early termination, the Nerviano Agreement shall remain in force until the later of (in all countries in which licensed products and services are marketed pursuant to the Nerviano Agreement): (a) the expiration of the last claim in an issued, unexpired patent within the licensed patents, subject to certain exceptions, which covers the sale of such licensed products or services, or (b) five years from the date of first commercial sale of such licensed product or service in such country.

16.4 ***Novimmune CD3 Agreement***

In December 2014, the Company entered into a license and sublicense agreement with Novimmune, or the Novimmune CD3 Agreement, pursuant to which the Company obtained a worldwide, exclusive license to certain patents owned or controlled by Novimmune, or the Novimmune CD3 License, together with a sublicense to certain patent licenses from Bristol-Myers Squibb Company, or BMS, or the BMS CD3 Sublicense, and any associated know-how, biologic materials, clinical data or other technology relating to CD3 receptor mAbs and their use in order to research, develop and commercialize products and services. The Novimmune CD3 License and BMS CD3 Sublicense both confer the right to the Company to grant sublicenses, and otherwise to employ third party manufacturers and distributors to produce and sell licensed products and services, respectively.

Pursuant to the Novimmune CD3 Agreement, Novimmune granted the BMS CD3 Sub-License to the Company. Novimmune effected such grant pursuant to a research and commercialization agreement between Novimmune and BMS dated 20 September 2014, or the BMS R&C Agreement, and the agreement for the exclusive commercial license for the CD3 licensed product (NI-0401) between Novimmune and BMS dated February 2005.

Under the Novimmune CD3 Agreement, the Company has full control and authority over the research, development and commercialization of licensed products and services, and is required to exercise commercially reasonable efforts to commercialize such licensed products and services at all times.

Upon the Company's entry into the Novimmune CD3 Agreement the Company paid an upfront fee of $750,000 to Novimmune (to be on paid by Novimmune to BMS pursuant to the terms of the BMS R&C Agreement), and a further upfront fee of $500,000 to Novimmune. The Company is required to pay Novimmune instalments of $250,000 on each of the 14-month, 26-month and 38-month anniversaries of the date of the Novimmune CD3 Agreement. For the term of the Novimmune Agreement, the Company is obligated to pay to Novimmune a royalty of a low-single-digit percentage on net sales of licensed products and services, together with any amounts owed to BMS incurred pursuant to the BMS CD3 Sub-License.

The Company may terminate the Novimmune CD3 Agreement at any time on 90 days' written notice, and either party may terminate the Novimmune CD3 Agreement by written notice for a payment breach or any other breach, subject to 45 day and 120 day cure periods, respectively. Absent early termination, the Novimmune CD3 Agreement will continue until the later of (in all countries in which licensed products are marketed pursuant to the Novimmune CD3 Agreement): (a) the expiration of the last claim in an issued, unexpired patent within the licensed patents or a claim that has not been pending more than five years, subject to certain exceptions, which covers the sale of such licensed product or service, or (b) the end of any market exclusivity period granted by the relevant governmental authority in a country that prevents another party from marketing the same licensed product or service.

16.5 ***Novimmune IL-6r Agreement***

In December 2016, the Company entered into a license and sublicense agreement with Novimmune, or the Novimmune IL-6r Agreement, pursuant to which the Company obtained a worldwide, exclusive license to certain patents owned or controlled by Novimmune, or the Novimmune IL-6r License, together with a sub-license to certain patent licenses from BMS, or the BMS IL-6r Sub-License, and any associated know-how, biologic materials, clinical data or other technology relating to IL-6r mAbs and their use in order to research, develop, commercialize products and services. The Novimmune IL-6r License and BMS IL-6r Sub-License both confer the right to the Company to grant sub-licenses, and otherwise to employ third party manufacturers and distributors to produce and sell licensed products and services, respectively.

Pursuant to the Novimmune IL-6r Agreement, Novimmune granted the BMS IL-6r Sub-License. Novimmune effected such grant pursuant to the BMS R&C Agreement and the agreement for the IL-6r exclusive commercial license for the IL-6r antibody licensed product (NI-1201) between Novimmune and BMS dated 20 September 2009, or the IL-6r Commercial License Agreement.

