STEALTH BIOTHERAPEUTICS CORP

FORM 20-F

(Annual and Transition Report (foreign private issuer))

Filed 04/01/20 for the Period Ending 12/31/19

Telephone	617-600-6888
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Symbol	MITO
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

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

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

for the transition period from to

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 001-38810

STEALTH BIOTHERAPEUTICS CORP

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Cayman Islands
(Jurisdiction of incorporation or organization)

Stealth BioTherapeutics Corp
c/o Intertrust Corporate Services (Cayman) Limited
190 Elgin Avenue, George Town
Grand Cayman
KY1-9005 Cayman Islands
(Address of principal executive offices)

Irene McCarthy, Chief Executive Officer
Stealth BioTherapeutics Inc.
275 Grove Street, Suite 3-107
Newton, MA 02466
(617) 600-6888
E-mail: IR@stealthbt.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 12 ordinary shares, par value U.S.$0.0003 per share	MITO	The Nasdaq Global Market LLC

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

None

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

None

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of the period covered by the annual report. 436,720,810 ordinary shares, $0.0003 par value per share.

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Emerging growth company	☒

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

†The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

U.S. GAAP ☒	International Financial Reporting Standards as issued by the International Accounting Standards Board ☐	Other ☐

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

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

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Accounting Principles

The consolidated financial statements presented at the end of this annual report have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP. Any reference in the notes to the consolidated financial statements to applicable guidance is meant to refer to authoritative GAAP, as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, of the Financial Accounting Standards Board, or FASB. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the company's management evaluates its estimates related to, but not limited to, estimates related to fair value of ordinary share, share-based compensation expense, recoverability of the company's net deferred tax asset-related valuation allowances, and certain prepaid expenses and accrued expenses. The company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

General Information

Except where the context otherwise requires and for purposes of this annual report on Form 20-F only:

- the "company," "we," "us," "our company" and "our" refer to Stealth BioTherapeutics Corp, or Stealth, and its consolidated subsidiaries, including Stealth BioTherapeutics Inc., or Stealth US; Stealth BioTherapeutics (HK) Limited, or Stealth HK; and Stealth BioTherapeutics (Shanghai) Limited, or Stealth Shanghai.
- "ordinary shares" refers to our ordinary shares, par value $0.0003 per share;
- "ADSs" refers to our American depositary shares, each of which represents 12 ordinary shares;
- "ADRs" refers to American depositary receipts, which, if issued, evidence our ADSs;
- unless otherwise indicated, all historical share and per-share data contained in this annual report on Form 20-F have been restated to give retroactive effect to a three-for-one reverse share split that became effective on December 28, 2018.

This annual report on Form 20-F includes our audited consolidated statements of operations for the years ended December 31, 2019, 2018 and 2017 and audited consolidated balance sheets as of December 31, 2019 and 2018.

We completed our initial public offering, or IPO, of 6,500,000 ADSs, each representing 12 ordinary shares, in February 2019, and we issued an additional 588,232 ADSs in March 2019 pursuant to our underwriters' partial exercise of their over-allotment option.

Our ADSs are listed on The Nasdaq Global Market under the symbol "MITO".

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 20-F contains forward-looking statements that relate to future events, including our future operating results and conditions, our prospects and our future financial performance and condition, all of which are largely based on our current expectations and projections. The forward-looking statements are contained principally in the sections entitled "Item 3.D.—Risk Factors," "Item 4.—Information on the Company" and "Item 5.—Operating and Financial Review and Prospects." These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. The words "anticipate," "expect," "hope," "plan," "potential," "possible," "will," "believe," "estimate," "intend," "may," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of known and unknown risks, uncertainties and other important factors, including but not limited to the following:

- our plans to develop and commercialize elamipretide and our other product candidates, including SBT-272, SBT-259, SBT-550, and to identify additional product candidates;
- ongoing and planned clinical trials and preclinical studies for our product candidates, including the timing of initiation of these trials and studies and the timing of the anticipated results;
- our plans to possibly enter into collaborations for the development of product candidates and the potential benefits of any collaboration;
- the timing of anticipated regulatory filings, meetings with regulatory agencies or regulatory approvals and plans and expectations for expedited regulatory review for our product candidates;
- the potential advantages and clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding the potential market opportunity for our product candidates; and
- our estimates regarding expenses, future revenue, capital requirements, sufficiency of our current cash and cash equivalent and our need for and ability to obtain additional funding.

The forward-looking statements made in this annual report on Form 20-F relate only to events or information as of the date on which the statements are made in this annual report on Form 20-F. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this annual report on Form 20-F completely and with the understanding that our actual future results may be materially different from what we expect.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected financial data.

The selected consolidated statement of operations data for the fiscal years ended December 31, 2019, 2018 and 2017, and the selected consolidated balance sheet data as of December 31, 2019 and 2018, are derived from our audited consolidated financial statements appearing elsewhere in this annual report. The selected consolidated statement of operations data for the fiscal year ended December 31, 2016, and the selected consolidated balance sheet data as of December 31, 2017 and 2016 have been derived from our respective audited consolidated financial statements and notes thereto that are not included within this report.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the related notes which are included in "Item 18. —Financial Statements" of this annual report. We prepare our consolidated financial statements in accordance with GAAP as issued by the FASB.

	Year Ended December 31,			
	2019	2018	2017	2016
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Revenue	$ 21,087	$ —	$ —	$ —
Operating expenses:				
Research and development	44,604	53,062	63,220	48,445
General and administrative	22,315	22,217	16,500	13,403
Total operating expenses	66,919	75,279	79,720	61,848
Loss from operations	(45,832)	(75,279)	(79,720)	(61,848)
Other income (expense), net	(25,896)	(21,433)	(3,190)	799
Net loss attributable to ordinary shareholders	$ (71,728)	$ (96,712)	$ (82,910)	$ (61,049)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.19)	$ (1.41)	$ (1.21)	$ (0.90)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders—basic and diluted	375,669,759	68,476,149	68,472,262	68,165,325

(1) See Notes 2 and 16 to our audited consolidated financial statements appearing elsewhere in this annual report for further details on the calculation of basic and diluted net loss per share attributable to ordinary shareholders.

	As of December 31,			
	2019	2018	2017	2016
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$ 50,768	$ 10,855	$ 4,119	$ 9,710
Working capital (deficit)	18,448	(27,318)	(18,675)	(338)
Net assets	17,267	(175,329)	(79,909)	1,546
Total assets	52,743	15,523	7,155	13,322
Total convertible preferred shares	—	211,377	211,377	211,377
Total accumulated deficit	(497,997)	(426,269)	(329,557)	(246,647)
Total shareholders' equity (deficit)	17,267	(386,706)	(291,286)	(209,831)

B. Capitalization and indebtedness.

Not applicable.

C. Reasons for the offer and use of proceeds.

Not applicable.

D. Risk factors.

Our business has significant risks. You should consider carefully the risks described below, together with the other information contained in this annual report, including our consolidated financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We will need substantial additional funding. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. Furthermore, we have incurred, and expect to continue to incur, significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed and on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of December 31, 2019, we had cash and cash equivalents of $50.8 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020.

Our existing cash and cash equivalents will not be sufficient to support our clinical development of elamipretide and SBT-272 for rare cardiomyopathies and neurological indications and rare and common ophthalmic indications, our planned Phase 3 trial for Leber's hereditary optic neuropathy, or LHON, or any clinical development for SBT-259, SBT-550 or any other product candidates we may develop in the future. We will be required to expend significant funds in order to advance the development of elamipretide, SBT-272, SBT-259 and SBT-550, as well as any other product candidates we may develop in the future. In addition, while we may seek one or more collaborators for future development of our product candidates, and, in particular, may conduct any large Phase 3 clinical trials of elamipretide, such as those we would likely be required to conduct for common age-related diseases such as dry age related macular degeneration, or dry AMD, in collaboration with one or more partners that would finance most of the associated costs, we may not be able to enter into a collaboration for any of our product candidates on

suitable terms, or at all. In any event, our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our estimate as to how long we expect our existing cash and cash equivalents to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of our current and future clinical trials;
- research and preclinical development efforts for any future product candidates that we may develop;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our current and future product candidates;
- our headcount growth and associated costs if and as we expand our research and development and establish a commercial infrastructure;
- costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- costs of operating as a public company.

Our recurring losses and negative cash flows could raise substantial doubt regarding our ability to continue as a going concern.

Based on our cash balances, recurring losses and projected spending, there could be doubt about our ability to continue as a going concern. Given our planned expenditures for the next several years, including, without limitation, expenditures in connection with our clinical trials of elamipretide, SBT-272, SBT-259, SBT-550 and other new compounds, we have concluded, in connection with the issuance of our consolidated financial statements for the year ended December 31, 2019 that there is a substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has issued a going concern opinion in connection with the audit of our annual financial statements for the fiscal year ended December 31, 2019. A going concern opinion means that there is substantial doubt that the company can continue as an ongoing business for the next 12 months. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect the price of the ADSs and our ability to raise new capital or to enter into critical contractual relations with third parties. There is no assurance that we will be able to adequately fund our operations in the future.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital through the sale of ordinary shares, ADSs, convertible securities or other equity securities, our existing shareholders' ownership interest may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a holder of ADSs. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. For example, in connection with our term loan facility with Hercules Capital, Inc., or Hercules, we granted a security interest on all of our assets, excluding our intellectual property, and agreed to a negative pledge on our intellectual property. The term loan facility also contains restrictive covenants including, subject to certain exceptions, covenants that prohibit us from incurring additional indebtedness, creating any lien on our property, making investments, paying dividends or redeeming shares, transferring any material portion of our assets, merging with or acquiring another entity, entering into a transaction that will result in a change of control and making certain other corporate changes. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have incurred significant losses since inception and expect to incur significant and increasing losses for at least the next several years. We may never achieve or maintain profitability.

We have incurred significant annual net operating losses in every year since our inception. Our net losses were $71.7 million, $96.7 million and $82.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $498.0 million. We expect to continue to incur significant and increasing operating losses for the foreseeable future, and we do not know whether or when we will become profitable. We have not generated any revenues from product sales, have not completed the development of any product candidates and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through the issuance of our ADSs, ordinary shares, Series A convertible preferred shares and debt financings and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to, elamipretide, including our ongoing Phase 2/3 and Phase 2b clinical trials for the treatment of Barth Syndrome, or Barth, and geographic atrophy, or GA, our anticipated Phase 2 clinical trial for the treatment of rare cardiomyopathy, our planned Phase 3 trial for the treatment of LHON and any future clinical trials;
- initiate and continue research and preclinical and clinical development efforts for our other product candidates, including SBT-272, SBT-259 and compounds in the SBT-550 series;
- seek to identify and develop additional product candidates;

- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control and scientific personnel;
- add operational, financial, management information systems and commercial personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add property, equipment and physical infrastructure to support our research and development programs in the United States, Europe and China.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require our, or any of our future collaborators', success in a range of challenging activities, including completing clinical trials of our product candidates; obtaining marketing approval for these product candidates; manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval; satisfying any post-marketing requirements; and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of increased expenses, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We began operations in 2006 and initiated our first clinical trial in 2010. Our operations have been limited to financing and staffing our company and developing our technology and conducting preclinical research and clinical trials for our product candidates. We have not demonstrated an ability to obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of December 31, 2019, we had $16.5 million of outstanding principal under our term loan facility with Hercules. We are currently obligated to pay interest on these borrowings, and commencing February 1, 2020, we are required to repay principal and interest on these borrowings in monthly installments through January 2021. Subject to the restrictions in this existing facility, we could incur additional indebtedness beyond our borrowings from Hercules.

Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from Hercules, combined with our other financial obligations and contractual commitments, could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under our term loan facility. Failure to make payments or comply with other covenants under our term loan facility could result in an event of default and acceleration of amounts due. Additionally, under our loan and security agreement with Hercules, an occurrence that has a material adverse effect on our business, operations, properties, assets or financial condition; on the collateral, liens or priority of such liens; or on our ability to perform under the terms of the loan or associated agreements could be considered an event of default. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual property. In addition, the covenants under our credit facility, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our approach to the discovery and development of product candidates and the development of therapies targeting mitochondria generally are unproven, and we do not know whether we will be able to develop any products of commercial value.

We are focused on discovering and developing therapies for diseases involving mitochondrial dysfunction, particularly by developing therapies that target mitochondria in order to normalize the function of dysfunctional mitochondria. While we believe that our approach may ultimately enable drug research and clinical development for mitochondrial diseases across a wide range of therapeutic areas, this approach is unproven. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in later stage clinical trials or in obtaining marketing approval thereafter. For example, we announced in December 2019 that our Phase 3 clinical trial in primary mitochondrial myopathy, or PMM, did not meet its primary efficacy endpoints. Furthermore, no products or therapies targeting mitochondrial dysfunction have ever obtained marketing approval from the U.S. Food and Drug Administration, or the FDA, or China's National Medical Products Administration, or NMPA, and the European Medicines Agency, or the EMA, has approved one therapy to treat LHON (Raxone, or idebenone, made by Santhera Pharmaceuticals Holding), which is the only approved therapy to treat any primary mitochondrial disease.

If we are unable to successfully discover and develop product candidates, our business prospects will be substantially harmed.

We are dependent on the success of our clinical product candidates. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize any of our product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

We have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of elamipretide for the treatment of rare primary mitochondrial diseases. Our prospects are substantially dependent on our ability, or the ability of any future collaborator, to develop, obtain marketing approval for and successfully commercialize elamipretide, SBT-272 or any of our other product candidates.

The success of elamipretide will depend on several factors, including the following:

- successful recruitment of subjects, enrollment in and completion of our ongoing clinical trials;
- initiation and successful recruitment of subjects, enrollment in and completion of additional clinical trials;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- our ability to identify success criteria and endpoints for our clinical trials such that the FDA and other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug products that are appropriately packaged for sale;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- accuracy of the estimates of the current and future number of patients with mitochondrial associated or inherited mitochondrial diseases;
- commercial acceptance by patients, the medical community and third-party payors following any marketing approval; and
- our ability to compete with other therapies targeting diseases involving mitochondrial dysfunction.

Many of these factors—including with respect to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator—are beyond our control, and clinical development of product candidates is inherently risky and uncertain. For example, although we observed trends towards improvement in a certain subset of patients, our Phase 2/3 clinical trial in Barth failed to reach its primary efficacy endpoints. Our Phase 3 trial in PMM also failed to meet its primary efficacy endpoints. If we are unable to develop, receive marketing approval for and successfully commercialize elamipretide, on our own or with any future collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

We are developing elamipretide for certain indications of the eye, including GA and LHON. Our clinical trial for the treatment of LHON involved administration of elamipretide by use of topical drops, and our clinical trial for the treatment of GA involves administration of elamipretide by subcutaneous injection. We are working to develop methods for intravitreal injection, or direct injection of drug into the eye, but we cannot predict whether those development efforts will be successful.

We may not be successful in our efforts to identify or discover and develop additional potential product candidates.

A significant portion of the research that we are conducting involves the development of new therapeutic compounds targeting the mitochondria. The drug discovery that we are conducting may not be successful in identifying compounds that have commercial value or therapeutic utility. Our discovery platform may initially show promise in identifying potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including the following:

- compounds we develop may not demonstrate improved efficacy, safety or tolerability;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

Our research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. Further, the results we obtain in preclinical testing and early clinical trials may not be predictive of results that are obtained in later studies, and we may suffer significant setbacks in advanced clinical trials, even after seeing promising results in earlier studies. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact the price of the ADSs.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our most advanced product candidates, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our applications.

Depending on the extent of these or any other FDA-required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, any marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly and materially harm our business.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development. We faced this type of setback when our Phase 3 clinical trial in PMM did not meet its primary efficacy endpoints despite encouraging signals in early clinical trials, and we cannot be certain that we will not face similar setbacks in other trials. 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. If our trial designs are not sufficient, our clinical programs may be delayed or we may decide to terminate one or more of such programs.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. During the regulatory review process, we will need to identify success criteria and endpoints at the time of the initiation of the trial such that the FDA or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop, and the resulting clinical data and results may be difficult to analyze. Even if the FDA or other regulatory authorities were to find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. Many companies that believed that their product candidates had performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain marketing approval of their product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Specifically, the clinical trials we have completed to date have enrolled only small numbers of subjects, we have experienced dropout among participants, and we have not always successfully achieved our pre-specified clinical trial endpoints to a degree of statistical significance.

To date, other than our Phase 3 clinical trial in PMM, we have only conducted small Phase 1 and Phase 2 clinical trials, many of which have been undertaken to help inform our clinical strategy and develop later stage clinical trials intended to assess efficacy. While the endpoints and populations for these later stage clinical trials, including our Phase 2b clinical trial for GA, our planned Phase 3 clinical trial for LHON and our anticipated Phase 2 clinical trial for rare cardiomyopathy, are or will be derived from results of our earlier trials and medical literature, in some cases we did not demonstrate a statistically significant effect in the population and on the efficacy endpoints in our prior clinical trials prospectively described in the clinical trial protocol. The lack of statistical significance could be attributed to various factors, including the lack of power to demonstrate significance, the design of the studies or the lack of a treatment benefit from our product candidate. In some cases, we conducted post hoc, retrospective analyses of data subsets and have designed, and expect to design later stage clinical trials based on the results of such post hoc analyses. For example, the improvements in stroke volume and other parameters of cardiac function as well as in functional endpoints observed in our Barth trial were not statistically significant during the placebo-controlled portion of the trial, which we believe was due to the duration of therapy being too short to derive benefit. Although we plan to design our future trials in rare cardiomyopathies with a longer duration of dosing, we cannot predict the successfulness of that approach. For example, despite improvements observed in similar endpoints during a Phase 2 trial, our Phase 3 clinical trial in PMM failed to reach its primary efficacy endpoints. Additionally, we observed in our Phase 3 clinical trial in PMM that subjective, effort-dependent endpoints such as the six-minute walk test, or 6MWT, may be influenced by a placebo effect, such that patients randomized to placebo may experience meaningful improvements. Although we have incorporated and plan to incorporate objective endpoints including disease biomarkers such as echocardiographic parameters of cardiac function for Barth and other rare cardiomyopathies, and optical coherence tomography and fundus autofluorescence imaging of geographic atrophy progression for GA, we have also assessed and expect to assess functional endpoints including 6MWT, for Barth, and visual function, for GA.

If we fail to receive positive results in clinical trials of our product candidates and do not achieve statistical significance for the prospectively specified primary endpoints in our planned Phase 3 clinical trials, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Reenie McCarthy, our Chief Executive Officer and a Director, as well as the other principal members of our management and scientific teams. Ms. McCarthy is employed "at will," meaning we or she may terminate the employment relationship at any time. In the future, we may be dependent on other members of our management, scientific and development team. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

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

In January 2020, we announced a 60% reduction in workforce as part of a strategic organizational restructuring plan, to principally align our operations around our Barth syndrome program and rare cardiomyopathy expansion efforts, our Phase 2b clinical trial in GA, our Phase 1 trial of SBT-272 and our discovery programs. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific and medical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

Because we are developing elamipretide for the treatment of several indications for which regulatory authorities have not issued definitive guidance as to how to measure and demonstrate efficacy, there is substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support marketing approval.