Under the Novimmune IL-6r Agreement, the Company has full control and authority over the research, development and commercialization of licensed products and services, and are required to exercise commercially reasonable efforts to commercialize such licensed products and services at all times.

Upon the Company's entry into the Novimmune IL-6r Agreement the Company paid an upfront fee of $100,000 to Novimmune. For the term of the Novimmune IL-6r Agreement, the Company is obligated to pay to Novimmune a royalty of a low-single-digit percentage on net sales of licensed products and services, or low-double- digit percentage of any sub-license royalty revenue which the Company receives that arises from sales of licensed products and services, together with any amounts owed to BMS incurred pursuant to the BMS IL-6r Sub-License.

The BMS R&C Agreement and the IL-6r Commercial License Agreement were amended pursuant to an agreement between Novimmune and BMS dated December 2016, or the Novimmune Amendment Agreement. Pursuant to the Novimmune Amendment Agreement, in the event that Novimmune (or, as the case may be, a sublicensee) commercializes a combination product comprising NI-1201 and NI-0401, then such product shall be subject to a single royalty.

The Company may terminate the Novimmune IL-6r Agreement at any time on 90 days' written notice, and either party may terminate the Novimmune IL-6r Agreement by written notice for a payment breach or any other breach, subject to 45 day and 120 day cure periods, respectively. Absent early termination, the Novimmune IL-6r Agreement will continue until the later of (in all countries in which licensed products are marketed pursuant to the Novimmune IL-6r Agreement): (a) the expiration of the last claim in an issued, unexpired patent within the licensed patents or a claim that has not been pending more than five years, subject to certain exceptions, which covers the sale of such licensed product or service, or (b) the end of any market exclusivity period granted by the relevant governmental authority in a country that prevents another party from marketing the same licensed product or service.

16.6 ***Brigham and Women's Hospital License***

On 29 May 2018, the Company entered into a license agreement, or the BWH License, with BWH pursuant to which the Company obtained a worldwide exclusive license to a patent owned by BWH for a novel technology discovered by Dr. Howard Weiner. The patent relates to a formulation of Foralumab in a medical device developed for nasal administration of Foralumab. The BWH License extends to any associated know-how, clinical data and use in order to research, develop and commercialize products and services. The BWH License confers on the Company the right to grant sub-licenses, and otherwise to employ third party manufacturers and distributors to sell licensed products and services.

Under the BWH License the Company has full control and amnesty over the research, development and commercialization of licensed products and services and are required to exercise commercially reasonable efforts to commercialize such licensed products and services at all times.

Upon the Company's entry into the BWH License the Company paid an upfront fee of $10,000 to BWH. The Company is required to pay annual maintenance fees, all ongoing patent maintenance and prosecution costs and a low single-digit royalty on annual net sales (and a 12 per cent. royalty of non-royalty sub-license revenues for the life of the intellectual property). The Company is also obliged to make certain milestone payments of: (a) $300,000 within 60 days of first patient enrolled in a Phase 1 human clinical trial; (b) $600,000 within 60 days of first patient enrolled in a Phase 2 human clinical trial; (c) $1,500,000 within 60 days of first patient enrolled in a Phase 3 clinical trial; and (d) $3,000,000 within 60 days of first commercial sale of a licensed product.

The Company may terminate the BWH License at any time on 90 days' written notice, and either party may terminate the BWH License by written notice for payment or other breach, subject to a 60 day cure period. Absent early termination the BWH License will remain in effect until the date on which all patents and filed patent applications have expired or been abandoned.

16.7 ***Demerger Agreement with Accustem Sciences Limited***

On 16 September 2020, the Company entered into the Demerger Agreement with Accustem Sciences Limited pursuant to the terms of which the Tiziana declared a dividend in specie on the Ordinary Shares equal to the book value (of approximately £3.07m) of Tiziana's shareholding in StemPrintER Sciences Limited, the entity within the Group which holds all of the assets and intellectual property relating to StemPrintER and SPARE and £1.0 million in cash. The dividend in specie was be satisfied by the transfer by Tiziana to Accustem of the shares in StemPrintER Sciences Limited. In return for this transfer, Accustem Sciences allotted ordinary shares in Accustem Sciences Limited ("**Accustem Shares**") to Tiziana Shareholders who were registered on the Tiziana Share Register at the Demerger Record Time (being 7am on 30 October 2020), on the basis of one Accustem Share for each Tiziana Share held by them at that time, save that the number of Accustem Shares allotted to the