We are developing elamipretide for several indications for which there are currently no approved therapies in the United States, China or the European Union, including Barth and dry AMD. We are developing elamipretide for LHON, for which there are no currently approved therapies in the United States or China and only one therapy approved in Europe. Furthermore, there has been limited historical

clinical trial experience for the development of drugs to treat many of these indications. As a result, the design and conduct of clinical trials for these indications is subject to substantial risk. In particular, regulatory authorities in the United States and in other jurisdictions, including Europe and China, have not issued definitive guidance as to how to measure and demonstrate efficacy for Barth, LHON or dry AMD and, as a result, there is substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support marketing approval. For example, the endpoints in our Phase 2/3 clinical trial of elamipretide for the treatment of Barth included change in six-minute walk distance and change in a total fatigue scale, or BTHS-SA Total Fatigue, from the Barth symptom assessment, or BTHS-SA, a newly developed patient reported outcome measure, which has not been utilized in prior trials and may not be accepted by regulators as a basis for approval. Even if this type of novel endpoint is accepted as a basis for approval in the United States, we cannot be certain that regulators outside of the United States will accept such endpoints or will not require us to conduct additional validation studies to support the suitability of such endpoints for approval in these jurisdictions.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. The clinical development of our product candidates is susceptible to the risk of failure at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. For example, Phase 3 clinical trials for common diseases associated with aging, such as dry AMD, would likely require a large number of subjects to be enrolled, which would cause any such trial to be very expensive. Moreover, it is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face additional setbacks. It is possible that any of our development programs may be placed on full or partial clinical hold by regulatory authorities at any point, which would delay and possibly prevent further development of our product candidates.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities impose similar restrictions. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Any inability to complete preclinical and clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (i) we, or any future collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we or they contemplate, (ii) we, or any future collaborators, are unable to successfully complete clinical trials of our product candidates or other testing, (iii) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (iv) there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators, may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Adverse events or undesirable side effects caused by, or other unexpected properties of, any of our product candidates may be identified during development that could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable regulatory authorities. If any of our product candidates is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, subjects in certain of our clinical trials have reported adverse events arising from reaction at the injection site and some subjects have withdrawn as a result. Moreover, laboratory findings have demonstrated mild to moderate elevations in eosinophils, a variety of white blood cells that combats parasites and infections and controls mechanisms associated with allergy and asthma, beginning at approximately three to four weeks after initiation of elamipretide treatment, although these have not been reported to be associated with any systemic clinical manifestations of eosinophilia and in general were demonstrated to have returned to within normal range or to baseline levels after withdrawal of elamipretide therapy and, in most subjects, to decrease to within normal range after approximately 16 weeks of elamipretide therapy (and without withdrawal of therapy). In addition, we observed a mean increase in certain liver enzymes in subjects who received the highest dose of our product candidate SBT-20 in our

Phase 1 clinical trial, although the principal investigator determined that no individual increases in such liver enzymes were clinically significant and similar increases were not observed in the highest dose cohort of a prior Phase 1/2 clinical trial of SBT-20. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound. If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We, or any future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval or commercialization of our product candidates, including the following:

- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we, or any future collaborators, may decide, or regulators may require us, or them, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we, or any future collaborators, anticipate, subject enrollment in these clinical trials may be slower than we, or any future collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or any future collaborators, anticipate;
- the cost of planned clinical trials of our product candidates may be greater than we anticipate;
- our third-party contractors or those of any future collaborators, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any future collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any future collaborators in a timely manner, or at all;
- regulators or institutional review boards may not authorize us, any future collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or any future collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- subjects that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subjects from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we, or any future collaborators, may have to delay, suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we, or any future collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable regulatory authorities may disagree with our, or any future collaborators', clinical trial designs or our or their interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any future collaborators, enter into agreements for clinical and commercial supplies;

- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us, or any future collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of any future collaborators, to bring products to market before we, or any future collaborators, do and impair our ability, or the ability of any future collaborators, to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

If we, or any future collaborators, experience delays or difficulties in the enrollment of subjects in clinical trials, our or their receipt of necessary regulatory approvals could be delayed or prevented.

We, or any future collaborators, may not be able to initiate or continue clinical trials for any of our product candidates if we, or they, are unable to locate and enroll a sufficient number of eligible subjects to participate in clinical trials as required by the FDA or comparable regulatory authorities. For example, we are developing elamipretide for the treatment of several rare diseases with small patient populations, such as Barth. Enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of subjects to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinician and patient perception as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Our inability, or the inability of any future collaborators, to enroll a sufficient number of subjects for our, or their, clinical trials could result in significant delays or may require us or them to abandon one or more clinical trials altogether. For example, our Phase 2a clinical trial of elamipretide in subjects pre-treated prior to a renal angioplasty was terminated early due to recruitment challenges after enrolling only 14 subjects of the 28 originally planned. Enrollment delays in clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our, or any future collaborators', ability to commence sales of and generate revenues from our product candidates, which could cause the value of our company to decline.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of subjects who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. In particular, because our product candidates will require chronic dosing over the lifetime of the patient, there may be undesirable side effects as a result of long-term exposure to the drug that were not observed in our clinical trials. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a medication guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact the price of the ADSs.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we estimate.

We have never commercialized a product. Even if one of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to inform the medical community and third-party payors of the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments;

- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products;
- availability of coverage and the adequacy of reimbursement from government payors, managed care plans and other third-party payors;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates that we develop if and when those product candidates are approved.

We do not have a sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We plan to use a combination of focused in-house sales and marketing capabilities and third-party collaboration, licensing and distribution arrangements to sell any of our products that receive marketing approval.

We generally plan to retain rights to participate in commercialization in the United States, particularly for products that we can commercialize with a specialized sales force and by building a focused sales and marketing organization in the United States to sell our products. Any efforts related to sales, marketing and distribution may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our products, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

We hope to collaborate with third parties for commercialization in the United States of any products that require larger sales, marketing and product distribution infrastructure. We plan to commercialize our products outside the United States through collaboration, licensing and distribution arrangements with third parties. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

We have modified our manufacturing processes so that we will be able to produce sufficient quantities of elamipretide for commercial distribution. Interruptions in this process could delay anticipated marketing authorization applications.

We previously used solid-phase peptide synthesis to produce elamipretide acetate batches for all completed and certain ongoing preclinical and clinical trials. Due to a lack of scalability, we deemed this process undesirable for production of commercial quantities of elamipretide and implemented a new solution-phase process. It is typical during the years prior to gaining approval for new drugs to continue to develop manufacturing processes to achieve larger scale production with a typical goal of implementing essentially the commercial process prior to supplying pivotal clinical trials. However, our transition to a solution-phase process is recent, and any interruption in continued production of supply needed to meet potential commercial demands could delay anticipated marketing authorization applications, including NDAs, and/ or significantly impact the anticipated cost of commercial production, if our product candidates are approved for sale.

We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. We expect that we, and any future collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any of our product candidates that we, or they, may seek to develop or commercialize in the future. Specifically, there are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the key indications of our most advanced programs.

We are initially developing elamipretide for the treatment of rare primary mitochondrial diseases and common diseases of aging in which mitochondrial function is impaired. There are several companies developing treatments that target mitochondria or mitochondria-associated diseases. The majority of these efforts are in preclinical or early clinical development, are focused on gene therapy or are proposing the use of generic compounds. To our knowledge, none of these is focused on cardiolipin remodeling. Our competitors include: NeuroVive Pharmaceutical AB, Reata Pharmaceuticals, Inc., LumiThera, Inc., Reneo Pharmaceuticals, Inc. and Santhera Pharmaceuticals Holding. In addition to competition from competitors who are developing treatments that seek to improve mitochondrial function or otherwise target the mitochondria, we also face competition from therapies that target the indications we are studying, particularly for diseases of aging such as GA. Such competitors who are developing or who have developed competing therapies include Apellis Pharmaceuticals Inc., Astellas Pharma Inc., Hemera Biosciences Inc., Ionis Pharmaceuticals, Inc. and IVERIC bio, Inc.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects or are less costly than any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we, or any future collaborators, may develop. Our competitors also may obtain FDA or other marketing approval for their products before we, or any future collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any future collaborators, are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If the FDA or comparable regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. We have an issued composition of matter patent on elamipretide. As such, the active ingredient will be treated as an NCE and any products containing elamipretide will be granted exclusivity based on that patent expiry date and other contributing factors. It is unclear whether the FDA will treat the active ingredients in our other product candidates as NCEs and, therefore, afford them five years of NCE data exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products, if any, may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of our product candidates in key potential markets will depend substantially on the extent to which the costs of our product candidates will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval. Moreover, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for products in the United States can differ significantly from payor to payor.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any of our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and worldwide. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The COVID-19 pandemic, which began in late 2019 in China and has spread worldwide. may affect our ability to recruit or retain patients for our clinical trials, disrupt regulatory activities, disrupt preclinical studies or have other adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019 in China and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain. We seek to enroll patients for our clinical trials at sites located in the United States and may be unable to continue trials as scheduled. We may face difficulties recruiting or retaining patients in our ongoing and planned clinical trials if patients are affected by the virus or are fearful of traveling to our clinical trial sites because of the outbreak. We and our third-party contract manufacturers, contract research organizations, academic collaborators and clinical sites may also face disruptions in accessing laboratory or clinical trial sites or procuring items that are essential for our research and development activities, including, for example, raw materials used in the manufacture of our product candidates, medical and laboratory supplies used in our clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, operations and financial condition.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is 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 we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial subjects or patients;

- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we believe we maintain adequate general and clinical trial liability insurance for a company at our stage, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin selling any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We expect to seek collaborators for the development and commercialization of one or more of our product candidates. For example, we hold worldwide rights for elamipretide and SBT-20 and we own our new pipeline compounds, including SBT-272. We may explore partnerships for development of elamipretide or SBT-272, as well as one or more of our pipeline compounds, in selected other indications and territories. For example, in October 2019, we granted Alexion Pharmaceuticals, Inc., or Alexion, an exclusive option to co-develop and commercialize elamipretide. Alexion terminated the option agreement in January 2020. Likely future collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain marketing approval for any of our product candidates from foreign regulatory authorities, we intend to enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates outside of the United States.

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

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

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

We may enter into collaborations for the development and commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

We rely on third parties to conduct our clinical trials. If they do not perform satisfactorily, our business could be significantly harmed.

We do not independently conduct clinical trials of any of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct these clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into

alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could materially impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, our reliance on these third parties for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a contract research organization for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, or cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. Similar regulatory requirements apply outside the United States, including the International Council for Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be impaired.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture and distribution of our product candidates for clinical trials and expect to continue to do so in connection with our future development and commercialization efforts. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on contract manufacturers to produce both drug substance and drug product required for our clinical trials. We plan to continue to rely upon contract manufacturers, and potentially collaboration partners, to manufacture commercial quantities of our product candidates and, if approved, products. Reliance on such third-party contractors entails risks, including:

- manufacturing delays if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. To date, we, or our partners on our behalf, have obtained materials for elamipretide and SBT-272 from third-party manufacturers. If any of our existing manufacturers should become unavailable to us for any reason, we may incur some delay in identifying or qualifying replacements.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations, delay our clinical trials and, if our products are approved for sale, result in lost sales. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales.

If any of our product candidates are approved by any regulatory agency, we plan to enter into agreements with third-party contract manufacturers for the commercial production and distribution of those products. It may be difficult for us to reach agreement with a contract manufacturer on satisfactory terms or in a timely manner. In addition, we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under current good manufacturing practices, or cGMPs, that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization efforts.

Third-party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States, such as the ICH. Facilities used by our third-party manufacturers must be approved by the FDA after we submit an NDA and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, and of any applicable foreign regulatory authority, we will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate.

In addition, our manufacturers are subject to ongoing periodic inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements both prior to and following the receipt of marketing approval for any of our product candidates. Some of these inspections may be unannounced. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could adversely affect supplies of our product candidates and significantly harm our business, financial condition and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive and time consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, term and commercial value of our patent rights are highly uncertain.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity, term or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. As a result, the inventorship or ownership of our intellectual property may be challenged in the future.

Our pending and future patent applications may not result in patents being issued which protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Our issued patents or any patents that may issue in the future may be invalidated or interpreted narrowly, such that they fail to provide us with any significant competitive advantage. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications have issued or do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

While we have obtained composition of matter patents with respect to our clinical-stage product candidates through an application family in-licensed from Cornell Research Foundation, Inc., a subsidiary of Cornell University, or Cornell, and Institut de recherches cliniques de Montréal, or the IRCM, we also rely on trade secret protection for certain aspects of our discovery platform. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees, certain consultants, contractors and collaborators. To our knowledge, such agreements have been entered into with all relevant parties; however we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be misappropriated or disclosed to, or independently developed by, a competitor, our business and competitive position could be harmed.

Certain aspects of our product candidates and technology are protected by patents exclusively licensed from academic institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our approved products will be harmed.

We are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by third parties. In particular, we hold exclusive licenses from Cornell and the IRCM for elamipretide and SBT-20, as well as for other compounds and certain methods. We may enter into additional license agreements as part of the development of our business in the future. If we are unable to maintain these patent rights or our license to these patent rights for any reason, or if we are unable to maintain any future material license we may enter into, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. For example, under our license agreement with Cornell, we have the first right to enforce the licensed patents against third-party infringement. However, our first right to enforce is subject to Cornell's consent.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. Despite our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to obtain regulatory approval and to market products covered by these license agreements. For example, under our license agreements with Cornell and the IRCM, if we fail to commercialize a product by December 31, 2020, Cornell may terminate the license, subject to specified exceptions for causes due to scientific and regulatory events that are common in drug development, such as institutional review board delays, clinical trial recruitment, clinical trial results and regulatory delays, and other events over which we cannot exert direct control. If our license agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our license agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our business prospects.

Our license agreements with Cornell and the IRCM impose, and future license agreements we may enter into may impose, various diligence, milestone payment, royalty and other obligations on us. For example, our license agreements with Cornell and the IRCM include an obligation to pay royalties on the net sales of product candidates or related technologies to the extent they are covered by the agreement. If we fail to comply with our obligations under our license agreement with Cornell and the IRCM or future license agreements, and if no such exceptions apply, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by the agreement or face other penalties under the agreement, such as loss of exclusivity. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Moreover, 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 our product candidates, 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 under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties 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 we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Some of our intellectual property that was discovered through government-funded programs may be subject to federal regulation such as "march-in" rights, certain reporting requirements and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements and limit our ability to contract with foreign manufacturers.

Some of our intellectual property with respect to our product candidates has been funded, at least in part, by the U.S. government and, therefore, would be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. For example, under the "march-in" provisions of the Bayh-Dole Act, the government may have the right under limited circumstances to require the patent owners to grant exclusive, partially exclusive or non-exclusive rights to third parties for intellectual property discovered through the government-funded program. The government can exercise its march-in rights if it determines that action is necessary because the patent owner fails to achieve practical application of the new invention or because action is necessary to alleviate health concerns or address the safety needs of the public. Intellectual property discovered under the government-funded program is also subject to certain reporting requirements, compliance with which may require us or our licensors to expend substantial resources. Such intellectual property is also subject to a preference for U.S. industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property. We may apply for additional U.S. government funding, and it is possible that we may discover additional compounds or product candidates as a result of such funding. Intellectual property under such discoveries would be subject to the applicable provisions of the Bayh-Dole Act. Similarly, intellectual property that we license in the future may have been made using government funding and may be subject to the provisions of the Bayh-Dole Act.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. We may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the ADSs. Moreover,

there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

In addition, we may from time to time become involved in disputes, including litigation, with respect to intellectual property. For example, in August 2013, a former vendor commenced an arbitration proceeding against us regarding a disputed license to the vendor's technology. In July 2014, the vendor commenced a lawsuit against one of our service providers, whom we had previously agreed to indemnify for certain liabilities. In February 2016, we entered into a settlement agreement that provided for mutual releases and dismissal with prejudice of each of the pending arbitration and litigation claims. In connection with the settlement, we paid $725,000 to the vendor and agreed to withdraw and/or not refile certain pending patent applications in satisfaction of all of our obligations under the settlement agreement.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties have U.S. and non-U.S. issued patents and pending patent applications relating to compounds and methods of use for the treatment of key indications for our priority programs, and we may be subject to claims that our research, development and commercialization activities infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates, including derivation or interference proceedings, post grant and *inter partes* reviews, opposition proceedings, and the like in the United States and in other jurisdictions. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms,

or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective in March 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including China, India and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and the extension only applies to those claims covering the approved drug, a method for using it or a method for manufacturing it. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. Furthermore, in the United States, only a single patent can be extended for each qualifying FDA approval, and any patent can be extended only once and only for a single product. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Because both elamipretide and SBT-20 compositions-of-matter are protected by a single family of patents and applications, we may not be able to secure patent term extensions for both of these product candidates in all jurisdictions where these product candidates are or may be approved, including the United States.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed by others, including universities and other biotechnology and pharmaceutical companies, some of which are our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical and clinical studies, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drug products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, which regulations differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of an NDA.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in key potential markets, we, and any future collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

We have obtained Fast Track designation from the FDA for elamipretide for the treatment of Barth, LHON and GA. However, Fast Track designation may not actually lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA Fast Track designation. If the Fast Track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides, and the FDA approves, a schedule for submission of the individual sections of the application. In November 2017, the FDA notified us that we had obtained Fast Track designation for elamipretide for the treatment of Barth and LHON and in November 2018, the FDA notified us that we had obtained Fast Track designation for elamipretide for the treatment of patients with geographic atrophy, an advanced form of dry AMD. Fast Track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures or that we will ultimately obtain regulatory approval of elamipretide. Additionally, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We have obtained orphan drug designation from the FDA for elamipretide for the treatment of Barth and LHON. However, we, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our other product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually 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. We have received orphan drug designation for elamipretide for Barth and LHON. We, or any future collaborators, may seek orphan drug designations for other product candidates or in other jurisdictions and may be unable to obtain such designations.

Even for product candidates for which we, or any future collaborators, may obtain orphan drug designation, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. 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 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 we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable

exclusivity period. The applicable period is seven years in the United States. The exclusivity period in the United States can be extended by six months if the sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. 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 we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product 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 or more effective or makes a major contribution to patient care. In the European Union, marketing authorization 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.

Even if we, or any future collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, or any of our future collaborators, are not able to comply with post-approval regulatory requirements, we, and any such future collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any of our product candidates for which we, or any future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our product candidates for which we, or any future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, which violations can result in the imposition of significant administrative, civil and criminal penalties.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Healthcare legislative reform measures may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 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;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- expansion of the entities eligible for discounts under the Public Health Service program; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current presidential administration and Congress will likely continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the ACA. This includes enactment of the Tax Cuts and Jobs Act, which, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance.

In addition, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and oral arguments are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers, if any, and accordingly, our financial operations.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures. For example, on December 23, 2019, the Trump administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our arrangements with third-party payors, healthcare providers and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. These include the following:

Anti-Kickback Statute. The federal healthcare Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; *False Claims Laws.* The federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalties laws, which provides for civil whistleblower or qui tam actions, prohibit, among other things, individuals and entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms and physical, administrative and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information;

Transparency Requirements. The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, biologics, devices and supplies to report payments and other transfers of value to physicians and teaching hospitals and ownership and investment interests by physicians; and

Analogous State and Foreign Laws. Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope, can apply to our business activities, including sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Certain state and local laws require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Regulatory or legislative developments regarding privacy and data security matters could adversely affect our ability to conduct our business.

We are subject to data privacy and security regulation in the jurisdictions in which we conduct our business, particularly in light of increased regulatory scrutiny of and user expectations regarding the processing, collection, use, storage, dissemination, transfer and disposal of user data. The regulatory frameworks regarding privacy issues in many jurisdictions are constantly evolving and can be subject to significant changes from time to time, and therefore we may not be able to comprehensively assess the scope and extent of our compliance responsibility at a global level. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. Data privacy concerns may result in increased costs of operations and threats of lawsuits, enforcement actions and related liabilities, including financial penalties.

The New Economic Substance Law in the Cayman Islands may have an adverse effect on our business.

The Cayman Islands is a member of the Organisation for Economic Co-operation and Development, or OECD, Inclusive Framework on Base Erosion and Profit Shifting, and, along with other OECD-compliant jurisdictions, enacted economic substance legislation in January 2019. Pursuant to the legislation, namely the International Tax Cooperation (Economic Substance) Law (as amended) together with related regulations and guidance, referred to as the ES Law, we may need to incur additional costs in order to comply with filing or other requirements. While we intend to comply with the ES Law, there is a risk of inadvertent non-compliance and the payment of associated penalties. International standards are continuing to develop and it is anticipated that the ES Law will evolve and be subject to further clarification. Hence, it is not possible to determine with certainty the extent to which the ES Law may affect us.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems may be vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

While we have not experienced a system failure, accident, cyber-attack or security breach that has resulted in a material interruption in our operations to date, if such an event were to occur, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business and the further development of our product candidates could be delayed.

The collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, responding to data subject requests, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20.0 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anticorruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Although we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

In the future, if we decide to market our products outside of the United States, such as in the European Union, the United Kingdom or China, we would need to obtain additional approvals and comply with additional regulatory requirements.

Our primary regulatory strategy is to apply first for approvals in the United States for our rare disease programs. We may in the future apply for approvals in Europe and the United Kingdom, or clinical trial waivers in China, following receipt of marketing authorization in the United States. However, as we also plan to consider collaboration for commercialization efforts in Europe, the United Kingdom and China, we anticipate that potential commercialization partners may have input into regulatory strategies in those jurisdictions. To date, we have focused our regulatory efforts primarily on achieving approvals and marketing authorization in the United States. In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not we obtain FDA approval for a product, we or our collaborators would need to obtain the necessary approvals by the comparable foreign regulatory authorities before marketing the product in those countries or jurisdictions. We cannot be sure whether and when we would be able to obtain the necessary approvals, which could adversely affect our business and prospects.

Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any.

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

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable regulatory authorities, provide accurate information to the FDA or comparable regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages,

fines, disgorgement, individual imprisonment, exclusion of products from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Ownership of ADSs

Morningside Venture (I) Investments Limited has a controlling ownership interest in our ordinary shares and the ability to substantially control all matters submitted to shareholders for approval.

As of February 29, 2020, Morningside Venture (I) Investments Limited, or MVIL, beneficially owns 61.0% of our ordinary shares. In addition, certain entities associated within MVIL beneficially own an additional 13.4% of our ordinary shares. As a result, MVIL and such entities will be able to control all matters submitted to our shareholders for approval that require an ordinary resolution or special resolution, as well as our management and affairs. For example, MVIL would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other shareholders may desire.

MVIL owns a controlling portion of our ordinary shares and may have conflicts of interest with us and other shareholders in the future.