initial subscriber in Accustem (who at the Demerger Record Time wa a Tiziana Shareholder) will be reduced by the number of Accustem Shares already held by them so that, on the Demerger becoming effective, each Tiziana Shareholder (including the initial subscriber in Accustem) held one Accustem Share for each Tiziana Share held at the Demerger Record Time. The Demerger was conditional, *inter alia*, upon the Court approval of a capital reduction which was approved by special resolution of Shareholders on 2 October 2020. The Court sanctioned the Capital Reduction on 27 October 2020 and the Demerger became effective on 30 October 2020.

17. ACCOUNTS

The Company's annual report and accounts are made up to 31 December in each year. The Company makes public its annual report and accounts within four months of each financial year end (or earlier if possible) and that copies of the annual report and accounts are sent to Shareholders within six months of each financial year end (or earlier if possible).

The Company has also prepared and published its unaudited historical information for each six month ended 30 June.

18. GENERAL

18.1 In March 2018, Mazars LLP whose address is Tower Bridge House St Katharine's Way London E1W 1DD, were re-appointed as auditor of the Company at the 2020 AGM. Mazars LLP is registered to carry out audit work by the Institute of Chartered Accountants in England and Wales and the Financial Reporting Council.

18.2 Optiva has given and not withdrawn its written consent to the issue of this prospectus with the inclusion of the references herein to its name in the form and context in which they appear.

18.3 The Company currently has ten employees (2018: 11; 2017:11) and occupies premises on short term leases at 55 Park Lane, London W1K 1NA and Pennsylvania Biotechnology Centre of Bucks County, 3805 Old Eastern Road, Doylestown, P.A. 18902-8400 USA.

18.4 The total expenses incurred (or to be incurred) by the Company in connection with Admission are approximately £120,000.

18.5 The Company is dependent on the patents, described in the Prospectus and industrial, commercial or financial contracts or new manufacturing processes which are material to the Company's business or profitability.

18.6 In accordance with the Prospectus Regulation Rules, the Company will file with the FCA, and make available for inspection by the public, details of the number of Ordinary Shares issued under this prospectus. The Company will also announce the issue of the Ordinary Shares through an RIS.

19. THIRD PARTY SOURCES

The Company confirms that information sourced from third parties has been accurately reproduced and, as far as the Company is aware and is able to ascertain from information published by those third parties, no facts have been omitted which would render the reproduced information inaccurate or misleading. Estimates extrapolated from these data involve risks and uncertainties and are subject to change based on various factors, including those discussed in Part II – *Risk Factors* of this prospectus. There is only a limited amount of independent data available about certain aspects of the industry in which the Company operates and the position of the Company relative to its competitors. As a result, certain data and information about its market contained in this prospectus are based on good faith estimates reflecting the Company's reasonable review of internal data and information obtained from customers and other third party sources, such as trade and business organisations and associations and other contacts within the pharmaceutical industry. The Company believes these internal surveys and management estimates are reliable; however, no independent sources have verified such surveys and estimates.

20. NO INCORPORATION OF INFORMATION BY REFERENCE

The contents of the Company's website (www.tizianalifesciences.com), unless specifically incorporated by reference, any website mentioned in this prospectus or any website directly linked to these websites have not been verified and do not form part of this prospectus, and prospective investors should not rely upon them.

21. AVAILABILITY OF DOCUMENTS

21.1 Copies of the following documents may be inspected at the registered office of the Company at 3rd Floor, 12 St. James's Square, London SW1Y 4LB during usual business hours on any day (except Saturdays, Sundays and public holidays) from the date of this prospectus until Admission:

(a) the Articles; and

(b) this prospectus.

21.2 In addition, this prospectus will be published in electronic form and be available on the Company's website at https://ir.tizianalifesciences.com/ subject to certain access restrictions applicable to persons located or resident outside the UK.