The interests of MVIL may not always be consistent with the interests of our company or of our other shareholders. Accordingly, MVIL could cause us to enter into transactions or agreements of which other holders of our ordinary shares would not approve or make decisions with which such holders would disagree. Gerald L. Chan, one of our directors, is a co-founder of the Morningside group, a private investment group with venture, private equity and property investments. In addition, Reenie McCarthy, our Chief Executive Officer and a director, served as a member of the investment team at Morningside Technology Advisory, LLC (and affiliates) from 1993 through 2016, and remains a director of Morningside Technology Advisory, LLC, which provides advisory services to entities associated with the Morningside group.

Although Dr. Chan is not an officer, director or employee of MVIL and has neither voting nor dispositive control over the ordinary shares held by MVIL and does not otherwise beneficially own such shares, as a result of his ongoing relationship with the Morningside group, transactions between us and MVIL may present an actual or perceived conflict of interest. Although Ms. McCarthy is not an officer, director or employee of MVIL, and has neither voting nor dispositive control over our ordinary shares held by MVIL and does not otherwise beneficially own such shares, as a result of her historic relationship with the Morningside group and her ongoing relationship with Morningside Technology Advisory, LLC, transactions between us and MVIL may present an actual or perceived conflict of interest. Any actual or perceived conflicts of interest may lead Dr. Chan and Ms. McCarthy to recuse themselves from actions of our board of directors with respect to transactions involving MVIL and its affiliates. For example, in a situation in which MVIL is adverse to us, such as if it breaches an agreement with us, a conflict could arise. We may not be able to resolve any potential conflicts, and even if we do, the resolution may be less favorable than if we were dealing with an unaffiliated party.

MVIL is in the business of making investments in companies and could from time to time acquire and hold interests in businesses that compete with us. MVIL may also pursue acquisition opportunities that may be complementary to our business, and as a result, desirable acquisitions may not be available to us. So long as MVIL continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions.

The price of the ADSs has been, and is likely to continue to be, highly volatile.

The price of the ADSs has been, and is likely to continue to be, highly volatile. 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. The market price for the ADSs may be influenced by many factors, including:

- our ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- announcements relating to our clinical trials, including any periodic updates relating to enrollment of trial subjects, adverse events, site initiation, and timing of release of interim analyses and final trial results;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results from, or any delays in, clinical trials relating to our product candidates, including our clinical trials for elamipretide;
- any need to suspend or discontinue clinical trials due to side effects or other safety risks, or any need to conduct studies on the long-term effects associated with the use of our product candidates;
- manufacturing issues related to our product candidates for clinical trials or future products for commercialization;
- commercial success and market acceptance of our product candidates following regulatory approval;
- undesirable side effects caused by product candidates after they have entered the market;
- ability to discover, develop and commercialize additional product candidates;
- announcements relating to collaborations that we may enter into with respect to the development or commercialization of our product candidates;
- success of our competitors in discovering, developing or commercializing products;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims related to our clinical trials or product candidates;
- business disruptions caused by earthquakes or other natural disasters or a public health crisis (for example, an outbreak of a contagious disease such as COVID-19);
- disputes concerning our intellectual property or other proprietary rights;
- FDA, EMA, NMPA or other regulatory actions affecting us or our industry;
- healthcare reform measures in the United States;
- future sales or issuances of equity or debt securities by us;
- fluctuations in our semi-annual operating results;
- announcement or expectation of additional financing efforts;
- sales of our ordinary shares by us, our insiders or other shareholders;
- actual and anticipated variations in our results of operations;
- changes in securities analysts' estimates or market perception of our financial performance;
- announcements by us of significant acquisitions, disposals, strategic alliances or joint ventures;

- market developments affecting us or the markets in which we operate;
- regulatory or legal developments, including litigation;
- the operating and share price performance of companies that investors consider to be comparable to us;
- the depth and liquidity of the market for the ADSs;
- the release or expiry of lock-up or other transfer restrictions on our ordinary shares and ADSs;
- general economic, political and stock market conditions in the United States and the countries in which we operate and elsewhere in the world; and
- the other factors described in this "Risk Factors" section.

Additionally, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us in light of the significant stock price volatility we and other pharmaceutical companies have experienced in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make the ADSs less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years from our IPO. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In this annual report, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company and a foreign private issuer. We cannot predict whether investors will find the ADSs less attractive if we rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price of the ADSs may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies. As a result, our financial statements may not be comparable to the financial statements of reporting companies that are required to comply with the effective dates for new or revised accounting standards that are otherwise applicable to public companies.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the Securities and Exchange Commission than U.S. companies. This may limit the information available to holders of the ADSs.

We are a "foreign private issuer," as defined in the rules and regulations of the Securities and Exchange Commission, or the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our senior management and supervisory board members are exempt from the

reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We intend to continue to rely on Nasdaq Stock Market rules that permit us to comply with applicable Cayman Islands corporate governance practices, rather than the corresponding domestic U.S. corporate governance practices, and therefore your rights as a shareholder will differ from the rights you would have as a shareholder of a domestic U.S. issuer.

As a foreign private issuer whose ADSs are listed on The Nasdaq Global Market, we are permitted in certain cases to follow Cayman Islands corporate governance practices instead of the corresponding requirements of the Nasdaq Stock Market rules. A foreign private issuer that elects to follow a home country practice instead of Nasdaq requirements must submit to Nasdaq in advance a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. In addition, a foreign private issuer must disclose in its annual reports filed with the SEC each such requirement that it does not follow and describe the home country practice followed instead of any such requirement. In accordance with Cayman Islands law:

- we do not require a remuneration committee to have entirely independent directors;
- we do not require an independent director oversight of director nominations; and
- we do not require the board of directors to have regularly scheduled meetings at which only independent directors are present.

For further information upon the differences between Delaware law and Cayman Islands law, please see "Description of Share Capital and Articles of Association—Differences in Corporate Law" in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we do not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors and more expensive to procure director and officer liability insurance.

We incur increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. Moreover, these requirements have increased our legal and financial compliance costs and make some activities more time consuming and costly.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe, or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of the ADSs to decline significantly, even if our business is doing well.

Sales of a substantial number of ADSs in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of ordinary shares intend to sell ADSs, could reduce the market price of the ADSs.

We have also registered 63.5 million ordinary shares that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates.

We do not anticipate paying any cash dividends on the ADSs in the foreseeable future. Accordingly, holders of ADSs must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our share capital. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of our existing loan and security agreement preclude us from paying cash dividends without the consent of our lender. As a result, capital appreciation, if any, of the ADSs will be your sole source of gain for the foreseeable future. However, if we do pay a cash dividend on our ordinary shares in the future, we may only pay such dividend out of our profits or share premium (subject to applicable solvency requirements) under Cayman Islands law.

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

The trading market for the ADSs will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us, or provide favorable coverage. If one or more analysts downgrade the ADSs or change their opinion of the ADSs, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price of the ADSs or trading volume to decline.

We may be classified as a passive foreign investment company for any taxable year, which may result in adverse U.S. federal income tax consequence to U.S. holders.

Based on our estimated gross income and average value of our gross assets, and taking into account the price of our ADSs, we do not believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our tax year ended December 31, 2019 and do not currently expect to be a PFIC during our tax year ending December 31, 2020. A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which at least 75% of its gross income is passive income or on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions. Our status in any taxable year will depend on our assets and activities in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any future taxable year. The market value of our assets may be determined in large part by reference to the market price of the ADSs, which may fluctuate considerably given that market prices of biotechnology companies have been especially volatile. If we were to be treated as a PFIC for any taxable year during which a U.S. holder held the ADSs, certain adverse U.S. federal income tax consequences could apply to the U.S. holder. See "Item 10.E.—Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders—Passive Foreign Investment Company Rules" in this annual report.

Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs have appointed the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote directly with respect to any specific matter. We cannot assure you that you will receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. See "Description of American Depositary Shares" in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

Holders of our ADSs may face limitations on transfer and withdrawal of underlying ordinary shares.

Our ADSs, which may be evidenced by American Depositary Receipts, or ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities. See "Description of American Depositary Shares" in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including in respect of claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with such matters, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law and many of our directors reside outside of the United States.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our Amended and Restated Memorandum and Articles of Association, referred to as our Articles of Association, the Companies Law (2020 Revision) of the Cayman Islands, referred to as the Companies Law, and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary duties of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England and Wales, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. Similarly, the rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States, and some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. As a Cayman Islands exempted company, we may not have standing to initiate a derivative action in a federal court of the United States. As a result, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you to sue in a United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in U.S. federal courts.

Shareholders of Cayman Islands exempted companies like us have very limited statutory rights under Cayman Islands law to inspect the corporate records of Cayman Islands exempted companies into which they are invested and have no statutory rights to obtain copies of registers of shareholders of Cayman Islands exempted companies. Although our shareholders may request access to our books and records, our directors have discretion under our Articles of Association to determine whether or not, and under what conditions, certain of our corporate records may be inspected by our shareholders. Under the Companies Law, shareholders are entitled to view our Articles of Association. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Certain corporate governance practices in the Cayman Islands, which is the jurisdiction of our incorporation, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. To the extent we choose to follow practice in the Cayman Islands with respect to corporate governance matters, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

The Cayman Islands has no legislation specifically dedicated to the rights of investors in securities or statutorily defined private causes of action to investors in securities such as those found under the Securities Act of 1933, or the Securities Act, or the Exchange Act. Subject to limited exceptions, under Cayman Islands law, a shareholder is not entitled to bring a derivative action against the board of directors. U.S.-style class action lawsuits are not recognized in the Cayman Islands, but groups of shareholders with identical interests may bring representative proceedings in a similar fashion.

As a result of all of the above, our shareholders may have more difficulty in protecting their interests in the face of actions taken by management, or members of the board of directors than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Law of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, see “Description of Share Capital and Articles of Association—Differences in Corporate Law” in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

Our corporate affairs and the rights of holders of ordinary shares are governed by our Articles of Association, the Companies Law, and the common law of the Cayman Islands. Certain rights and responsibilities of our shareholders, ADS holders and members of our board of directors under Cayman Islands law are different from those that apply to a Delaware corporation.

Directors of Cayman Islands exempted companies are required to observe certain fiduciary duties. These fiduciary duties are owed to the Cayman Islands company and include the duty to act in the best interests of the company and the shareholders as a whole. However, the fiduciary duties of a director of a Cayman Islands exempted company may not be the same as the fiduciary duty of a director of a U.S. corporation.

In addition, controlling shareholders of U.S. corporations owe fiduciary duties to minority shareholders, while shareholders (including controlling shareholders) of Cayman Islands companies generally owe no fiduciary duties to the company or other shareholders.

The rights of our shareholders to bring shareholders’ suits against us or our board of directors under Cayman Islands law are much more limited than those of shareholders of a U.S. corporation. For example, under Cayman Islands law, a shareholder who wishes to bring a claim against a director would generally need to obtain permission from the Grand Court of the Cayman Islands, or Cayman Islands Court, to bring a derivative action, in the name of the company, against the director. This is because the director of a Cayman Islands exempted company owes duties to the company and not to individual shareholders. As a result, our shareholders, including holders of ADSs, may have more difficulty protecting their rights in connection with actions taken by our directors than they would as shareholders of a U.S. corporation.

Minority shareholders in a Cayman Islands exempted company have more limited rights than minority shareholders in a U.S. corporation in relation to mergers and similar transactions that the company may carry out. For example, if a merger under the Companies Law involving a Cayman Islands exempted company is approved by the requisite majority of shareholders, a dissenting minority shareholder would have the right to be paid the fair value of their shares (which, if not agreed between the parties, will, following the course of legal proceedings, be determined by the Cayman Islands Court) if the shareholders follow the statutorily prescribed procedure for initiating such proceedings, subject to certain exceptions. Such dissenter rights differ substantially from the appraisal rights, which would ordinarily be available to dissenting shareholders of Delaware corporations. Further, if a takeover offer is made to the shareholders of a Cayman Islands exempted company and accepted by holders of 90% of the shares affected, the offeror may require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Cayman Islands Court, but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion. A minority shareholder in this scenario would have no rights comparable to the appraisal rights which would generally be available to a dissenting shareholder of a U.S. corporation in similar circumstances. For a discussion of significant differences between the provisions of the Companies Law of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, see "Description of Share Capital and Articles of Association—Differences in Corporate Law" in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

Item 4. Information on the Company

A. History and development of the company.

Our registered office is located at c/o Intertrust Corporate Services (Cayman) Limited, 190 Elgin Avenue, George Town, Grand Cayman, KY1-9005 Cayman Islands. We have three wholly-owned subsidiaries: Stealth BioTherapeutics Inc., a Delaware company, which we refer to as Stealth Delaware; Stealth BioTherapeutics (HK) Limited, a company incorporated with limited liability under the laws of Hong Kong; and Stealth BioTherapeutics (Shanghai) Limited, a limited liability company established in the People's Republic of China. Our agent for service of process in the United States is Stealth Delaware, and the executive offices of Stealth Delaware are located at 275 Grove Street, Suite 3-107, Newton, MA 02466, and the telephone number there is (617) 600-6888. Our website address is www.stealthbt.com. We have included our website address in this annual report as an inactive textual reference only. The information contained in, or accessible through, our website does not constitute part of this annual report on Form 20-F. The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

Stealth BioTherapeutics Corp was incorporated in Grand Cayman, Cayman Islands as Stealth Peptides International, Inc. in April 2006. Its wholly owned subsidiary, Stealth BioTherapeutics Inc., was incorporated in Delaware as Stealth Peptides Inc. in October 2007. In addition, a wholly owned subsidiary, Stealth BioTherapeutics (HK) Limited, was incorporated in Hong Kong in September 2017. In May 2018, Stealth BioTherapeutics (Shanghai) Limited was formed as a wholly foreign-owned enterprise in China.

We conduct our operations in the United States through Stealth Delaware. All of our employees are employed by Stealth Delaware. We are a clinical stage biotechnology company focused on the discovery and development of novel pharmaceutical agents to treat patients suffering from diseases involving mitochondrial dysfunction through our mitochondrial medicine platform. Since inception, we have devoted substantially all of our efforts to research and development, business planning, acquiring operating assets, seeking intellectual property protection for our technology and product candidates, and raising capital.

We closed our IPO of 6,500,000 ADSs, each representing 12 ordinary shares, on February 20, 2019. We issued an additional 588,232 ADSs on March 4, 2019 in connection with our underwriters' partial exercise of their over-allotment option. In October 2019, we entered into an option agreement with Alexion Pharmaceuticals, Inc., or Alexion, pursuant to which we received gross proceeds of $30.0 million. Prior to our IPO, we entered into numerous debt and equity issuances with MVIL and other investors, and we financed our operations from the issuance of preferred shares, ordinary shares, convertible debt and term debt. Since inception, we have incurred net losses and negative cash flows from operations and had an accumulated deficit of $498.0 million and $426.3 million as of December 31, 2019 and 2018, respectively.

Our capital expenditures for the years ended December 31, 2019, 2018 and 2017 amounted to $0.1 million, $0.01 million and $0.2 million, respectively. In the three-year period ended December 31, 2019, we have invested a total of $0.3 million in equipment and facilities.

B. Business overview.

Overview

We are a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel therapies for diseases involving mitochondrial dysfunction. Mitochondria, found in nearly every cell in the body, are the body's main source of energy production and are critical for normal organ function. Dysfunctional mitochondria characterize a number of rare genetic diseases and many common age-related diseases, leading to devastating cardiac, ophthalmic and neurological symptoms. We believe our product candidates have significant potential to treat the cardiac, ophthalmic and neurological symptoms of both rare genetic and common age-related mitochondrial diseases. Our mission is to be the leader in mitochondrial medicine, and we have assembled a highly experienced management team, board of directors and group of scientific advisors to help us achieve this mission. Our leadership team has decades of experience leading drug discovery and development programs, including at GlaxoSmithKline, Novo Nordisk, Lilly and Sanofi Genzyme.

Our first clinical product candidate, elamipretide, is a small peptide that targets and binds reversibly to cardiolipin, an essential structural element of mitochondria, stabilizing it under conditions of oxidative stress. This novel mechanism of action has shown potential clinical benefit in both rare genetic and common age-related cardiac and ophthalmic diseases entailing mitochondrial dysfunction.

We are studying elamipretide in the following indications:

- Barth Syndrome, or Barth, for which we have conducted a Phase 2/3 clinical trial and a retrospective natural history comparative control efficacy study in the United States;
- Geographic atrophy, or GA, an advanced form of dry age-related macular degeneration, for which we have conducted a Phase 1 clinical trial in the United States and in March 2019 initiated a Phase 2b clinical trial in the United States; and
- Leber's hereditary optic neuropathy, or LHON, for which we have conducted a Phase 2 clinical trial in the United States.

We are evaluating the potential for additional clinical trials in cardiomyopathy, or heart muscle weakness, associated with Duchenne's muscular dystrophy, or DMD, and Friedreich's ataxia, or FDRA, which are phenotypically similar to the Barth cardiac phenotype assessed in our Barth program. We hope to initiate a clinical development program for elamipretide in rare cardiomyopathy by early 2021. We also expect to initiate a Phase 3 global clinical trial for LHON when resources permit, but in no event earlier than 2021.

Elamipretide has been generally well tolerated in over 900 subjects exposed to it systemically and 53 subjects exposed to it via topically instilled eye drops as of December 31, 2019.

Our second clinical product candidate, SBT-272, is a novel peptidomimetic that has been shown to increase adenosine triphosphate, or ATP, production and decrease levels of reactive oxygen species, or ROS, in dysfunctional mitochondria in preclinical studies. In early experiments, SBT-272 demonstrated higher mitochondrial uptake, greater concentrations in the brain, and improved oral bioavailability relative to elamipretide. We are developing SBT-272 for rare neurological diseases involving mitochondrial dysfunction. We initiated a Phase 1 clinical trial in healthy subjects in January 2020, and we are conducting preclinical studies in amyotrophic lateral sclerosis, or ALS, and multiple system atrophy, or MSA, models to inform our decisions regarding our first Phase 2 indication.

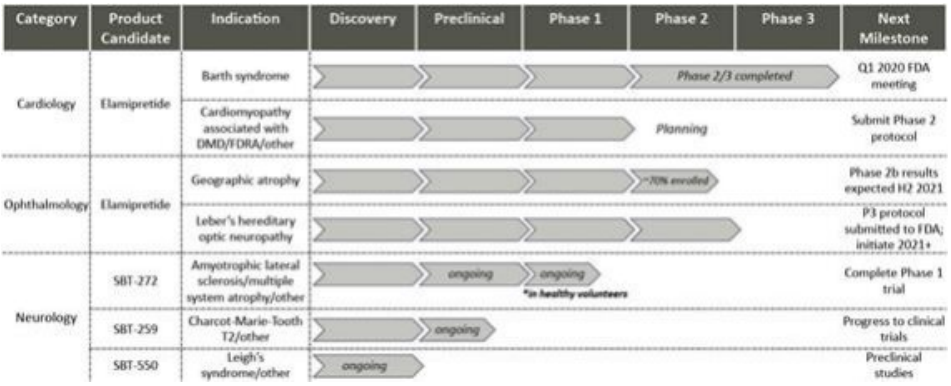
We have discovered and own over 100 compounds, including SBT-272, SBT-259, and the SBT-550 family, that also target the mitochondria and form the basis of our broad proprietary pipeline of mitochondria-targeted product candidates. We are evaluating compounds in the SBT-259 family, including SBT-20 and SBT-259, as well as compounds in the SBT-550 family, for rare neurological indications. In addition, our internal discovery platform has generated a library of over 100 differentiated proprietary compounds which could have clinical benefit for diseases related to mitochondrial dysfunction and from which we plan to designate potential product candidates. We may also utilize certain of these compounds as part of our carrier platform, in which they could potentially serve as scaffolds to deliver other beneficial compounds to the mitochondria.

As of December 31, 2019, we held exclusive worldwide rights or an option for exclusive worldwide rights under 423 issued patents and 242 patent applications to protect our platform and product candidates. We have exclusive worldwide rights to elamipretide and SBT-20, both of which we licensed from Cornell and IRCM, in 2006. The unique mitochondrial activity of elamipretide was first published in *The Journal of Biological Chemistry* in August 2004. Since licensing elamipretide and SBT-20, we and our collaborators have published approximately 100 peer-reviewed articles highlighting the activity of our compounds in several disease models, including heart failure, kidney disease, skeletal muscle weakness, diabetic retinopathy and neurodegenerative diseases. Our compounds have been evaluated in preclinical and clinical studies at academic and clinical institutions, including Charité Berlin, Children's Hospital of Philadelphia, Columbia University, Cornell University, Duke University, Massachusetts General Hospital, Mayo Clinic, Stanford University, University of California Los Angeles, University of California San Diego and University of Washington.

In October 2019, we entered into an option agreement with Alexion, under which Alexion had the exclusive option to negotiate a license to co-develop and commercialize elamipretide for PMM. Alexion terminated the option agreement in January 2020.

Our Pipeline

The following table summarizes our development pipeline, including preclinical studies and ongoing and planned clinical trials of our product candidates.



Our Strategy

We aspire to lead the development of mitochondrial medicine to improve the lives of patients with severe unmet medical needs. Our strategy is to focus on near-term rare disease opportunities in cardiac, ophthalmic and neurological indications, while continuing to progress the potential of our approach to treat diseases associated with aging in which mitochondrial dysfunction has been implicated. Particularly for larger common disease indications associated with aging, we plan to assess development collaborations with industry leaders. To achieve our goals, we intend to:

Expand the clinical development of elamipretide in rare cardiomyopathies

We are developing elamipretide for rare mitochondrial diseases affecting cardiac function. We have seen improvements in cardiac parameters during the open-label extension portion of our Barth trial, and met with the U.S. Food and Drug Administration, or FDA in March 2020 to discuss this data and our goal of seeking regulatory approval for the commercialization of elamipretide in Barth. We have received Fast Track and Orphan Drug designations for this indication in the United States. We are also evaluating the potential for clinical trials in cardiomyopathy associated with DMD and FDRA, which are phenotypically similar to the Barth cardiac phenotype assessed in our Barth program.

Progress the clinical development of elamipretide in ophthalmology

We are developing elamipretide for ophthalmic conditions associated with mitochondrial dysfunction. We intend to continue to rapidly advance elamipretide through the completion of our Phase 2b clinical trial in GA, which we expect to be fully enrolled in the second half of 2020 with data expected during the second half of 2021. We have received Fast Track designation for this indication in the United States. We are also seeking FDA feedback on our Phase 3 clinical protocol to assess elamipretide in patients with LHON, for which we expect to initiate a global Phase 3 clinical trial no earlier than 2021. We have received Fast Track and Orphan Drug designations for this indication in the United States.

Advance our second-generation and pipeline mitochondrial medicines for rare neurological diseases

We are developing our second-generation and pipeline mitochondrial medicines for rare neurological diseases involving mitochondrial dysfunction. In January 2020, we initiated a Phase 1 clinical safety trial for our second-generation compound, SBT-272, which has shown promising signals in a preclinical model of ALS and is being evaluated in ongoing preclinical studies for ALS and MSA. We are evaluating compounds in the SBT-259 family, including SBT-259 and SBT-20, for rare peripheral neuropathies. We are also assessing additional new pipeline compounds, including those in the SBT-550 family, for rare neurological disease indications.

Deliver on the promise of our carrier platform

We have extensive experience in optimizing delivery of our compounds to the mitochondria, which has been a challenge for other drug delivery technologies. We have demonstrated capability to deliver beneficial payloads to mitochondria by conjugating them with our proprietary compounds, which serve as vectors or carriers to mitochondria. This approach has the potential to confer mitochondrial specificity to promising therapies that do not otherwise localize to mitochondria, potentially increasing the efficacy of a payload by targeting it to the part of the cell where it is needed most. These payloads might include small molecules, proteins, oligonucleotides, nanoparticles and liposomes. This delivery platform, which we call our carrier platform, has the potential to enable delivery of small molecules, enzymes, proteins or gene therapy to address inherited mitochondrial disorders.

Explore potential strategic partnerships

We may explore select strategic partnerships and alliances to support our drug development programs, while preserving significant development and commercialization rights, if we believe that such alliances will enable us to leverage the financial support and therapeutic area expertise and resources of a strategic partner to accelerate the development and commercialization of our product candidates.

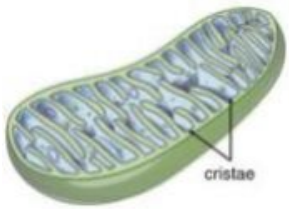
Background

Mitochondria

Mitochondria, found in almost all human cells, are the “powerhouse of the cell.” Mitochondria produce 90% of our energy by converting food into ATP, a molecule that carries energy within cells. Mitochondria produce approximately our body weight in ATP daily, providing the energy that allows cardiac muscles, for example, to beat an estimated 100,000 times every 24 hours, or 2.5 billion times by age 70, without stopping. Our heart, kidney, eyes, brain and skeletal muscle are among the highest producers and users of mitochondrial ATP in our bodies, as ATP is required for their critical functions such as the contraction of skeletal, cardiac, vasculature and lung muscle, maintenance of cell membrane potential, cellular transport and secretion of hormones and neurotransmitters. Normal mitochondrial function is essential for human life and for the proper functioning of many systems in our bodies.

Mitochondria are highly specialized structures. They have their own DNA, called mitochondrial DNA, or mtDNA, which is inherited only from our mothers and is separate and distinct from nuclear DNA, or nDNA. Mitochondria are located within the cell, which is protected by the cell membrane, and they also have their own inner and outer membrane, which create further barriers to the effective delivery of therapeutics to these specialized organelles. In normal mitochondria, the inner mitochondrial membrane, or IMM, is highly folded, creating curves, called cristae. The cristae house the electron transport chain, or ETC, which is composed of five protein complexes responsible for mitochondrial ATP production through a process known as oxidative phosphorylation. The curved architecture of the cristae in the IMM is

essential to keep the electron transport chain complexes in optimal close configuration for normal oxidative phosphorylation. Our product candidates target and bind to cardiolipin, an important structural component of the cristae and the IMM, stabilizing it from degradation due to dysfunction caused by inherited or acquired mutations in mtDNA or nDNA. An illustration of a healthy mitochondria and its curved cristae structure is shown below.



Mitochondrial Dysfunction, Aging and Human Disease

Mitochondrial dysfunction most often arises from mutations in mtDNA or nDNA, that can either be inherited or, in the case of mtDNA mutations, can occur as we age. Dysfunctional mitochondria not only produce less ATP, which impairs the normal functioning of our major organ systems, but they also generate unhealthy levels of ROS, which damages cardiolipin. ROS-mediated damage of cardiolipin can lead to pathological oxidative stress, causing the inflammation, fibrosis and cell death which are causal or contributory to the process of human aging.

Mitochondrial dysfunction, whether inherited or acquired, often impacts high energy-demanding organs such as those of the cardiac, renal, visual, neurological, central nervous, skeletal muscle, circulatory or endocrine systems. Mitochondrial diseases arising from inherited genetic defects, called primary mitochondrial diseases, are typically rare diseases which can impact multiple organ systems within the body and may lead to reduced lifespan. Symptoms of primary mitochondrial disease include cardiovascular and kidney problems, vision problems and chronic pain.

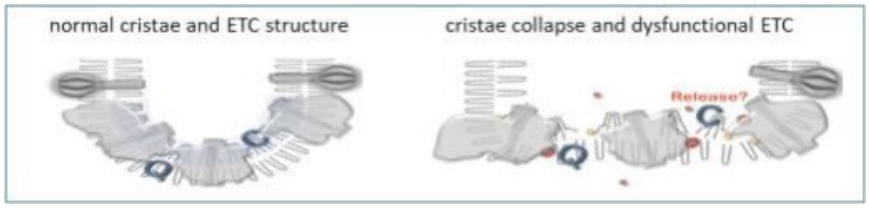
Although mtDNA is originally inherited from our mothers, it is replicated within cells as mitochondria reproduce and is highly susceptible to mutation within specific cells and organ systems as we age. Mitochondrial diseases arising from these spontaneous mutations in our mtDNA, called secondary mitochondrial diseases, include heart disease (such as heart failure and atherosclerosis), diabetes, ophthalmic conditions (such as age-related macular degeneration, glaucoma, diabetic retinopathy and diabetic macular edema), neurodegenerative diseases (such as Alzheimer's, Parkinson's and ALS), senescence, cancer, diabetes, skeletal muscle dysfunction (such as sarcopenia) and kidney diseases.

Targeting Mitochondrial Dysfunction: Role of Cardiolipin

Several of our product candidates, including elamipretide and SBT-272, target cardiolipin in the IMM, stabilizing it under conditions of oxidative stress.

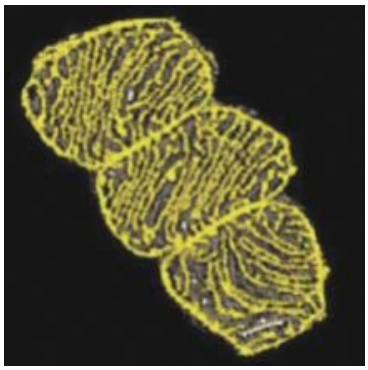
Cardiolipin is a conically shaped phospholipid that plays an important role in establishing the cristae architecture within the IMM and optimizing the function of the ETC. Reduced and damaged cardiolipin content has been observed in many diseases, and a deficiency of normal cardiolipin is thought to be centrally involved in mitochondrial dysfunction.

Cardiolipin is essential for normal oxidative phosphorylation, the process by which ATP is made. Cardiolipin congregates in and around the cristae of the IMM. Cardiolipin's conical shape is responsible for creating the curved architecture of the cristae. This curvature helps to keep the electron transport chain complexes in close association with one another, increasing the efficiency of ATP production and minimizing the electron leakage that leads to oxidative stress, as illustrated below.



Cardiolipin is embedded within the complexes of the ETC, as can be seen above, and its interaction with the ETC complexes facilitates super-complex association, a process by which electron transport chain complexes selectively associate with, or merge with, one another, to optimize the efficiency of the oxidative phosphorylation process.

Correct mitochondrial morphology is also essential for mitochondrial network connectivity and function. Mitochondrial networks exhibit coordination of inner mitochondrial membrane cristae at inter-mitochondrial junctions, as illustrated below.



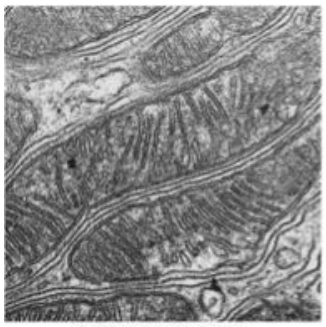
This mitochondrial network connectivity is associated with cellular signaling pathways, including:

- fusion, in which mitochondria join to spread metabolites, enzymes and mitochondrial gene products through the mitochondrial network, optimizing mitochondrial function and counteracting the accumulation of mitochondrial mutations during aging;
- fission, or the division of mitochondria, which plays an important role in the removal of damaged organelles;
- mitophagy, a mechanism to remove damaged mitochondria;
- ROS-mediated pathways, including the PI3K/Akt pathway, an intracellular signaling pathway important in regulating the cell cycle, and the tumor necrosis factor alpha (TNFα) signaling pathway, a proinflammatory pathway involved in various biological processes including regulation of cell proliferation, differentiation, apoptosis and immune response;
- calcium regulation, entailing the transfer of calcium from the endoplasmic reticulum to the mitochondrial to facilitate mitochondrial respiration (disrupted calcium regulation is thought to be implicated in cardiomyopathy associated with DMD and FDRA, as well as in heart failure with preserved ejection fraction, or HFpEF);

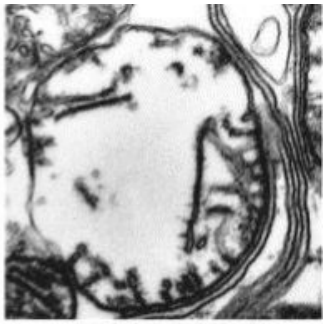
- various transcription factors, which are proteins that control the rate of transcription of genetic information from DNA to messenger RNA; and
- certain protein kinase C (PKC) signaling pathways that can affect cardiomyocyte function and are involved in the induction of mitophagy.

Cardiolipin is also required for the structural integrity of the translocase of outer membrane, or TOM, which serves as a central entry gate for almost all mitochondrial proteins including tafazzin, which is deficient in Barth, and frataxin, which is deficient in FDRA.

Cardiolipin is susceptible to peroxidation, or degradation, by oxidative stress produced by dysfunctional mitochondria. When cardiolipin is degraded, it can lose its conical shape, compromising the structural integrity of the IMM by leading to a relaxation of the cristae and a drifting apart of the electron transport chain complexes. Shuttling of electrons through the electron transport chain becomes less efficient with the complexes further apart from one another, resulting in lower ATP production and higher ROS generation. Disruption of mitochondrial morphology also impairs fission and fusion, impacting signaling pathways including mitophagy. This can trigger the cellular and extra-cellular cascades involving inflammation, fibrosis and cell death that underlie many diseases. The images below show healthy mitochondria, on the left, with normal cardiolipin content and cristae structure, and unhealthy mitochondria, on the right, with reduced cardiolipin content and collapsed cristae.



Normal Mitochondria



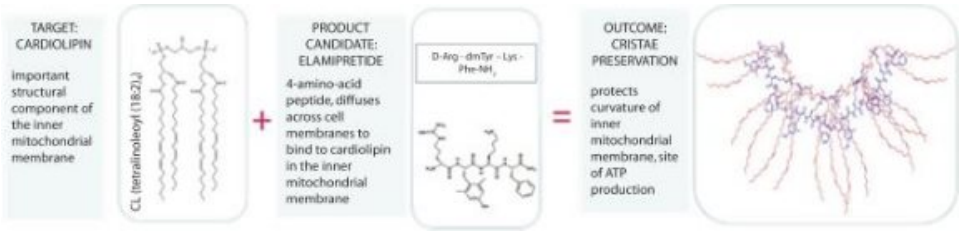
Unhealthy Mitochondria

Various diseases alter cardiolipin composition and reduce cardiolipin content within the mitochondria. In Barth, which entails a cardiolipin deficiency, experiments in patient-derived lymphoblastoid cell lines showed 50%-60% less cardiolipin than control cell lines, and work done in Barth patient-derived cardiomyocytes, or heart cells, showed up to 75% less cardiolipin than control cardiomyocytes. Cardiolipin and lipid peroxidation have also been implicated in FDRA, and cardiolipin decrements have been observed in both pediatric and adult patients with heart failure. Aging has also been shown to decrease cardiolipin content in high energy-demanding organs, such as the heart, brain, liver and kidney, as well as the epidermis. Studies suggest that oxidative stress and peroxidation of cardiolipin may contribute to the overall loss of cardiolipin content in these diseases.

Our Approach to Mitochondrial Medicine

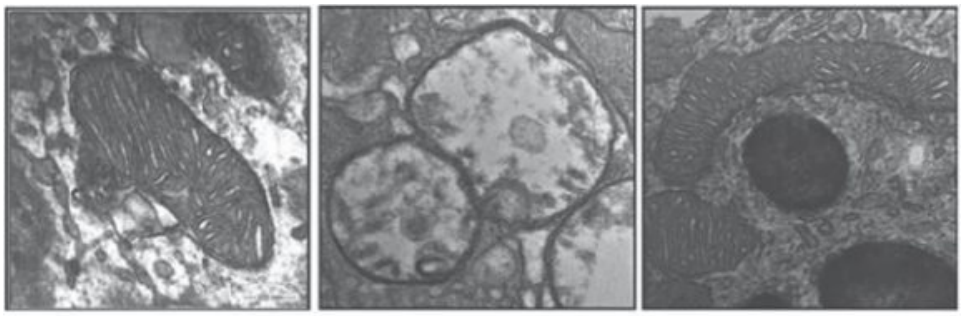
We have focused our development efforts on diseases and conditions that affect the organs in the body that generate significant energy because of the high mitochondrial content found in the cells comprising these organs. The activity of our compounds has been studied in several disease models, including heart failure, kidney disease, skeletal muscle weakness, diabetic retinopathy and neurodegenerative diseases. We believe that our product candidates may be most relevant for the cardiorenal system, the visual system and the brain, all of which are innately highly dependent on mitochondrial bioenergetics.

By stabilizing cardiolipin under conditions of oxidative stress, several of our pipeline compounds (including elamipretide and SBT-272) are able to preserve the curved architecture of the IMM, as illustrated below.



In preclinical studies or clinical trials, we have observed that elamipretide normalized function in dysfunctional mitochondria, including by reducing peroxidation of cardiolipin, increasing mitochondrial respiration (the process by which mitochondria produce energy), improving ATP levels, reducing formation of ROS and reducing inflammation, fibrosis and cell death. Importantly, we have not observed any effect of elamipretide on healthy or normal mitochondria.

Following treatment with elamipretide and SBT-20, we observed normalization of mitochondrial morphology across various disease models, including models of diabetic retinopathy, as illustrated by the electron microscopic images below, and kidney reperfusion injury, each of which were published in *Clinical Pharmacology & Therapeutics* in December 2014.



Retinal Mitochondria of Normal Mouse | **Placebo-Treated Diabetic Mouse** | **Elamipretide-Treated Diabetic Mouse**

We are also developing products to address other aspects of mitochondrial dysfunction beyond cardiolipin. We believe that our SBT-550 series of compounds acts upon the ferroptosis pathway, a recently recognized pathway for regulated cell death characterized morphologically by the presence of smaller than normal mitochondria with condensed mitochondrial membrane densities, reduction or vanishing of mitochondria crista, and outer mitochondrial membrane rupture. The ferroptosis pathway has been implicated in many neurological diseases, including Huntington's disease, Alzheimer's disease and Leigh's syndrome. We are also progressing our carrier platform in which we utilize our proprietary compounds as scaffolds to deliver other beneficial compounds to the mitochondria.

Our Product Candidates

We believe that our product candidates have significant potential to address the cardiac, ophthalmic and neurological symptoms of various diseases associated with mitochondrial dysfunction. In addition to our clinical and preclinical focus on rare cardiomyopathies, including Barth, DMD and FDRA; rare and common age-related ophthalmic diseases, including GA and LHON; and rare neurological diseases, including ALS and MSA; we have conducted preclinical studies and Phase 1 and Phase 2 clinical trials in common diseases and conditions that affect the organs in the body that have significant mitochondrial content to meet their high energy needs; these include the heart, the kidney, the brain (inclusive of the visual system) and skeletal muscle. We believe that our product candidates may be most relevant for the cardiorenal system, the visual system and the brain, which are innately highly dependent on mitochondrial bioenergetics, and we expect these to continue to be key focus areas with respect to some of our pipeline compounds.

We believe that there is significant potential for mitochondrial medicine beyond the indications we are currently studying, including with respect to common diseases associated with aging. In addition to our clinical-stage product candidates, we have a growing pipeline of over 100 compounds in preclinical testing that have been screened for mitochondrial activity, including in some cases preferential mitochondrial targeting characteristics; improved tissue distribution in targeted tissues, such as the heart and brain; and differentiated mechanistic targets, including the ferroptosis pathway of cell death. Some of these compounds, as well as our clinical product candidate SBT-272, may be suitable for oral formulations, which we believe may be more appropriate for development for common diseases associated with aging. We have also designed proprietary compounds, which we refer to as carriers, that can potentially deliver beneficial payloads to mitochondria; for example, if genetic mutations impact the production of certain proteins necessary for proper mitochondrial function, this proprietary technology might help us deliver those missing proteins to the mitochondria.

Elamipretide

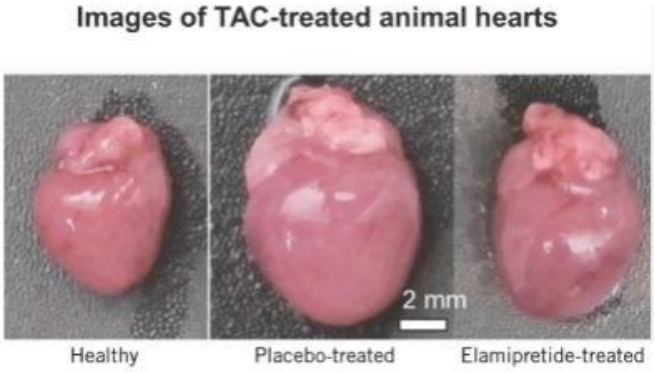
Elamipretide is a small peptide that targets and binds reversibly to cardiolipin, stabilizing mitochondrial structure and function under conditions of oxidative stress. Elamipretide has been reported to be well tolerated in over 900 subjects exposed to it systemically and 53 subjects exposed to it topically as of December 31, 2019. See "—*Elamipretide Safety Data*" below. We are evaluating or plan to evaluate elamipretide in rare cardiomyopathies where we have the potential for expedited regulatory review, including Barth, for which we have received Fast Track and Orphan Drug designations from the FDA. We met with the FDA to discuss a potential new drug application, or NDA, submission for Barth in March 2020, and we hope to initiate a clinical development program for elamipretide in rare cardiomyopathy by early 2021. We are also evaluating elamipretide in ophthalmic indications, including GA, for which we have received Fast Track designation from the FDA, and LHON, for which we have received Fast Track and Orphan Drug designations from the FDA. We met with the FDA with respect to our LHON data in 2019 and submitted a Phase 3 protocol in December 2019.

Rare Cardiomyopathies

Background on Elamipretide in Cardiac Settings. We have extensive preclinical and early clinical support for the use of elamipretide in the setting of heart failure, which can arise due to dysfunction of either the contractile or filling mechanisms of the heart. In a study published in *JACC: Basic to Translational Science* in April 2019, elamipretide was shown to improve multiple parameters of mitochondrial function in freshly explanted subsarcomal tissue from heart failure transplant subjects, including samples taken from pediatric and adult patients across a broad range of phenotypes, including dilated cardiomyopathy, hypertrophic cardiomyopathy, ischemic cardiomyopathy and muscular dystrophy.