Date: 18 December 2020

PART XV

DEFINITIONS

The following definitions apply throughout this prospectus (unless the context requires otherwise):

"**ABI**"	the Association of British Insurers;
"**ADSs**"	American Depositary Shares;
"**Admission**"	admission of the Ordinary Shares to the standard listing segment of the Official List and to trading on the main market for listed securities of the London Stock Exchange;
"**AIM**"	the market of that name operated by the London Stock Exchange;
"**AIM Rules**"	the rules published by the London Stock Exchange with set out the rules and responsibilities in relation to companies with a class of securities admitted to trading on AIM;
"**Affiliate**" **or** "**Affiliates**"	an affiliate of, or person affiliated with, a person; a person that, directly or indirectly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the person specified;
"**AGM**"	an Annual General Meeting of the Company;
"**Articles**" or "**Articles of Association**"	the memorandum and articles of association of the Company in force from time to time;
"**ATM**"	at-the-market;
"**Business Day**"	any day (other than a Saturday or Sunday) or an English bank or public holiday;
"**certificated**" **or** "**in certificated form**"	in relation to a share, warrant or other security, a share, warrant or other security, title to which is recorded in the relevant register of the share, warrant or other security concerned as being held in certificated form (that is, not in CREST);
"**Change of Control**"	following any acquisition, the acquisition of Control of the Company by any person or party (or by any group of persons or parties who are acting in concert);
"**CMO**"	a contract manufacturing organisation;
"**Companies Act**"	the Companies Act 2006;
"**Company**" or "**Tiziana**"	Tiziana Life Sciences plc, a company incorporated in England and Wales with registered number 03508692;
"**Control**"	(i) the power (whether by way of ownership of shares, proxy, contract, agency or otherwise) to: (a) cast, or control the casting of, more than 50 per cent. of the maximum number of votes that might be cast at a general meeting of the Company; or (b) appoint or remove all, or the majority, of the Directors or other equivalent officers of the Company; or (c) give directions with respect to the operating and financial policies of the Company with which the Directors or other equivalent officers of the Company are obliged to comply; and/or (ii) the holding beneficially of more than 50 per cent. of the issued shares of the Company (excluding any issued shares that carry no right to participate beyond a distribution of either profits or capital), but excluding in the case of each of (i) and (ii) above any such power or holding that arises as a result of the issue of Ordinary Shares by the Company in connection with the acquisition;

"**CREST**" or "**CREST System**"	the paperless settlement system operated by Euroclear enabling securities to be evidenced otherwise than by certificates and transferred otherwise than by written instruments;
"**CREST Regulations**"	the Uncertificated Securities Regulations 2001 (*SI 2001 No. 3755*);
"**CRO**"	a contract research organisation;
"**Demerger**"	has the meaning given in Part I – *Summary;*
"**Directors**", "**Board**" or "**Board of Directors**"	the directors of the Company, whose names appear in Part VII – *The Board of Directors* of this prospectus, or the board of directors from time to time of the Company, as the context requires, and "Director" is to be construed accordingly;
"**Disclosure Guidance and Transparency Rules**" or "**DTRs**"	the disclosure guidance and transparency rules of the FCA made in accordance with section 73A of FSMA as amended from time to time;
"**EEA**"	the European Economic Area;
"**EMA**"	the European Medicines Agency;
"**Existing Issued Share Capital**"	the issued share capital of the Company as at the time of this prospectus and at Admission;
"**EU**"	the European Union;
"**Euroclear**"	Euroclear UK & Ireland Limited;
"**Existing Ordinary Shares**"	194,612,289 Ordinary Shares of nominal value 3 pence each in the capital of the Company in issue as at the date of this prospectus;
"**FCA**"	UK Financial Conduct Authority;
"**FDA**"	the U.S. Food and Drug Administration;
"**FSMA**"	the Financial Services and Markets Act 2000 of the UK, as amended;
"**general meeting**"	a meeting of the Shareholders of the Company or a class of Shareholders of the Company (as the context requires);
"**Group**"	the Company and its subsidiaries;
"**IFRS**"	International Financial Reporting Standards, as adopted by the EU;
"**Listing Rules**"	the listing rules made by the FCA under section 73A of FSMA as amended from time to time;
"**London Stock Exchange**"	London Stock Exchange plc;
"**Market Abuse Regulation**"	Market Abuse Regulation (EU) No. 596/2014;
"**Member States**"	the member states of the European Union and the EEA;
"**Memorandum**"	the memorandum of association of the Company in force from time to time;
"**NASDAQ**"	the NASDAQ Global Market operated by NASDAQ, Inc.;
"**Official List**"	the official list maintained by the FCA;
"**Optiva**"	Optiva Limited;
"**Ordinary Shares**"	the ordinary shares of nominal value 3 pence each in the capital of the Company;
"**Premium Listing**"	a premium listing under Chapter 6 of the Listing Rules;

"**Prospectus Regulation**"	Regulation (EU) 2017/1129;
"**Prospectus Regulation Rules**"	the prospectus regulation rules of the FCA made in accordance with section 73A of FSMA, as amended from time to time;
"**Register**"	the register of holders of Ordinary Shares to be maintained by the Registrar;
"**Registrar**"	Link Market Services or any other registrar appointed by the Company from time to time;
"**Regulation S**"	Regulation S promulgated under the US Securities Act;
"**Relevant Member State**"	a Member State which has implemented the Prospectus Regulation;
"**Restricted Jurisdiction**"	the United States, Canada, Japan, Australia and the Republic of South Africa;
"**Reverse Takeover**"	a reverse takeover as defined in the Listing Rules;
"**RIS**"	a Regulatory Information Service;
"**Securities Act**"	US Securities Act of 1933, as amended;
"**Senior Managers**"	the members of the senior management team of the Company, whose names appear in Part VII – *The Board of Directors and Senior Members of Management*;
"**Share Dealing Code**"	the Company's policy on director dealings in securities which is consistent with the Marker Abuse Regulation;
"**Shareholder**"	a holder of Ordinary Shares;
"**Special Resolution**"	a resolution of Shareholders requiring a majority of not less than 75 per cent.;
"**Standard Listing**"	a standard listing under Chapter 14 of the Listing Rules;
"**StemPrintER**"	has the meaning given in Part I – *Summary;*
"**Takeover Code**"	the City Code on Takeovers and Mergers;
"**Takeover Panel**"	the UK Panel on Takeovers and Mergers;
"**TPL**"	Tiziana Pharma Limited;
"**UK Corporate Governance Code**"	the UK Corporate Governance Code issued by the Financial Reporting Council in the UK from time to time;
"**uncertificated**" or "**uncertificated form**"	in relation to a share or other security, a share or other security, title to which is recorded in the relevant register of the share or other security concerned as being held in uncertificated form (that is, in CREST) and title to which may be transferred by using CREST;
"**United Kingdom**" or "**UK**"	the United Kingdom of Great Britain and Northern Ireland;
"**United States**" or "**US**"	the United States of America;
"**US Person**"	any person who is a US person within the meaning of Regulation S adopted under the US Securities Act;
"**VAT**"	(i) within the EU, any tax imposed by any Member State in conformity with the Directive of the Council of the European Union on the common system of value added tax (2006/112/EC), and (ii) outside the EU, any tax corresponding to, or substantially similar to, the common system of value added tax referred to in paragraph (i) of this definition; and
"**2020 AGM**"	the AGM of the Company which occurred on 16 July 2020.

References to a "**company**" in this prospectus shall be construed so as to include any company, corporation or other body corporate, wherever and however incorporated or established.

PART XVI

DOCUMENTS INCORPORATED BY REFERENCE

The Company's annual report and accounts for the period ended 31 December 2019 contain information which is relevant to Admission. This prospectus available on the Company's website at https://www.tizianalifesiences.com.

The table below sets out the various sections of the documents which are incorporated by reference into this prospectus so as to provide the information required under the Prospectus Regulation Rules and to ensure that shareholders and others are aware of all information which, according to the particular nature of Company and of the Ordinary Shares, is necessary to enable shareholders and others to make an informed assessment of the assets and liabilities, financial position, profit and losses and prospects of the Company.

Any non-incorporated parts of the documents are either not relevant for the purposes of Admission or the relevant information is included elsewhere in this prospectus. Any documents themselves incorporated by reference or referred or cross-referred to in the documents referred to below shall not form part of this prospectus.