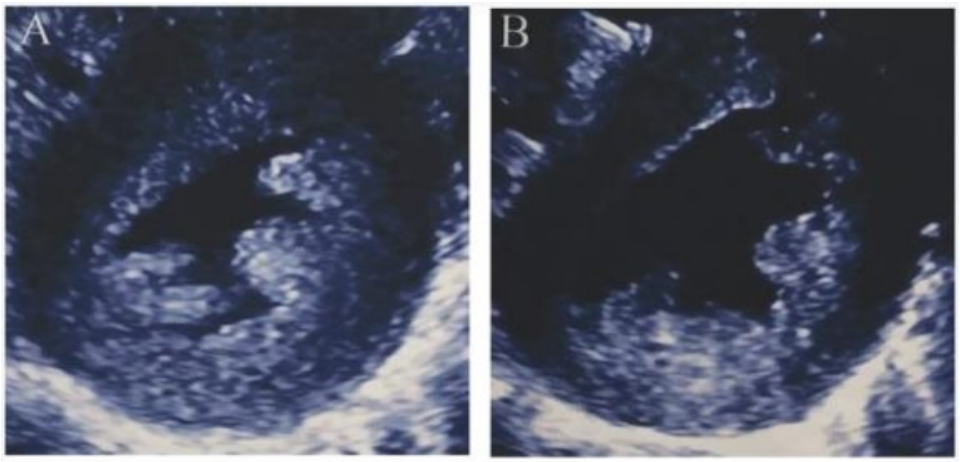
For rare cardiomyopathies associated with diseases entailing mitochondrial dysfunction, including Barth, DMD and FDRA, typical phenotypes include hypertrophic cardiomyopathies, dilated cardiomyopathies and conduction disorders. Hypertrophic cardiomyopathy entails a thickening of the heart muscle and resulting reduced left ventricular cavity size, so that the heart cannot fill adequately with blood. With less blood entering the heart, less blood is then available to expel from the heart, leading to lack of adequate perfusion throughout the body. Hypertrophic cardiomyopathy in metabolic diseases such as Barth, DMD or FDRA may ensue in response to metabolic challenges as the heart switches from fatty acid to glucose metabolism in response to physiological stress. In some cases, there appears to be a progression from a hypertrophic to a dilated phenotype, in which the heart muscle becomes stiff and is unable to relax properly. Dilated cardiomyopathy may lead eventually to congestive heart failure and death.

In a study of a mouse model of hypertrophic cardiomyopathy published in *Circulation: Heart Failure* in September 2013, treatment with elamipretide attenuated heart failure induced by transverse aortic constriction, or TAC. As shown in the images below of a healthy mouse heart, a mouse heart with TAC-induced hypertrophic cardiomyopathy treated with placebo, and a mouse heart with TAC-induced hypertrophic cardiomyopathy treated with elamipretide, elamipretide-treated mice retained normal cardiac structure despite the TAC intervention.



Sengers syndrome is an ultra-rare (approximately 40 cases have been reported worldwide), autosomal recessive mitochondrial disorder which is etiologically and pathophysiologically similar to Barth. Sengers is associated with mutations in the AGK gene encoding for proteins involved in lipid metabolism, which result in reduced levels of a lipid kinase that catalyzes the formation of phosphatidic and lysophosphatidic acids impacting protein biogenesis (ATP synthase) and lipid biogenesis (cardiolipin-metabolism defects). The disease is associated with multiple ETC defects, low complex I activity, pathological oxidative stress, lipid peroxidation and abnormal IMM cristae structure, resulting in early onset hypertrophic cardiomyopathy, skeletal myopathy, lactic acidosis, congenital cataracts and delayed motor development. Approximately half of all patients diagnosed with Sengers die within the first year of life due to cardiac failure associated with a fatal neonatal form of the disease.

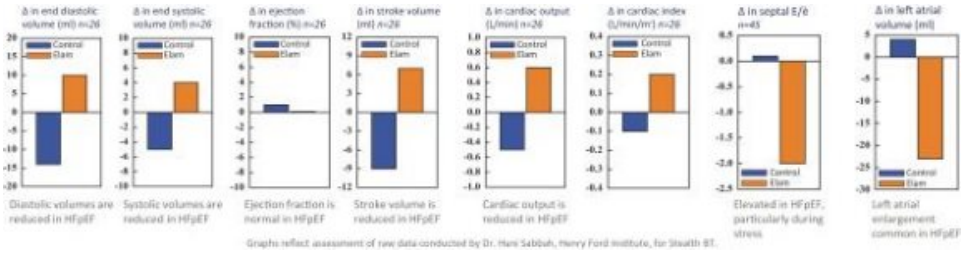
We implemented an elamipretide expanded access (compassionate use) program for a 3-month old infant with Sengers presenting with a severe hypertrophic cardiomyopathy, an associated outflow obstruction, bilateral cataracts and hypotonia. Average published survival of children presenting at this age is approximately 4.2 months. The patient's case was presented as a case study in May 2019 at the 53rd Annual Meeting for European Paediatric and Congenital Cardiology. The patient's cardiac function improved with treatment, demonstrating a 53% increase in left ventricular internal dimension in end-diastole and stabilization of left ventricle septal and posterior wall thickness despite a 40% weight gain due to normal growth; this is further illustrated by the echocardiogram images below. The patient was discharged to home where he was treated with elamipretide for approximately six months prior to succumbing from complications following an unrelated surgery. During the course of treatment, his condition improved from markedly ill, as noted on a clinician global impression, or CGI, scale, to borderline ill.



Parasternal short axis view of the left ventricle in end-diastole at week 1 (A) and week 20 (B) of treatment.

Dilated cardiomyopathy with ataxia syndrome, or DCMA, also known as 3-methylglutaconic aciduria type V, is a rare autosomal recessive disorder which is phenotypically related to Barth. DCMA is characterized by 3-methylglutaconic aciduria, dilated cardiomyopathy, developmental delay, neuromotor abnormalities, growth failure and prolongation of the QT interval. End-stage heart failure leading to death in early childhood is common. In a preclinical study published in *Frontiers in Cardiovascular Medicine* in November 2019, in which primary dermal fibroblasts isolated from pediatric DCMA patients were treated with elamipretide, the high fragmentation and significant increased ROS production observed in DCMA fibroblasts was reversed.

Heart failure with preserved ejection fraction, or HFpEF, is characterized by the inability of the heart to relax properly. In a porcine model of HFpEF, in which percutaneous renal angioplasty and stenting, or PTRS, of animals with renovascular hypertension resulted in myocardial damage in placebo-treated animals, treatment with elamipretide attenuated that damage across several parameters of cardiac function, as reported in the *Journal of Hypertension* in January 2014. The effect of elamipretide in patients with HFpEF was assessed in a double-blind, placebo-controlled, Phase 2 clinical trial enrolling 47 subjects with HFpEF who were randomized on a one-to-one basis to receive 28 days of 40 mg subcutaneous elamipretide injections or placebo. Trends favoring elamipretide were observed across various endpoints, particularly on assessments conducted during submaximal exercise when clinical symptoms most commonly present in this patient population. A key secondary endpoint of change in left ventricular filling pressures during submaximal exercise trended towards significance (-2.44; p=0.09), as did the change during submaximal stress in left ventricular systolic global longitudinal strain (-3.63; p=0.09). Notably, left ventricular end systolic volume, an important functional parameter in this disease in which the heart is not filling to its full potential, also improved (p=0.06). Although the trial did not meet its primary endpoint of change in filling pressure at rest, overall, most endpoints favored elamipretide, as illustrated below in a comparison of matched baseline and end-of-treatment echocardiographic parameters from participating subjects.



Overall, the improvements in cardiac function observed across multiple clinical and preclinical hypertrophic heart failure phenotypes lead us to believe that elamipretide may be a promising therapeutic treatment for the cardiac dysfunction presenting in Barth, DMD, FDRA and other rare cardiomyopathies.

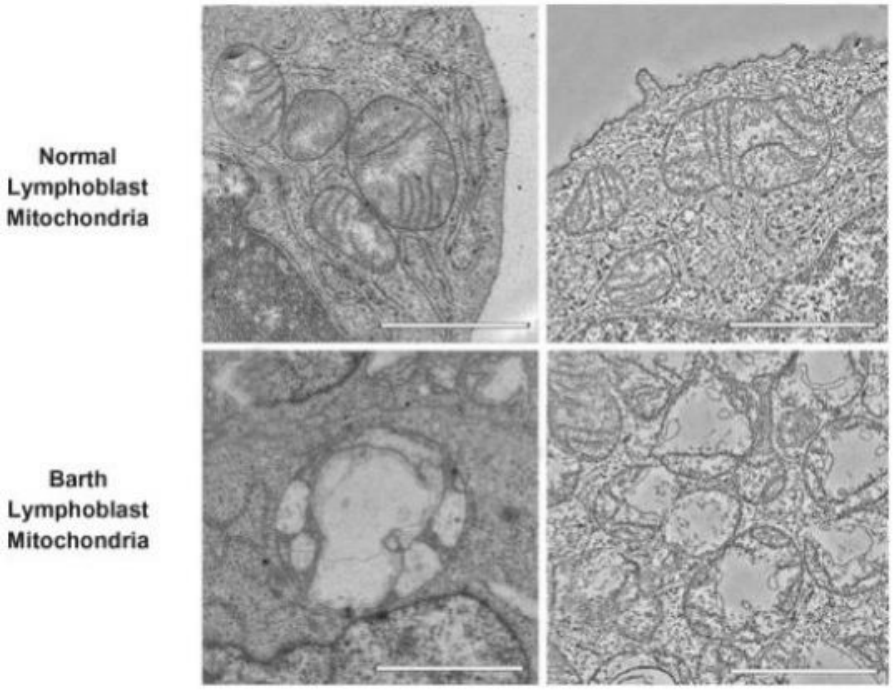
The paragraph above references, and elsewhere in this annual report we reference, p-values, which is a conventional statistical method for measuring the statistical significance of clinical trial results. A p-value of 0.05 or less represents statistical significance, meaning that there is a 1-in-20 or less statistical probability that the observed results occurred by chance, although when multiple testing occurs, the error rate may be higher.

Barth Syndrome. Barth is estimated to affect between one in 300,000 to one in 400,000 births in the United States and there are estimated to be less than 300 known living patients worldwide with Barth. There are no therapies approved by the FDA, the European Medicines Agency, or EMA, or China's National Medical Products Administration, or NMPA, for the treatment of Barth. We have received Fast Track designation and Orphan Drug designation from the FDA for the development of elamipretide in Barth. In February 2020, the FDA granted rare pediatric disease designation for elamipretide for the treatment of Barth, and we may therefore be eligible for a voucher that can be used to obtain priority review for a subsequent human drug application if our Barth product candidate meets relevant statutory requirements associated with the program, including FDA approval of the drug in this indication.

Barth typically presents in infancy or early childhood. The disease is characterized by cardiomyopathy, which makes it harder for the heart to pump blood to the rest of the body; reduced muscle tone and muscle weakness; delayed growth; fatigue; low white blood cell count, or neutropenia, which can compromise the body's ability to fight off infections; and varying degrees of physical disability. Some individuals with Barth require one or more heart transplants, including during infancy. Implantable cardioverter defibrillators may be used to prevent sudden death due to life-threatening ventricular arrhythmias, and other heart failure medications including ACE-inhibitors and beta blockers may also be used to help manage cardiac dysfunction. In addition to medical and surgical intervention, individuals with Barth may require physiotherapists and occupational therapists, speech and language therapists, psychologists and educational support workers. Barth can be a lethal infantile and early childhood disease, and mortality is highest in the first four years of life. Although improvements in the management of the disease have increased survival for some patients, with reports of individuals with Barth living into their late 40's and a single individual with Barth reported as surviving to age 51, the disease nevertheless is associated with premature death, most often due to cardiac problems.

Barth is caused by a genetic mutation in the TAZ gene that leads to decreased production of tafazzin, an enzyme required to assemble cardiolipin; as a result there is an abnormal composition of cardiolipin in individuals with Barth, particularly in the heart and skeletal muscle mitochondria. Barth patients have less tetralinoleylcardiolipin, or L4-CL, and increased amounts of monolysocardiolipin, or MLCL, than healthy subjects, and the disease can be diagnosed by the ratio of MLCL to L4-CL, called the MLCL:CL ratio, or by genetic testing. MLCL, a phospholipid found in the inner mitochondrial membrane, is considered to be an immature form of cardiolipin. MLCL is structurally differentiated from L4-CL due to its lack of a fourth acyl chain, which alters the typical conical structure of the lipid causing alterations to mitochondrial morphology. These morphological alterations result in destabilization of respiratory chain supercomplexes and increased oxidative stress. Studies have shown increased susceptibility of cardiolipin to peroxidation in Barth patient-derived pluripotent stem cells, leading to increased accumulation of MLCL. Analyses of cardiolipin levels in Barth patient-derived lymphoblasts have shown up to 60% lower levels of cardiolipin than in healthy control cells; this cardiolipin deficit has been found to range to up to 95% in other Barth cell lines or animal models.

The images of lymphoblast mitochondria below indicate that, compared to normal mitochondria, the mitochondria of individuals with Barth have unhealthy morphology, including a lack of inner membranes, a poor alignment of cristae, which are the curves of the IMM, and swollen or collapsed segments of cristae.



The Barth Syndrome Foundation, an advocacy group for Barth awareness and research, asked us to conduct a clinical trial of elamipretide for Barth. As the mechanism of elamipretide is to bind reversibly to cardiolipin, which is deficient in individuals with Barth, we undertook preclinical work to better characterize the safety profile of elamipretide for Barth as well as to gain insight into whether there would be adequate target engagement for elamipretide given the severe depletion of cardiolipin that characterizes this disease.

These experiments suggested that elamipretide may improve mitochondrial respiration in cardiomyocytes derived from individuals with Barth. In lipid model systems intended to simulate a cardiolipin deficiency in the IMM, although elamipretide ameliorated the reduced membrane-surface area attributable to the cardiolipin deficiency, elamipretide's effect was more pronounced with less severe cardiolipin loss, suggesting that therapeutic benefit may be more pronounced or more rapidly observed in subjects with more moderate cardiolipin loss.

While Barth patients have some normal cardiolipin, the ratio of abnormal MLCL to normal cardiolipin may vary from patient to patient. The MLCL:CL ratio has been observed to correlate with functional impairment; patients with a lower MLCL:CL ratio are typically less impaired than those with a higher MLCL:CL ratio. For example, a prior observational study of 34 Barth patients suggests that the MLCL:CL ratio is inversely correlated with performance on the six-minute walk test, or 6MWT ($p=0.00014$). Accordingly, if elamipretide's reaction to normal cardiolipin is critical to therapeutic effect, such therapeutic effect may also vary among patients, and as a result may be more rapidly observed in a subset of patients.

We initiated TAZPOWER, a clinical trial of elamipretide for individuals diagnosed with Barth, in the third quarter of 2017 at Johns Hopkins. TAZPOWER was a double-blind, placebo-controlled cross-over trial to evaluate the efficacy of once daily subcutaneous administration of elamipretide in 12 individuals who were 12 years of age or older and had been diagnosed with Barth. Subjects were randomized in a one-to-one ratio to either 40 mg elamipretide or placebo administered daily by subcutaneous injection for an initial 12-week treatment period, or Treatment Period 1. After an initial treatment period, on either the 40 mg elamipretide treatment arm or the placebo treatment arm, treatment was discontinued for a four-week wash-out period, following which the subjects crossed over to the other treatment arm for a second 12-week treatment period, or Treatment Period 2. Subjects enrolled in TAZPOWER were eligible for participation in an optional open-label extension trial that is contributing to our safety database and includes periodic efficacy assessments to support the durability of any effects observed in the placebo-controlled phase of the trial.

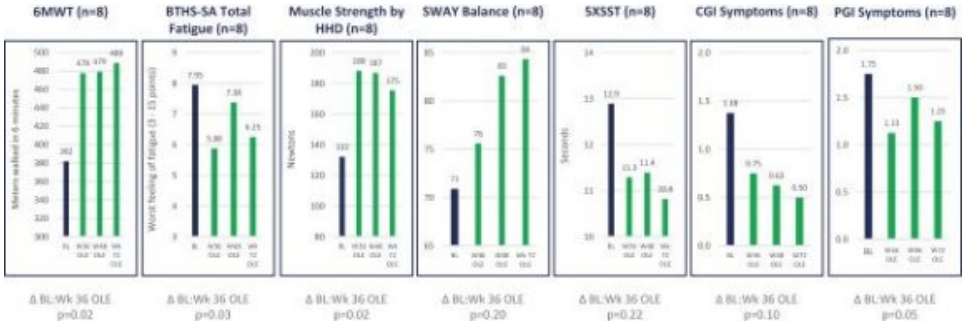
The objectives of the trial were to evaluate the safety, tolerability and efficacy of once daily subcutaneous elamipretide injections in individuals with Barth. During each of treatment periods one and two, subjects completed assessments including the 6MWT at the beginning of each treatment period, four weeks into each treatment period and at the end of each treatment period. Certain assessments were also conducted at initial screening, and at a follow-up visit, four weeks following the end of the second treatment period. In addition, the Barth Syndrome Symptom Assessment, or BTHS-SA, a patient-reported outcome questionnaire developed based upon interviews of individuals with Barth to measure the fatigue and muscle weakness associated with the disease, was completed by subjects daily and assessed based on the average of seven days of daily values preceding the assessment date.

Elamipretide was reported to be well tolerated by patients with Barth. Other than injection site reactions, which were experienced in both groups but with higher frequency in the elamipretide treatment group, there were overall less events reported during the elamipretide treatment periods of the trial, as compared to the placebo treatment periods.

TAZPOWER did not meet its primary efficacy endpoints of (i) change in the 6MWT between end of treatment on elamipretide and end of treatment on placebo or (ii) change in Total Fatigue on the BTHS-SA, which is composed of three questions from the BTHS-SA, assessing tiredness at rest and during activities and muscle weakness during activities, between end of treatment on elamipretide and end of treatment on placebo.

We conducted a prespecified subgroup analysis intended to assess whether elamipretide's association with normal cardiolipin is related to therapeutic effect, that is, whether elamipretide may provide greater benefit to a subset of Barth patients who have lower MLCL:CL ratios. This entailed an assessment of the six patients above ("high ratio subjects") and six patients below ("low ratio subjects") the median MLCL:CL ratio of the subjects enrolled in TAZPOWER, which was 17.3. In this subgroup analysis, we observed a correlation between improvements in 6MWT and baseline MLCL:CL ratios. We also observed that the prespecified subgroup of low ratio subjects showed improvement in endpoints including 6MWT and BTHS-SA Total Fatigue when on elamipretide relative to placebo. We believe these observations suggest that elamipretide therapy may more rapidly affect low ratio subjects with relatively more normal levels of cardiolipin at baseline.

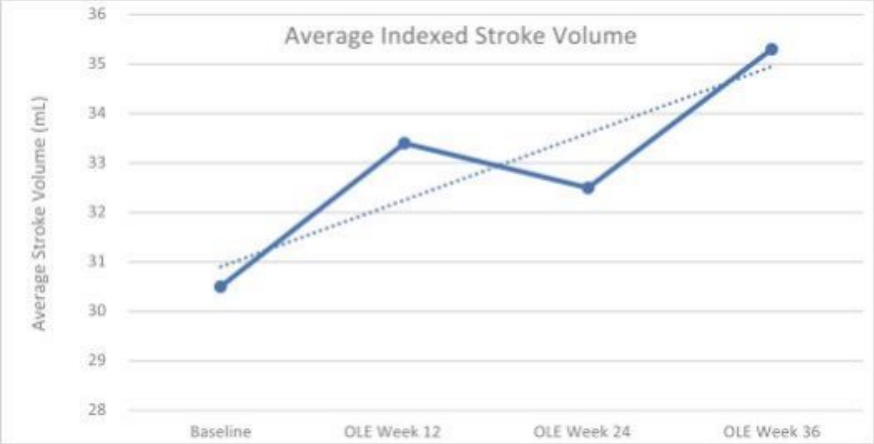
We are observing continued improvement in distance walked on the 6MWT and other functional endpoints during the open-label extension portion of the TAZPOWER trial, in which eight subjects are enrolled and have completed the week 72 visit. The functional endpoints we assessed in addition to 6MWT included BTHS-SA Total Fatigue; muscle strength as measured by hand-held dynamometry, or Muscle Strength by HHD; the SWAY Balance Score, a measure of postural sway that is an important indicator of possible balance deficits; five times sit to stand, or 5XSST, in which patients are required to sit and stand five times in succession; CGI symptoms; and Patient Global Impression, or PGI, symptoms. The results of these assessments are depicted graphically below.



The improvements we have observed are irrespective of baseline MLCL:CL ratios, supporting our hypothesis that longer duration of therapy may be important in the treatment of Barth. Although MLCL:CL ratio is showing improvement overall for those patients in open-label extension, with the six patients whose ratios have been assessed at week 72 of open-label extension improving from an average 19.2 at screening to 5.3 at week 72, there are some inherent limitations regarding the degree of precision with which this diagnostic biomarker is assessed.