Document	Section	Page numbers	Section in this prospectus
Annual Report for the period ended 31 December 2019 (https://ir.tizianalifesciences.com/static-files/22aa8342-15ae-4f65-8345-771190416a47**)**	Statutory and other information	1	Part XVII – *Historical Financial Information of the Company*
	Executive Chairman's Statement	2-7	
	Strategic Report	8-14	
	Directors' Report	15-21	
	Directors' Remuneration Report	22-30	
	Independent Auditor's Report to the members of the Company	31-34	
	Consolidated Statement of Comprehensive Income	35	
	Consolidated Statement of Financial Position	36	
	Company Statement of Financial Position	37	
	Consolidated Statement of Cash Flows	38	
	Company Statement of Cash Flows	39	
	Consolidated Statement of Changes in Equity	40	
	Company Statement of Changes in Equity	41	
	Notes to the Consolidated and Company Financial Statements	42-65	
Annual Report for the period ended 31 December 2018 (https://ir.tizianalifesciences.com/static-files/75b98d55-26f5-442c-af33-8b95cc751f11**)**	Statutory and other information	1	Part XVII – *Historical Financial Information of the Company*
	Executive Chairman's Statement	2-6	
	Strategic Report	7-11	
	Directors' Report	12-17	
	Directors' Remuneration Report	18-25	
	Independent Auditor's Report to the members of the Company	26-30	
	Consolidated Statement of Comprehensive Income	31	
	Consolidated Statement of Financial Position	32	
	Company Statement of Financial Position	33	
	Consolidated Statement of Cash Flows	34	

Document	Section	Page numbers	Section in this prospectus
	Company Statement of Cash Flows	35	
	Consolidated Statement of Changes in Equity	36	
	Company Statement of Changes in Equity	37	
	Notes to the Consolidated and Company Financial Statements	38-55	
Annual Report for the period ended 31 December 2017 (https://ir.tizianalifesciences.com/static-files/8e6e1b07-660d-412f-ad70-d9b0fdfddcb1**)**	Statutory and other information	1	Part XVII – *Historical Financial Information of the Company*
	Executive Chairman's Statement	2-6	
	Strategic Report	7-9	
	Directors' Report	10-12	
	Independent Auditor's Report to the members of the Company	13-17	
	Consolidated Statement of Comprehensive Income	18	
	Consolidated Statement of Financial Position	19	
	Company Statement of Financial Position	20	
	Consolidated Statement of Cash Flows	21	
	Company Statement of Cash Flows	22	
	Consolidated Statement of Changes in Equity	23	
	Company Statement of Changes in Equity	24	
	Notes to the Consolidated Financial Statements	25-45	
Interim historical financial information for the six months ended 30 June 2020 (https://ir.tizianalifesciences.com/static-files/7dddd8c2-f75c-4b31-8aec-aba24897af4b**)**	Executive Chairman's Statement	1-2	Part XVII – *Historical Financial Information of the Company*
	Statement of comprehensive income	2-3	
	Statement of financial position	3-4	
	Statement of cash flows	4-5	
	Statement of changes in equity	6-8	
	Notes to the interim financial statements	9-23	
Interim historical financial information for the six months ended 30 June 2019 (https://ir.tizianalifesciences.com/static-files/a6b0b739-b06c-4b72-ad91-6d86cc4e458a**)**	Highlights during the period	1-4	Part XVII – *Historical Financial Information of the Company*
	Executive Chairman's Statement	5-6	
	Statement of comprehensive income	7	
	Statement of financial position	8	
	Statement of cash flows	9	
	Statement of changes in equity	10-11	
	Notes to the interim financial statements	12-23	

PART XVII

HISTORICAL FINANCIAL INFORMATION ON THE COMPANY

The unaudited interim financial statements relating to the Group for the six months ended 30 June 2020 are incorporated by reference into this prospectus as described in Part XVII – *Historical Financial Information of the Company* of this prospectus.

The audited financial statements relating to the Group for the financial year ended 31 December 2019 are incorporated by reference into this prospectus as described in Part XVII – *Historical Financial Information of the Company* of this prospectus.

The unaudited interim financial statements relating to the Group for the six months ended 30 June 2019 are incorporated by reference into this prospectus as described in Part XVII – *Historical Financial Information of the Company* of this prospectus.

The audited financial statements relating to the Group for the financial year ended 31 December 2018 are incorporated by reference into this prospectus as described in Part XVII – *Historical Financial Information of the Company* of this prospectus.

The audited financial statements relating to the Group for the financial year ended 31 December 2017 are incorporated by reference into this prospectus as described in Part XVII – *Historical Financial Information of the Company* of this prospectus.