In addition, we conducted a 2-D and 3-D echocardiographic protocol as part of TAZPOWER in which echocardiographic assessments were collected during each visit of the double-blind and open-label extension portions of the trial. All subjects' baseline echocardiographic data demonstrated low left ventricular end systolic volumes, which is the volume of blood in the left ventricle at the end of contraction and the beginning of filling, and end diastolic volumes, which is the volume of blood in the left ventricle at the end of filling, before contraction. Volumes were on average lower than the eighth percentile of normal ranges as reported by Boston Children's Hospital, with seven subjects at or below the second percentile on end systolic or end diastolic volume and six below the second percentile on both. Low left ventricle volumes are associated with reduced stroke volume, or the amount of blood pumped by the heart's left ventricle per contraction, which is one of the primary determinants of cardiac output, or the volume of blood pumped by the heart, and an important indicator of how efficiently the heart can meet the body's demands for perfusion to various organs. Baseline stroke volume of 40.8 mL in the TAZPOWER study population was much lower than the 85 mL expected for unaffected adolescent boys.

A review of the echocardiographic data comparing changes from baseline through the latter of each patient's last visit (for those no longer enrolled in open-label extension) and week 36 of open-label extension suggests positive changes in various parameters of heart function for 11 out of the 12 TAZPOWER participants. In addition, for the eight patients who completed week 36 of open-label extension, stroke volume improved by more than 15% with an improvement in mean baseline z-scores from the 20th percentile, at baseline, to the 33rd percentile, at week 36 of the open-label extension trial. A slope model analysis incorporating all data points through week 36 of open-label extension shows a significant trend of an increase in stroke volume over time ($p<0.01$), which may be suggestive of a durable reversal of disease pathology not predicted by natural history data showing that left ventricular diastolic volume, a component of stroke volume, stays the same or declines over time in patients with Barth.



Stroke volume has been reported to be a major determinant of peak exercise capacity in patients presenting with this cardiac phenotype. We similarly observed that the improvement in left ventricular stroke volume directionally correlated with increasing improvements in functional endpoints observed during open-label extension, including improvements in 6MWT (95.9, 97.4 and 106.8 meters from study baseline to week 36, 48 and 72 of open-label extension, respectively (week 36, R_S0.21, p=0.29; week 48, R_S0.36, p=0.39; week 72, R_S 0.52, p=0.18)). We believe these objective surrogate endpoint data facilitate the interpretability of the clinical improvements observed during open-label extension.

The paragraph above references the Spearman's Rank Correlation Coefficient, or R_S, which is a is a statistical measure of the strength of a link or relationship between two sets of data. An R_S of 1.0 indicates a perfect positive correlation and -1.0 indicates a perfect negative correlation. An R_S of 0 indicates no association between the sets of data.

In February 2020, we completed a natural history study *(A Retrospective Study to Evaluate the Efficacy of Subcutaneous Injections of Elamipretide Compared to a Natural History Control in Subjects with Barth Syndrome*) to serve as a natural history control for the TAZPOWER open-label extension data. The FDA published guidance in 2019 recognizing the utility of natural history controls as a possible control group for single-arm or open-label trials, noting that while the inability to control for certain biases could limit the ability of externally controlled trials to demonstrate substantial evidence of effectiveness, this bias may be mitigated in certain situations where the disease course is predictable and the treatment effect is dramatic. Moreover, although it is understood that the 6MWT, which is one of the primary efficacy endpoints in TAZPOWER and the primary efficacy endpoint in the natural history study, is heavily effort-dependent with high intra-patient variability which may make it difficult to interpret based on comparisons with an external historical control group, other secondary endpoints in the natural history study, including muscle strength and 5XSST, demonstrated less variability.

The natural history study met the primary efficacy endpoint of change in the 6MWT between the eight patients treated with elamipretide through week 36 of open-label extension and 19 prognostically matched natural history controls, with a least square means improvement of 81.26 meters on elamipretide versus 0.59 meters in the natural history control cohort (p=0.0005). A similar finding at a later timepoint, corresponding to week 48 of open-label extension, suggests the durability of this response, with a least square means improvement of 93.08 meters on elamipretide versus 0.88 meters in the natural history cohort (p=0.0006).

The natural history study also met several secondary efficacy endpoints:

- Statistically significant differences in muscle strength as measured by hand-held dynamometry, or Muscle Strength by HHD, were observed for eight patients treated with elamipretide as compared to 19 prognostically matched natural history controls across a cumulative time period corresponding to both week 36 of open-label extension (difference of 41.8 newtons; p=0.0002) and week 48 of open-label extension (difference of 47.9 newtons; p=0.0004).
- Statistically significant differences in 5XSST were observed for eight patients treated with elamipretide as compared to 15 prognostically matched natural history controls across a cumulative time period corresponding to both week 36 of open-label extension (difference of -2.3 seconds; p=0.047) and week 48 of open-label extension (difference of -2.8 seconds; p=0.039).
- Although no statistically significant differences in the SWAY Balance Score were observed for eight patients treated with elamipretide as compared to 12 prognostically matched natural history controls across a cumulative time period corresponding to week 36 of open-label extension (improvement of 6.46 out of 100; p=0.1275) and week 48 of open-label extension (improvement of 7.6 out of 100; p=0.1232), the improvements appear to be markedly different between the two groups and this endpoint analysis may have been limited by a reduction in the sample size for the natural history control group from 19 to 12 subjects.
- A multi-domain responder index was included to inform as to the clinical meaningfulness of any changes observed. For this index, a 10% improvement on any of the 6MWT, Muscle Strength by HHD, 5XSST, and SWAY Balance Score by the eight patients treated with elamipretide as compared to 12 prognostically matched natural history controls was considered clinically meaningful and scored as +1, and a 10% decline on any endpoint was considered clinically meaningful and scored as -1, with any other changes scored as 0. This endpoint demonstrated statistically significant differences across a cumulative time period corresponding to both week 36 (2.4; p=0.0001) and week 48 (2.4; p=0.0001).

In March 2020, we met with the FDA to discuss the natural history data, the cardiac data from the open-label extension and regulatory next steps.

Other Rare Cardiomyopathies. In addition to Barth and Senger's, cardiomyopathy is a leading cause of death in diseases including Duchenne's muscular dystrophy, or DMD, an inherited muscle wasting disease affecting an estimated one in 3,500 to 5,000 male births in the United States; Friedreich's ataxia, or FDRA, the most common form of hereditary ataxia, or loss of coordination, affecting an estimated one in 40,000 people in the United States; and Becker muscular dystrophy, or BMD, an inherited muscle wasting disease affecting an estimated one in 30,000 male births in the United States. There are no therapies approved by the FDA, EMA or NMPA for the treatment of FDRA or BMD, and there are no therapies approved by the FDA, EMA or NMPA for the treatment of cardiac manifestations of DMD. Most DMD, FDRA and BMD patients develop cardiomyopathy, and heart failure and sudden cardiac death are the most commonly reported causes of early mortality among these patients. We plan to explore the potential of elamipretide as a treatment for DMD, FDRA, BMD and other rare cardiomyopathies involving mitochondrial dysfunction.

DMD, FDRA and BMD patients often suffer from a hypertrophic cardiomyopathy, a similar phenotype as observed in our TAZPOWER trial. Also similar to what is believed to occur with progression of cardiac symptoms in Barth, their hearts typically maintain adequate systolic function until shortly before death. We believe based on the improvements in hypertrophic cardiomyopathic symptoms observed in

TAZPOWER as well as in the Senger's compassionate use case, elamipretide therapy may help ameliorate the cardiac manifestations of DMD, FDRA and BMD. In preclinical studies, elamipretide and/or its analogs have been shown to improve mitochondrial bioenergetics, or the cellular processes by which energy is produced and used, in a mouse model of DMD, improve mitochondria structure and function in FDRA patient lymphoblasts and fibroblasts and improve mitochondrial respiration in failing cardiac tissue from a patient with BMD.

We are working with patient advocacy and key cardiology opinion leaders who treat DMD, FDRA and BMD patients to ascertain the best indication for our first expansion trial, and to develop a Phase 2 protocol assessing echocardiographic and magnetic resonance imaging parameters of cardiac function. We hope to initiate a trial in one of these indications by early 2021.

Ophthalmic Diseases

Normal mitochondria play a critical role for ocular function, and dysfunctional mitochondria are implicated in several rare and common diseases of the eye. Ophthalmologic diseases that have not traditionally been considered to have obvious mitochondrial origins are increasingly recognized to result in part from impaired mitochondrial function, increased oxidative stress and increased apoptosis. As a high energy-demand organ, the eye is particularly susceptible to the consequences of mitochondrial damage. Oxidative damage that results over time from inherited mtDNA mutations or spontaneous mtDNA instability leads to cumulative mitochondrial damage, which is recognized to be an important pathogenic factor in inherited ophthalmologic disorders such as LHON as well as age-related ophthalmologic diseases such as diabetic retinopathy, glaucoma and dry AMD.

We have observed beneficial effects of treatment with elamipretide in preclinical models of diabetic retinopathy, dry AMD and glaucoma. We have dosed elamipretide both topically, instilled as a topical ophthalmic solution, and systemically, by subcutaneous injection, in different animal models and in early clinical trials. We observed improvement from baseline in visual function in subjects enrolled in a Phase 1 clinical study of elamipretide in dry AMD who were treated with 40 mg subcutaneous systemic elamipretide injections once daily for six months. We also observed signs of clinical benefit in a Phase 1/2 clinical trial of elamipretide topical ophthalmic solution in patients with Fuchs' corneal endothelial dystrophy, or Fuchs, and in the open-label extension portion of a Phase 2 clinical trial of elamipretide topical ophthalmic solution in patients with LHON. Based on our studies in animals, we believe that higher concentrations of elamipretide may be found in the retina following subcutaneous administration than topical ophthalmic administration.

Geographic Atrophy. We are advancing development of elamipretide for GA, an advanced form of dry AMD. Dry AMD is a common ophthalmic disease associated with aging and the leading cause of blindness among older adults in the developed world. GA is estimated to impact approximately one million individuals in the United States. There are no treatments approved by the FDA, the EMA or the NMPA for the disease.

The earliest clinical manifestation of dry AMD is often a reduction in low luminance, or low light, visual acuity, which can make it challenging to conduct normal daily activities such as reading in artificial light, driving at dusk or at night and navigating indoors in low light. The disease may progress to the GA stage, which includes blurred vision and loss of central vision, which can impair facial recognition, mobility, watching television and computer use, and can eventually lead to blindness. These limitations may impair the independence of older adults and have been associated with increased depression.

The pathophysiology of GA involves the gradual deterioration, or geographic atrophy, of the central part of the retina, known as the macula. The retinal pigment epithelium provides nutrition to the retina, which has a very active metabolism and rids the eye of waste by phagocytosis of photoreceptor outer segments, protects against photooxidation and enables perception of light through retinal recycling. The eye is the highest consumer of mitochondrial ATP in the central nervous system, due to the intensive bioenergetics required to support visual function. Preclinical studies suggest that diseases of the retinal pigment epithelium, such as dry AMD, may be exacerbated by light-induced mitochondrial dysfunction, and that mitochondrial DNA mutations appear to accumulate over time in diseased retinal pigment epithelium as a consequence of chronic and ongoing oxidative stress. Cigarette smoking and high fat diets, both of which contribute to mitochondrially deleterious oxidative stress, are known to be environmental risk factors for dry AMD onset and progression. These findings suggest a key role for mitochondrial dysfunction in the pathology of the disease.

The table below provides a summary of our completed and ongoing trials for dry AMD and GA.

TRIAL	INDICATION	STAGE; STATUS	TRIAL DESIGN
ReCLAIM	dry AMD	Phase 1; completed in March 2018	Open-label, single-center clinical trial involving 19 subjects with non-central geographic atrophy, which occurs when the photoreceptors no longer work and the patients develop a blind spot or spot of poor vision in the macula, and 21 subjects with high risk drusen, which are large deposits of debris located between the retina and the Bruch's membrane, that can interfere with waste products getting removed from the macula. Subjects received once daily subcutaneous injections of elamipretide for 24 weeks.
ReCLAIM-2	GA	Phase 2b; initiated March 2019	Double-blind, placebo-controlled, multi-center clinical trial involving approximately 180 subjects with non-central geographic atrophy, receiving once daily subcutaneous injections of either elamipretide or placebo for approximately 48 weeks.

Elamipretide was evaluated in several preclinical models of dry AMD, with data suggesting that treatment with elamipretide improved mitochondrial morphology. In a preclinical model, 24-month old atherosclerotic mice (roughly equivalent to a human octogenarian) accumulated drusen-like deposits when fed a high fat diet, and, after one month of subcutaneous administration of elamipretide, showed normal mitochondrial morphology and ultrastructure of the retinal pigment endothelium cells. Additionally, the animals treated with elamipretide were observed to have normalization of b-wave amplitudes on electroretinograms, which suggests an improvement in photoreceptor function reflecting improved visual acuity.

We conducted our ReCLAIM Phase 1 open-label clinical trial at Duke Eye Center to evaluate the safety, tolerability and efficacy of daily subcutaneous injections of 40 mg elamipretide given over 24 weeks to 40 individuals with intermediate characteristics of dry AMD. We enrolled 21 subjects who have high-risk drusen, the most common early signs of dry AMD, and 19 subjects who have non-central geographic atrophy, or areas of dysfunctional macula. Individuals with high-risk drusen typically have difficulty seeing in low light conditions and mild to moderate deficits in visual acuity under normal light condition, while those with non-central geographic atrophy have more advanced symptoms but are not yet blind. The primary endpoint was safety and tolerability, evaluated based on review of adverse events, or AEs, and compliance of self-administration of subcutaneous elamipretide, measured at 24 weeks compared to baseline. Secondary endpoints included change from baseline in visual acuity in low light conditions, or low luminance visual acuity, or LLVA, a five-letter deficit in which was required for inclusion in the trial, visual acuity in standard light conditions, BCVA, reading speed and acuity in low light conditions and standard light conditions, drusen volume and patient reported outcome assessments. Assessments for most secondary endpoints occurred at baseline, week four, week eight, week 12 and week 16.

We analyzed the data for subjects in each cohort who completed 24 weeks of therapy, which included 19 subjects with high-risk drusen and 15 subjects with non-central geographic atrophy. We observed improvements in functional assessments across both cohorts, as summarized below. As noted above, a five-letter deficit in LLVA, which is among the first clinical symptoms of the disease, was a required inclusion criterion for the trial, and improvements in this endpoint were statistically significant across both the drusen (p=0.0055) and geographic atrophy (p=0.0186) cohorts.

ENDPOINT	DRUSEN COHORT (N=19)	GEOGRAPHIC ATROPHY COHORT (N=15)
Best corrected visual acuity (regular light) mean letters gained/p value	3.58 (p=0.0253)	4.60 (p=0.0034)
Low luminance visual acuity mean letters gained/p value	5.63 (p=0.0055)	5.40 (p=0.0186)
Reading speed (regular light) mean reduction in time/p value	-0.11 (p=0.0054)	-0.02 (p=0.5501)
Low luminance reading speed mean reduction in time/p value	-0.28 (p<0.0001)	-0.52 p=0.0172
Visual function questionnaire composite score	9.25 (p=0.0004)	6.59 (p=0.0125)
Low luminance questionnaire general dim light vision score	20.75 (p=0.0003)	10.32 (p=0.027)

Since we did not have a placebo, or control group, in this study, we evaluated natural history data and prior placebo-controlled trials of subjects with similar disease burden to understand the likelihood that we would observe a learning or placebo effect in this study. In a number of other reported interventional studies conducted by others, including Chroma, Spectri and Filly (combined n>700), as well as in several natural history studies conducted by others, including Proxima, Holz and Ladd (combined n>250), BCVA was observed to decline in similar patient groups by four to six letters over an up to one-year period, and LLVA was observed to decline in similar patient groups by approximately two letters over a six-month to one-year period. This supports our belief that the improvements observed in the ReCLAIM trial are unlikely to be due to the natural variability of the disease.

While each subject in ReCLAIM had one eye designated as a study eye, which met the inclusion criteria for the trial, the other eye was not required to meet inclusion criteria. Fourteen subjects in the trial had neovascular age-related macular degeneration, or wet AMD, that was at the quiescent stage, meaning that it was stable on standard-of-care anti-vascular endothelial growth factor, or anti-vegF, therapy. While there is an improvement in visual acuity when some subjects are first dosed with anti-vegF therapy, improvement typically plateaus and even declines slightly when the disease reaches the quiescent state. We observed that subjects with wet AMD experienced similar improvements in vision as was observed in the study eyes, with a 5.6 letter mean gain from baseline in BCVA, which was statistically significant at p=0.0027, and a 6.1 letter mean gain from baseline in LLVA, which was statistically significant at p=0.0012.

We also assessed the rate of progression of geographic atrophy in the non-central geographic atrophy cohort relative to what has been observed in other studies. The typical rate of geographic atrophy progression in dry AMD is well understood from prior studies and the natural history, and we believe slowing of geographic atrophy progression could be a meaningful endpoint as we pursue approval by the FDA. This analysis was conducted using several types of imaging technologies including fundus auto-

fluorescence, or FAF, an advanced imaging technique for observing the fundus, which is the interior surface of the eye opposite the lens including the retina, optic disk, macula, fovea and posterior pole, FAF squared, or FAF SQRT, a calculation performed to eliminate dependence of growth rates on lesion measurements, and optical coherence tomography, or OCT, a non-invasive imaging test which uses light waves to take cross-sectional pictures of the retina, also squared, or OCT SQRT, to eliminate dependence of growth rates on lesion measurements. Each of these imaging technologies showed that six months' treatment with elamipretide was associated with slower progression of geographic atrophy than was observed in prior published studies conducted by others (assuming, for prior studies which were completed over a longer time period, a linear progression of geographic atrophy enabling calculation at the 6-month time point). FAF demonstrated mean growth of 0.50 mm^2, versus 0.91 mm^2 mean observation from ten prior studies over a similar time period (assuming linear progression), FAF SQRT demonstrated mean growth of 0.14 mm, versus 0.19 mm mean observation from five prior studies over a similar time period (assuming linear progression), and OCT SQRT demonstrated mean growth of 0.11 mm, versus 0.18 mm mean observation from five prior published studies over a similar time period (assuming linear progression).

We initiated ReCLAIM 2, a Phase 2b placebo-controlled clinical trial with once daily subcutaneous dosing in subjects with non-central geographic atrophy in March 2019. ReCLAIM 2 is designed to enroll up to 180 subjects, of whom 120 will be treated with an elamipretide 40 mg once daily subcutaneous injection, and the remainder will receive placebo for a 48-week period. Eligible subjects are required to have a geographic atrophy area greater than or equal to 0.05mm^2 and less than 10.16 mm^2, BCVA greater than or equal to 55 letters and greater than 5 letters low luminance deficit. Efficacy endpoints in ReCLAIM 2 include BCVA, FAF, OCT, low-luminance best-corrected visual acuity, low-luminance reading acuity, National Eye Institute Visual Function Questionnaire-39 score, visual function by the Low-luminance Questionnaire and conversion to choroidal neovascularization.

Although we believe that individuals experiencing a progressive decline in visual activity will be compliant with daily subcutaneous injections, we may consider a second Phase 2b placebo-controlled clinical trial using the topical drop drug product because it may be commercially advantageous. We observed signs of clinical benefit with elamipretide topical ophthalmic drops in our ReVEAL Phase 1/2 clinical trial enrolling subjects with Fuchs, as well as in our ReSIGHT trial. We are also evaluating the feasibility of developing a sustained-release formulation for intravitreal injection for this indication.

LHON. We estimate that approximately 10,000 individuals in the United States have LHON, of whom an estimated 70% have the genetic mutation, G11778A, that we studied in our Phase 2 trial. Currently, there are no treatments approved by the FDA or the NMPA for the treatment of LHON. Raxone (idebenone), a synthetic form of Coenzyme Q10, has been approved by the EMA for the treatment of LHON, although actual availability varies by country. Raxone has orphan designation, and its marketing authorization was granted by the EMA under its authority to grant marketing authorization under "exceptional circumstances" due to the lack of comprehensive data on efficacy and safety.

We have received Fast Track and Orphan Drug designations from the FDA for the development of elamipretide for this indication. China has recently included LHON as an orphan disease on its published list of orphan diseases.

LHON is a mitochondrially inherited genetic disorder passed from a mother carrying the mutation to her children. LHON causes degeneration of the optic nerve in the back of the eye and leads to bilateral blindness. LHON primarily affects young men between the ages of 18 and 30, although it can affect women as well as younger children. The initial clinical expression of LHON is often a sudden, painless, acute or sub-acute central vision loss, frequently accompanied by loss of color vision and reduced visual acuity. A typical presentation involves a young man experiencing increased oxidative stress, sometimes from increased alcohol and/or tobacco consumption, leading to sudden vision loss in one eye that typically progresses within six months of onset to bilateral blindness. The disease has a substantial impact on day-to-day functioning, making it difficult to read and perform everyday activities, including employment-related activities and driving. The disease has a severe negative impact on quality of life and LHON individuals may require social services, occupational rehabilitation and visual aids.

A subclass of LHON patients also present symptoms, including muscle weakness, poor coordination, numbness, tremors, and cardiac conduction defects, or abnormalities of the electrical signals that control the heartbeat. Some families have particularly severe manifestations, including ataxia, juvenile onset encephalopathy, spastic dystonia and psychiatric disturbances. These phenotypes have been called “LHON plus syndromes.”

Mitochondria are central to retinal cell function and survival and dysfunctional mitochondria may lead to death of retinal ganglion cells, which are neurons located near the inner surface of the retina. Mitochondrial dysfunction is a key factor in LHON and other genetic optic neuropathies characterized by loss of visual function resulting from impaired cellular energetics within retinal ganglion cells of the optic nerve.

We believe based on preclinical and early clinical findings that systemic elamipretide may be beneficial for subjects with LHON and LHON plus, in which the mitochondrial dysfunction is the result of a mutation in a subunit of Complex I of the electron transport chain which impacts the retinal ganglion cells and the optic nerve. Preclinically, elamipretide has been observed to improve mitochondrial function under oxidative stress conditions in mouse-derived retinal ganglion cells, the type of cells most affected by LHON, by dose-dependently reducing ROS production, mitochondrial depolarization, cytochrome c release, morphological change, apoptosis and cell death. Experiments in a mouse model of acute traumatic optic neuropathy also suggest that systemic administration of elamipretide post-trauma may improve retinal ganglion cell survival and visual function, supporting the plausibility of therapeutic benefit in the presence of LHON-associated, oxidative-stress mediated damage of the optic nerve. In addition, we observed trends that we believe are suggestive of potential clinical benefit in our ReSIGHT Phase 2 clinical trial and open-label extension of topical ophthalmic drops for patients with the G11778A mutation of LHON.

The table below provides a summary of our completed and planned trials for LHON.

TRIAL	INDICATION	STAGE; STATUS	TRIAL DESIGN
ReSIGHT	LHON	Phase 2; completed in May 2018	Double-masked, placebo-controlled, single-center clinical trial enrolling 12 subjects with LHON with the mt.11778G>A mutation, eight of whom received a single drop of elamipretide 1.0% ophthalmic solution or placebo, twice daily, in each eye, and four of whom received a single drop of elamipretide 1.0% ophthalmic solution twice daily in both eyes for 52 weeks, before continuing into open-label extension.
ReSIGHT-3	LHON	Phase 3; expect to initiate post-2020	Double-masked, placebo controlled, multi-center clinical trial involving approximately 160 subjects with the mt.11778G>A, mt.3460G>A, or mt.14484T>C mutation randomized on two-to-one basis to receive once-daily subcutaneous injections of either 40 mg. elamipretide or placebo for approximately 78 weeks.

ReSIGHT, our first clinical trial of elamipretide for the treatment of LHON, was a 52-week, randomized, double-masked, vehicle-controlled clinical trial of elamipretide topical ophthalmic drops in 12 subjects with LHON. Subjects were randomized to a single drop of elamipretide 1.0% ophthalmic solution or placebo, twice daily, with four subjects receiving elamipretide dosed in both eyes and eight subjects receiving elamipretide in one eye and placebo in the other eye. The endpoints were safety, tolerability and efficacy. The primary efficacy endpoint was change in best corrected visual acuity, or BCVA, during the period from week 20 through the end of treatment at week 52; secondary endpoints included changes in color vision, changes in photopic negative response electroretinography, a biomarker measuring the response of the retinal ganglion cells to light, changes in the retinal nerve fiber layer and retinal ganglion

layer thickness and changes in visual field, or field of vision, as measured by the Humphrey visual field score, which measures the expanse of space visible at a given instant without moving the eyes. Subjects enrolled in ReSIGHT were eligible for participation in an optional open-label extension trial that contributed to our safety database and included periodic efficacy assessments to support the durability of any effects observed in the controlled phase of the trial. We have completed the open-label extension trial and have implemented an expanded access protocol under which ten subjects continue to receive the study drug in a subcutaneous injection.

ReSIGHT enrolled individuals with the G11778A LHON genetic mutation who experienced loss of vision in both eyes of greater than one year and less than ten years, because the degree of visual impairment in these patients was expected to remain stable absent therapeutic intervention. It is considered unlikely that individuals with the G11778A genetic mutation will experience visual recovery spontaneously, meaning without any therapeutic intervention; the partial recovery rate, most commonly occurring within the first year following vision loss, has been reported to be between 4% and 33% for these individuals.

We observed trends suggestive of therapeutic effect in ReSIGHT, but the trial did not meet its primary endpoint of change in BCVA, measured as the average change over week 20 to 52 from baseline. We believe this was largely due to unexpected variability in the placebo group, in which two subjects experienced gains in BCVA of more than 20 letters on a standard eye chart and one subject experienced a loss of more than 20 letters, resulting in no change overall between elamipretide- and placebo-treated groups. However, improvement in elamipretide-treated eyes was observed across a number of other endpoints over the treatment period, as shown below.

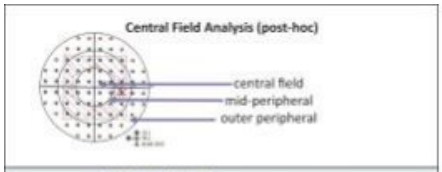
The following table sets out certain data with respect to the ReSIGHT clinical trial measuring the endpoints from baseline to week 52 (averaged, in the case of BCVA, Humphrey Visual Field and Color Discrimination, over the entire treatment period). We utilized a forest plot construct in our submission of the ReSIGHT data to the FDA.

ReSIGHT Summary of Data

ENDPOINT	LEAST SQUARE MEAN (CONFIDENCE INTERVAL)	P-VALUE
BCVA (letters)	0.6 (-0.9, 2.1)	0.4370
Humphrey Visual Field (mean deviation)	0.8 (0.1, 1.4)	0.0173
Color Discrimination	0.2 (0.0, 0.4)	0.0826
Retinal Nerve Fiber Layer Thickness	1.9 (-3.3, 7.0)	0.4390
Retinal Ganglion Cell Layer Thickness	1.6 (-0.5, 3.7)	0.1274
Visual Function Questionnaire Composite*	6.0 (2.1, 9.9)	0.0063

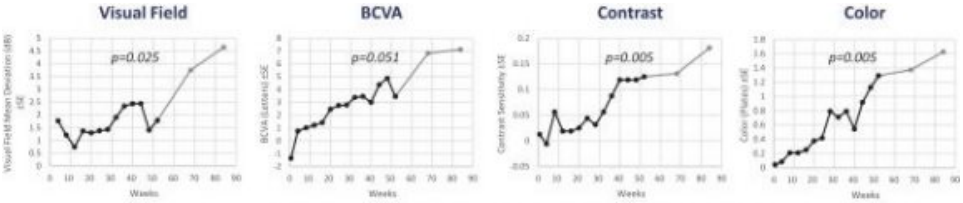
* Post-hoc analysis of change from baseline (all subjects).

The below further summarizes certain post hoc analysis of the data from ReSIGHT, which was conducted with a central field analysis.



HVF Pattern	Elam Δ from Baseline	Placebo Δ from Baseline	Treatment Effect	p-value
Central	1.27668	-0.67919	1.96 (1.0514, 2.8604)	0.00003
Mid-peripheral	1.01822	1.61448	-0.60 (-1.4449, 0.2524)	0.16758
Outer peripheral	0.91471	0.57106	0.34 (-0.3562, 1.0435)	0.33421

After six months of open-label extension, we observed continued improvement from study baseline in multiple parameters of visual function, including BCVA, color sensitivity, contrast sensitivity and visual field, particularly central visual field, as illustrated below, in which the black line depicts the average between each subject's eyes during the double-masked portion of the trial and the gray line depicts the average between each subject's eyes during the open-label portion of the trial.



Raw values averaged between eyes; black = double-masked portion of trial, gray = open-label extension; n=12

We met with the FDA in June 2019 to review the data from the ReSIGHT trial. FDA concurred with our proposal to conduct a pivotal Phase 3 trial, and in December 2019, we submitted to the FDA our draft Phase 3 protocol for elamipretide for the treatment of LHON. Our draft Phase 3 protocol design is to enroll up to 160 subjects, of whom approximately two-thirds will be treated with an elamipretide 40 mg once daily subcutaneous injection, and the remainder will receive placebo for a 78-week period. Although subjects with any of the mt.11778G>A, mt.3460G>A, or mt.14484T>C mutation associated with LHON may be enrolled, as requested by the FDA, the primary efficacy analysis will be conducted only on the fraction of patients with the mt.11778G>A mutation studied in ReSIGHT. One eye will be designated as the study eye, and eligible subjects are required to have lost vision in the study eye within two years prior to enrollment. Efficacy endpoints include central visual field, full visual field, National Eye Institute Visual Function Questionnaire, BCVA, color discrimination, contrast sensitivity, neurofilament light chain (NfL), retinal nerve fiber layer by optical coherence tomography, or OCT, retinal ganglion cell thickness by OCT, EQ-5D-5L Questionnaire and efficacy in the non-study eye. We expect to initiate our Phase 3 trial when resources permit, but in no event earlier than 2021.

Elamipretide Safety Data

We have a significant amount of clinical trial data indicating that elamipretide is generally well tolerated. As of December 31, 2019, 27 clinical trials had been completed with single and multiple intravenous and subcutaneous administrations of elamipretide at dose levels ranging from approximately 0.7 mg/day to 300 mg/day. These included 15 clinical pharmacology studies enrolling approximately 312 healthy subjects in which the primary objective was to assess safety rather than to treat a disease state, and 12 clinical trials enrolling approximately 618 subjects across multiple patient populations, including subjects with primary mitochondrial myopathy, skeletal muscle mitochondrial dysfunction, stable chronic heart failure, acute coronary syndrome and acute kidney injury and dry AMD.

The most commonly reported systemic treatment-emergent adverse events, or TEAEs, that were reported in greater frequency among elamipretide-treated subjects as compared to placebo-treated subjects included headache and dizziness in both single dose and repeat dose cohorts. TEAEs observed exclusively in repeat-dosed elamipretide-treated patients included incidences of increased blood immunoglobulin E (though no associated clinical signs or symptoms were present), urinary tract infections and viral gastroenteritis, as well as upper respiratory tract infections in an open-label trial in an elderly population where there was no placebo-control group. A mild to moderate increase in eosinophils, a variety of white blood cells that combat parasites and infections and control mechanisms associated with allergy and asthma, were observed in a significant percentage of patients treated with longer-term dosing regimens, with no associated clinical signs and symptoms. These appear to decrease to within normal limits with longer duration of elamipretide administration and return to pre-treatment levels after the end of elamipretide treatment. In addition, injection site reactions were reported in the majority of subjects receiving elamipretide by subcutaneous injection; most commonly these entailed mild redness, swelling and itchiness which usually resolved within four hours of dosing.

We have completed three clinical trials with topical ophthalmic elamipretide: ReSIGHT for the treatment of LHON, ReVEAL for the treatment of Fuchs', and ReVIEW for the treatment of either diabetic macular edema, or DME, or dry AMD. In the ReSIGHT clinical trial, 12 subjects were treated with 1.0% ophthalmic solution twice daily for 52 weeks. There were no discontinuations in the ReSIGHT clinical trial. Ocular related TEAEs were reported in 56.3% of the elamipretide-treated and half of the placebo-treated eyes. In our ReVEAL clinical trial, 22 subjects were enrolled in one of two dosing cohorts, 1.0% ophthalmic solution or 3.0% ophthalmic solution, administered in the eye twice daily for 12 weeks. In this trial, there were two discontinuations, one of which was due to failure to meet inclusion criteria and one of which was due to a reported allergic reaction. Two unrelated systemic TEAEs were reported. In the 3.0% dose arm, two subjects reported ocular TEAEs of itching, foggy vision, redness and/or allergic conjunctivitis that led to discontinuation, each of which was deemed likely related to study drug. In the REVIEW clinical trial, 20 subjects were enrolled in one of two dosing cohorts, 0.3% ophthalmic solution or 1.0% ophthalmic solution, administered to one eye twice daily for 28 days. A total of four TEAEs were reported in the ReVIEW clinical trial and none were considered related to elamipretide by the investigator. There were no local tolerability issues reported, and there were no significant findings on physical examinations, ophthalmic examinations, vital signs or laboratory measurements.

Earlier Clinical Trials of Elamipretide

We have studied elamipretide in three clinical trials for the treatment of primary mitochondrial myopathy, a disease characterized by debilitating skeletal muscle weakness, exercise intolerance and fatigue accompanied by a confirmed molecular genetic diagnosis with mutations in one or more of an estimated 250 different nDNA or mDNA genes. Although we observed improvement in the 6MWT in our Phase 1/2 and Phase 2 clinical trials and in endpoints measuring fatigue in our Phase 2 clinical trial, our Phase 3 clinical trial did not demonstrate efficacy on either of these endpoints. We observed a larger than expected placebo effect in the Phase 3 trial, such that subjects randomized to placebo improved similarly to subjects randomized to elamipretide on these endpoints. This finding underscores our belief in the importance of assessing diseases involving organ systems in which the demand for mitochondrial energetics is not effort dependent, such as cardiac and ophthalmic diseases including Barth, DMD, FDRA, GA and LHON. It also underpins our intent to identify objective, non-effort dependent endpoints in our future development efforts, such as the echocardiographic parameters of heart function, OCT and FAF assessments of retinal health, and biomarkers which we have incorporated into our ongoing programs in rare cardiomyopathies, ophthalmic disorders, and rare neurological disorders.

We have studied elamipretide in clinical trials in several diseases associated with aging, including studies enrolling subjects with reduced skeletal muscle mitochondrial function, subjects with heart failure with reduced ejection fraction, or HFrEF, subjects with HFpEF, subjects undergoing percutaneous transluminal renal angioplasty, subjects with acute coronary syndrome and subjects with Fuchs. These trials were designed as small proof-of-concept studies to inform our decision whether to progress later stage development in these indications, and as such were generally not well powered to achieve statistical significance. Although we have decided not to independently progress development of elamipretide for these common disease indications, we saw signs of clinical benefit from treatment with elamipretide in several of these indications, which may help inform our future development of pipeline compounds for age-related diseases.

In April 2010, we submitted an investigational new drug application, or IND, to the FDA for purposes of conducting clinical trials of elamipretide for the prevention and treatment of ischemia reperfusion injury. In October 2014, we submitted an IND to the FDA for the purpose of conducting clinical trials of elamipretide for the treatment of primary mitochondrial myopathy. Although this IND was also intended to cover our Barth clinical trial, when the FDA granted Fast Track designation to this program they recommended we file a new IND covering Barth, which we have done. Additionally, in October 2014, we submitted an IND for purposes of conducting clinical trials of elamipretide for the treatment of DME and dry AMD; this IND also covers our clinical trials of Fuchs' and LHON. The initial study under this IND was a Phase 1/2 safety study in 15 patients with DME and 5 patients with dry AMD, in which elamipretide topical ophthalmic drops at concentrations of 0.3% and 1% were well tolerated over four weeks of dosing. We were the sponsor for each of those INDs.

SBT-272

SBT-272, our second clinical-stage pipeline compound, is a second-generation novel peptidomimetic that targets the mitochondria, stabilizing mitochondrial function under conditions of oxidative stress. SBT-272 has been shown to increase ATP production and decrease levels of ROS in dysfunctional mitochondria in preclinical studies. Our primary objective in designing this compound was to increase brain exposure relative to elamipretide, as we believe that mitochondrial therapeutics may be beneficial in various neurological disorders. We also sought to improve the potency and stability of the compound relative to elamipretide.

In January 2020, we initiated a double-blind, placebo-controlled, single-ascending dose study enrolling up to 40 healthy subjects across multiple cohorts. Based on SBT-272's improved oral bioavailability relative to elamipretide in early animal studies, SBT-272 is being administered orally in the study. As a primary objective, the study will evaluate safety and tolerability of SBT-272. Secondary objectives include an analysis of the pharmacokinetic profile and appropriate dose range.

Rare neurological diseases

Increasing evidence suggests that mitochondria are involved in both inherited and age-related neurological diseases, including ALS, MSA, Charcot-Marie-Tooth and other inherited neuropathies, Alzheimer's disease and Parkinson's disease. Mitochondrial-generated ROS is postulated to be one factor in the development and progression of late-onset neurodegenerative diseases. Moreover, mitochondrial dysfunction is a common cellular change observed during the disease process in inherited neurodegenerative diseases.

An important differentiating aspect of SBT-272 from elamipretide is that the compound demonstrates higher mitochondrial uptake and greater concentrations in the brain than elamipretide. In early experiments, SBT-272 demonstrated approximately three times greater maximum concentration in the brain of rats relative to elamipretide, in each case dosed 10 mg/kg subcutaneously. SBT-272 has demonstrated more than 25 times greater area under the drug concentration-time curve in the brains of rats relative to elamipretide, in each case dosed 10 mg/kg subcutaneously, suggesting significantly higher brain exposure and residence time. In addition, the compound has shown greater than six times higher mitochondrial uptake relative to elamipretide in cell-based assays of isolated mitochondria, suggesting improved potency. In a murine stroke model, SBT-272 demonstrated improved respiratory control ratio in brain mitochondria after ischemia reperfusion injury relative to placebo (p=0.006), suggesting neuroprotective benefit.

ALS. ALS, a progressive neurodegenerative disease characterized by motor neuron deterioration and muscle atrophy, is estimated to affect one in 50,000 people in the United States. It is estimated that 16,000 patients in the United States are living with ALS. There is no cure for ALS, and treatment approaches to date primarily focus on symptom control. Mitochondrial dysfunction is believed to contribute to the progression of ALS, which affects nerve cells in the brain and the spinal cord, causing loss of muscle control that may lead to the inability to speak, eat, move and breathe.

In a preclinical SOD-1 mouse model of ALS, which is considered to be the gold-standard model, 60 ALS model mice were randomized to daily intraperitoneal injections of placebo, 0.5 mg/kg of SBT-272 or 5.0 mg/kg of SBT-272 for up to 10 weeks. The 10 male mice treated with the higher dose of SBT-272 demonstrated a statistically significant delay in the onset of neurological symptoms and increase in lifespan compared with male mice treated with placebo. Statistically significant reductions in circulating plasma levels of neurofilament light chain—a biomarker of nerve damage—were also noted with the 5.0 mg dose versus placebo. Significant differences were not seen with SBT-272 versus placebo in the female mice, which are known to present with a milder phenotype and lower levels of neurofilament light chain.

We are evaluating SBT-272 in a second preclinical model of ALS, the TDP-43 (transitive response DNA/RNA-binding protein 43 kDa) model, and expect to have data available by the end of 2020 to inform our selection of our first Phase 2 clinical indication for SBT-272.

MSA. MSA, a neurological disorder characterized by a combination of symptoms affecting both the autonomic nervous system and movement, is estimated to affect one in 20,000 to 50,000 people in the United States. There is no FDA, EMA or NMPA approved treatment for MSA. Cerebellar mitochondrial dysfunction is believed to be involved in the pathogenesis of MSA, which leads to parkinsonism, cerebellar ataxia, dysautonomia and other motor and non-motor symptoms. We are evaluating SBT-272 in a preclinical model of alpha-synucleinopathy representative of MSA and expect to have data available by the end of 2020 to inform our selection of our first Phase 2 clinical indication for SBT-272.

SBT-20

Our other product candidate, SBT-20, is a small peptide in the SBT-259 family that also targets and binds reversibly to cardiolipin, stabilizing mitochondrial structure and function under conditions of oxidative stress. SBT-20 has been generally well tolerated in 75 subjects exposed to it systemically as of December 31, 2019. We plan to evaluate SBT-20 as well as pipeline compound SBT-259, both of which are in the SBT-259 family, for rare peripheral neuropathies.

Based on preclinical studies, we believe that SBT-20 readily penetrates cell membranes and targets and binds reversibly to the inner membrane of mitochondria.

SBT-20 has been observed to protect the normal morphology of the mitochondria from injury in a preclinical ischemic reperfusion model. In a preclinical study of rats treated with SBT-20 or placebo prior to occlusion and reperfusion of renal blood flow, published in the *American Journal of Physiology—Renal Physiology* in October 2014, researchers at Weill Cornell Medical College observed that SBT-20 preserved normal mitochondrial structure and function, including mitochondrial density, mitochondrial matrix density, mitochondrial respiration and ATP levels.

SBT-20 was observed to have a protective effect against the development of chemotherapy-induced peripheral neuropathy in a mouse model, in which the mitotoxic effects of cancer chemotherapeutic agents are believed to contribute to dysregulation of primary afferent sensory neurons resulting in pain. In an experiment in which nine mice were treated with SBT-20 5 mg/kg/day, 10 mice were treated with SBT-20 10 mg/kg/day (the high dose cohort) and six mice were treated with vehicle, or normal saline, for two days prior to and for a three-week period during which oxaliplatin, a mitotoxic chemotherapy agent, was administered once-weekly, SBT-20 treated mice in the high dose cohort exhibited significantly decreased neuropathic pain measured by paw sensitivity to mechanical stimuli ($p=0.009$ relative to vehicle) and cold stimuli ($p<0.001$ relative to vehicle). Additionally, the loss of intraepidermal nerve fibers in the hind paw was observed to be significantly reduced in SBT-20 treated mice in the high dose cohort ($p=0.006$ relative to vehicle).

We have conducted two clinical safety studies of SBT-20, one of which, our CHALLENGE-HD trial, was a Phase 1/2 clinical trial evaluating the safety, tolerability and efficacy of daily subcutaneous injections of SBT-20 compared to placebo in 24 subjects with early stage Huntington's, and the other of which was a Phase 1 clinical trial involving 24 healthy adults exposed to single subcutaneous injections of SBT-20 and 32 healthy adults exposed to multiple subcutaneous doses of SBT-20, ranging from 5 mg to 30 mg. Injection site reactions, such as erythema, swelling, itching, or pain, were the most frequently reported AEs. No subject experienced injection site reactions that were assessed as severe with one exception, which was also reported as clinically significant. We did not observe any clinically significant findings in any laboratory assessments, vital signs or ECGs.

We plan to evaluate compounds in the SBT-259 family for rare diseases entailing mitochondrial dysfunction, including rare peripheral neuropathies associated with mitochondrial dysfunction. Mitochondrial dysfunction is thought to be involved in peripheral neuropathies including chemotherapy-induced peripheral neuropathy, neuropathies associated with mitochondrial myopathy, neuropathy, and gastrointestinal encephalopathy, or MNGIE, and both the axonal and demyelinating forms of Charcot-Marie-Tooth disease, or CMT, the most common inherited neuromuscular disorder.

We have initiated preclinical studies for both SBT-259 and SBT-20 in an animal model of CMT and expect to have data by the end of 2020 to inform our future development plans for this indication.

Discovery Compounds

We have an active discovery and development program focused on novel compounds targeting mitochondria. Mitochondria have been an extremely challenging therapeutic target, due in part to difficulty in targeting delivery of drugs to mitochondria. Successful delivery requires traversing not only the cell membrane, which may have reduced membrane potential in disease states, but also achieving intracellular diffusion/transport to mitochondria and subsequent electrical potential across outer and IMM. We believe the differentiated mitochondrial targeting characteristics of our compounds, our development of proprietary assays to screen new compounds for mitochondrial targeting and activity characteristics, and our experience working with various models of mitochondrial dysfunction position us to lead next generation development of mitochondrial product candidates, including SBT-272, that are improved relative to elamipretide and SBT-20.

We have developed multiple series of novel compounds with improved pharmacokinetic properties. These include over 100 different compounds, including peptidomimetics, small molecules and novel peptides, that we are actively screening to broaden our existing mitochondrial product candidate portfolio. We are focused on producing agents with mitochondrial therapeutic potential with improved properties over our first-generation compounds, by altering the rate and extent of absorption, the bio-distribution and the routes of metabolism and excretion.

Certain compounds within the SBT-259 family, which includes SBT-20, have shown greater potency than SBT-20 and elamipretide in ischemia reperfusion and myocardial infarction models. Relative to SBT-20, SBT-259 has demonstrated increased (approximately 5X) exposure in peripheral tissues. SBT-259 and SBT-20 are both being evaluated in a CMT model, with data expected in 2020 to inform future development efforts. See "*SBT-20*" above.

Compounds within the SBT-550 family of compounds, which are small molecules that may be suitable for oral formulations, appear to be mechanistically differentiated from elamipretide, SBT-272 and SBT-20. Preliminary in vitro studies in primary fibroblast cells from FDRA patients stressed by eliminating the glutathione defense mechanism (typically leading to cell death) show dose-dependent improvements in cell viability (survival) with SBT-550 family compounds. We plan to evaluate compounds in the SBT-550 family for rare neurological indications such as Leigh's syndrome, a severe neurological condition affecting an estimated one in 40,000 newborns.

Carrier program

We have also conducted experiments in our carrier program in which we observed that we can use our proprietary compounds as vectors or carriers to selectively deliver various therapeutic payloads to mitochondria, conferring organelle specificity to promising therapies. Many individuals diagnosed with primary mitochondrial disease, for which there are no therapies approved by the FDA, take a so-called "mito cocktail" of vitamins and supplements, usually in high doses and comprising up to 50 pills per day if not compounded. These may typically include co-enzyme Q-10, or Co Q-10, or its analogs, L-carnitine, B vitamins and antioxidants. The reason these are taken in such high doses is because delivery to the mitochondria is likely confounded by permeability challenges traversing the cell and outer mitochondrial membranes. By contrast, we have observed mitochondria-targeting capabilities in our proprietary compounds and have also observed that we can conjugate payloads to our compounds and direct the conjoined carrier/payload to the mitochondria.

For example, idebenone is a Co Q-10 analog that introduces electrons into the electron transport chain downstream of complexes I and II, a promising mechanism for bypassing defective complexes in genetic diseases. Because idebenone is poorly absorbed and does not specifically target mitochondria, it has demonstrated limited pharmacologic activity even at high doses. Preliminary preclinical data shows that our idebenone-conjugated peptide was effective at stimulating complex III enzyme activity at a concentration of approximately 100 times lower than the dose achieved with systemically administered idebenone. We believe this is promising support for the potential of our carrier program, and we are actively evaluating other mitochondrial beneficial payloads for evaluation in this program.

Manufacturing

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. We have also obtained key raw materials for elamipretide from third-party manufacturers. For elamipretide, we intend to identify and qualify a single manufacturer to provide the active pharmaceutical ingredient and other manufacturers for fill-and-finish services for each of our elamipretide-containing drug products (vials and cartridges) prior to submission of an NDA to the FDA. This approach allows us to reduce the risk to NDA approval by focusing our resources on preparing only one manufacturing site for active pharmaceutical ingredient and one for each drug product for pre-approval inspections. We can sufficiently reduce the supply risk usually associated with a single source of product based on our capability to build pre-launch inventory and the relatively small demand for material projected for our rare disease indications.

All of our product candidates are small molecules and are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale up and does not require unusual equipment in the manufacturing process. Elamipretide has been produced historically by a solid-phase manufacturing process that has been commonly used to produce commercial peptides. Due to a lack of scalability, we deemed this process undesirable for production of commercial quantities of elamipretide. A new solution-phase process for producing elamipretide as a hydrochloride salt has been developed and implemented at a contract manufacturing site at a scale sufficient to meet the projected commercial demand. The solution-phase process for manufacturing is proprietary to us, and the equipment and the unit operations used in the process are not unique to any particular contract manufacturer. We have transferred this process to contract manufacturing sites capable of using such processes to manufacture large quantities of similar drug substances, and we have completed the drug supply for pivotal clinical trials and are now progressing into commercial production. Manufacturing at a higher production scale has led to a significant reduction in our cost-of-goods and provided us with the ability to respond to any need to supply large clinical trials or unanticipated commercial demand in the future. Following FDA review of test results demonstrating the same/similar identity, quality, purity and strength of elamipretide from early and commercial-scale processes, the FDA has stated that non-clinical and clinical trials with drug substance from the former processes can be used to support further development and registration of elamipretide made by the commercial process.

We have active clinical programs for which our contract manufacturing organizations, or CMOs, are routinely manufacturing a sterile solution product for subcutaneous injection. Our CMOs have successfully produced these products on a scale of tens of thousands of units and shown, using validated stability-indicating methods, that these products would meet specifications over a shelf life typical of commercial products. We believe we are well positioned to validate our manufacturing processes at commercial-ready CMOs and support a commercial launch of these products. We have successfully filed regulatory documents to use multi-use cartridges and pens for subcutaneous self-administration in our Phase 2 and Phase 3 clinical trials. We believe, based on these clinical cartridge and pen injector designs, that we can produce and commercialize this combination product, as well as the simpler vial product, successfully.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover our lead product candidates, elamipretide and SBT-272, and related compositions, our core clinical applications and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary or intellectual property rights worldwide. Our patent portfolio, which includes patents and patent applications that we own, as well as those that we have exclusively in-licensed, is structured to provide layers of protection for the proprietary technologies central to our business. Our portfolio includes claims to the elamipretide, SBT-272 and SBT-20 peptides, compositions comprising the same, and use of the peptides and other therapeutically active molecules for our core clinical applications. As of December 31, 2019, the patent portfolio included 423 granted patents (45 U.S., 378 foreign, which include individual national patents based on granted European patents) and 242 pending applications, including provisional applications (64 U.S., 171 foreign, 7 Patent Cooperation Treaty).

We also rely on trade secret protection, technical knowledge, and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, scientific advisors, employees, consultants and select contractors, and invention assignment agreements with our employees.

We also have agreements with selected contractors, consultants, scientific advisors and collaborators requiring assignment of inventions or, in limited cases, the grant of an exclusive, worldwide license or option to license intellectual property rights developed in the course of their work with or for us. As with other biotechnology and pharmaceutical companies, our capacity to obtain, maintain and protect our proprietary and intellectual property positions for our products and technologies depends on our continued ability to obtain relevant patent rights and to enforce those patent rights, if necessary. However, patent applications that we may file or license from third parties may not necessarily result in the grant of rights. We also cannot predict the scope of rights that may be granted to us in the future, our desire or ability to seek enforcement of any granted rights, or the willingness of courts or other administrative bodies to uphold or enforce our rights.

In addition, any currently issued patents or any future patents, should they issue, may be challenged, invalidated, or circumvented, such as through district court proceedings or inter partes review. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications, and proceedings to establish our rights could result in substantial costs, even if the eventual outcome is favorable. Due to the extensive time required for clinical development and regulatory review, it is possible that, before any of our product candidates can be commercialized, any related patent right may expire or its term may have substantially run, leaving its remaining term in force for only a short period following commercialization. To the extent that occurs, the possible commercial advantage conferred by such patents would be reduced. Accordingly, we have attempted to design a patent portfolio with both breadth and depth of potential protection, with the goal of maximizing coverage for elamipretide and related peptides and their uses in commercially relevant countries.

Elamipretide

Patent rights relating to elamipretide peptide and compositions comprising elamipretide have been granted in Australia, Canada, China, Europe, Hong Kong, Japan and the United States. The U.S. patent claiming elamipretide has an adjusted statutory expiration date in 2026, which includes 717 days of patent term adjustment, or PTA, granted by the USPTO upon issue of the patent. The foreign patents have a statutory expiration date in 2024. We hold an exclusive license to these rights from Cornell and the IRCM.

Patent rights to the use of elamipretide as a carrier for the transport of therapeutic molecules into a cell as well as related compositions have been granted or allowed in Australia, Canada, China, Europe, Hong Kong, Japan, the United States and six other countries. The first of three issued U.S. patents in this family has an adjusted statutory expiration date in 2027, which includes 1,215 days of PTA granted by the USPTO upon issue of the patent. The remaining two issued U.S. patents and the foreign patents have a statutory expiration date in 2024. We hold an exclusive license to these patent rights from Cornell.

Patent rights related to compositions including elamipretide and a second therapeutic compound have also been granted. For example, claims directed to elamipretide-cyclosporine conjugates have been granted in the United States and are pending in Europe. The U.S. patent has a statutory expiration date in 2031, and any patent that may issue from the pending European application will similarly have a statutory expiration date in 2031. Each of these patent rights are owned exclusively by us. Additional patent rights related to compositions including elamipretide and glucagon-like peptide-1, or GLP-1, are pending in applications filed in Canada, China, Europe, Japan and the United States and, if granted, these will have statutory expiration dates in 2033. Each of these patent rights are owned exclusively by us.

Patents directed to methods of treating or preventing various diseases and medical conditions by administering elamipretide have been granted to us, or have been in-licensed by us, in a number of countries. Where possible, the scope of granted claims has been tailored to provide broad generic support encompassing a wide range of conditions as well as specific disease states. By way of example, there are granted patents related to the use of elamipretide to treat basic, adverse cellular events that contribute to disease, such as mitochondrial permeability transition, or MPT, and oxidative damage associated with a neurodegenerative disease.

Patents related to MPT have been granted in Australia, Canada, China, Europe, Hong Kong, Japan and the United States. Two of the granted U.S. patents in this family have an adjusted statutory expiration date in 2026, and one of them is the same patent referred to above as covering the composition of elamipretide. The other two issued patents and all related foreign patents have statutory expiration dates in 2024. We hold exclusive rights to these patents by way of a license agreement with Cornell and the IRCM.

Our patent portfolio also protects or aims to protect the use of elamipretide to treat or prevent specific clinical indications. By way of example, our portfolio includes granted claims drawn to the use of elamipretide to treat diabetes, metabolic syndrome, renal diseases, certain cardiovascular diseases, ocular diseases, and neurodegenerative diseases (including Alzheimer's disease, Huntington's disease and ALS) that are in patents owned by us or in-licensed to us. Claims relating to the use of elamipretide to treat Barth were recently granted in the United States and in Europe, and applications related to treating this clinical indication remain pending in the United States, Europe, Canada, China, Japan and Hong Kong. Other clinical indications covered by pending claims in our patent portfolio include LHON, primary mitochondrial myopathy, Friedreich's ataxia, traumatic optic neuropathy, Sengers syndrome and mitochondrial diseases associated with certain gene mutations are pending in applications owned by us. Furthermore, our portfolio includes granted and pending claims drawn to the process we use to produce elamipretide, as well as certain intermediates and processes that produce crystalline drug substance. Our portfolio also includes granted and pending claims that disclose similar processes that we have conceived that could be competitive with our preferred process to produce commercial quantities of elamipretide.

SBT-272

Claims drawn to the SBT-272 peptide are currently pending in a Patent Cooperation Treaty, or PCT, application that claims priority to a now expired United States provisional patent application. If granted (and not subject to any statutory adjustment or extension of time), any patent claiming priority to this PCT application will have a statutory expiration date in 2038. These patent rights are owned exclusively by us.

Claims drawn to the use of the SBT-272 peptide and compositions for the treatment of amyotrophic lateral sclerosis is currently pending as a United States provisional patent application. If granted (and not subject to any statutory adjustment or extension of time), any patent claiming priority to this U.S. provisional patent application is expected to have a statutory expiration date in 2040. These patent rights are owned exclusively by us.

SBT-20

Claims drawn to the SBT-20 peptide and compositions comprising the SBT-20 peptide have been granted in Australia, Canada, Japan and the United States, and are pending in Europe. The U.S. patent has an adjusted statutory expiration date in 2026, which includes 717 days of PTA granted by the USPTO upon issue of the patent, and is the same patent described above as related to elamipretide peptide. The foreign patents have statutory expiration dates in 2024. We hold exclusive rights to the patents and applications by way of an exclusive agreement with either Cornell alone or Cornell in conjunction with the IRCM.

Our patent portfolio also protects or aims to protect the use of SBT-20 to treat or prevent specific clinical indications. By way of example, our portfolio includes granted claims drawn to the use of SBT-20 to treat complications of diabetes, renal diseases, ocular diseases, and neurodegenerative diseases that are owned by us or in-licensed. Claims relating to the use of SBT-20 to treat Parkinson's disease, Alzheimer's disease, Huntington's, and ALS are granted in Australia, in a patent in-licensed to us with a statutory expiration date in 2024. Furthermore, our portfolio includes pending claims drawn to the SBT-20 peptide produced in crystalline salt forms.

We hold patent rights to additional pipeline compounds in the portfolio, and are continuing to expand coverage in the United States and commercially relevant foreign jurisdictions. Subject matter for new filings is expected to include, but will not necessarily be limited to, the use of peptides or other therapeutically active molecules to treat additional disease indications, new combination therapies, new peptide formulations, new compositions and uses of the same.

The term of a patent depends upon the legal length of the term of patents in the jurisdiction in which it is issued. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. Patent term adjustment is a process of extending the term of a United States patent beyond the 20-year statutory patent term to accommodate for delays caused by the USPTO during prosecution. By contrast, a patentee or applicant may file a terminal disclaimer which disclaims or dedicates to the public the entire term or any terminal part of the term of a patent or patent to be granted.

In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the regularly scheduled expiration of a patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA, only one patent applicable to an approved drug may be extended, and a given patent can only be extended based on one approved drug. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. We anticipate that we will apply for patent term extensions for relevant U.S. patents, if and when our pharmaceutical products receive FDA approval. We also anticipate seeking patent term extensions for issued patents in any jurisdiction where patent term extension is available, however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. Unless specifically indicated, the above statutory patent terms refer to the 20-year base statutory term and do not include any patent term adjustment or extension that may be available in any jurisdiction.

Cornell License Agreements

We have entered into several license agreements with Cornell and the IRCM, pursuant to which Cornell granted us specified exclusive, worldwide rights under patents related to elamipretide, SBT-20, and other technology described below, which we refer to collectively as the licensed patents. The original Cornell agreement was entered into with Cornell and the IRCM in April 2006 and subsequently amended in October 2010. Concurrent with our execution of the original Cornell agreement, we entered into a sponsored research agreement with Cornell in which we agreed to fund specified research at Cornell for three years. We retained the right to license inventions arising under such sponsored research agreement, as well as certain material transfer agreement entered into between us and Cornell, through entry into license agreements on substantially the same terms as the original Cornell agreement. Such subsequent agreements under which we obtained rights under additional patent families, which we refer to as other Cornell license agreements, and collectively with the original Cornell agreement as the Cornell license agreements, were entered into in November 2010, November 2011, December 2012, August 2013 and March 2019. In each of the Cornell license agreements, Cornell granted us an exclusive, worldwide license under specified patents and patent application families claiming certain inventions, including inventions related to elamipretide, SBT-20, certain other peptides and/or specified uses of the foregoing, which we refer to collectively as the licensed patents, to make, use, sell, lease, import, export or otherwise dispose of products or services that incorporate, utilize or are otherwise described and claimed in the licensed patents, which we refer to as the licensed products, in any and all fields. Our rights under the Cornell license agreements are subject to the rights of the United States government and other applicable restrictions imposed by the Bayh-Dole Act and its implementing regulations, and the rights of Cornell, and in some cases certain other specified institutions, to practice the inventions claimed in the licensed patents for educational and research purposes.

We have agreed to use best efforts (as defined in each of the Cornell license agreements) to commercialize licensed products and to achieve specified diligence milestones by specified target dates. We are also required to periodically set forth additional milestones until first commercial sale of a specified licensed product. We believe that to date we have met each diligence milestone with respect to our licensed products and the specific licensed indications and/or formulations which we are developing. If however we fail in the future to meet any diligence milestone within a specified period after the corresponding target date, our exclusive license under the applicable Cornell license agreement will convert to a non-exclusive license and, in the case of the original Cornell agreement, such conversion will occur only with respect to the peptide, indication and/or formulation that is subject of the unachieved milestone.

In connection with the licenses granted under the original Cornell agreement, we issued Cornell 666,667 ordinary shares. With respect to the other Cornell license agreements, we paid Cornell upfront license fees of $60,000 and royalties on net sales, if any, by us and our sublicensees of any licensed product, on a product-by-product and country-by-country basis. Subject to specified reductions and royalty offsets, such royalties are calculated as a tiered, low-to-mid single digit percentage of net sales of licensed products under each of the Cornell license agreements, except that for licensed products under the original Cornell agreement, such royalties are calculated as a tiered, low single digit to sub-teen percentage of net sales, depending on patent coverage, amount of net sales and type of licensed product. Our obligation to pay royalties as to any licensed product extends until the later of the expiration of the last-to-expire valid claim of any licensed patent covering such licensed product or 15 years after the date of our first commercial sale of such licensed product. If a licensed product is covered by licenses granted under the original Cornell agreement and another Cornell license agreement, then, for each unit of product, royalties will only be due under the original Cornell agreement.

We are obligated to pay Cornell a low double digit percentage of specified payments we receive in connection with granting a sublicense under the Cornell license agreements. We have also agreed to reimburse Cornell for its out-of-pocket expenses incurred in preparing, filing, prosecuting and maintaining the licensed patents, except for any licensed patents as to which we elect to waive our licensed rights. We also have agreed to pay Cornell annual license maintenance fees in the mid-five digits for the original Cornell agreement, and mid-four digits for each of the other Cornell license agreements starting on a date specified in each such agreement, in all cases until the first commercial sale of a specified type of licensed product under such agreement.

If Cornell identifies any licensed product that we are not actively developing or commercializing and we do not elect within a specified period to develop or commercialize such licensed product ourselves or through a sublicensee, or, if we do so elect, we do not then agree on reasonable diligence goals with Cornell or enter into an agreement with such a sublicensee within specified periods as to such licensed product, then Cornell may terminate our rights under the applicable Cornell license agreement for such licensed product.

Unless earlier terminated, each of the Cornell license agreements will remain in effect until the expiration or invalidation of the last of all licensed patents and as long as no licensed patent applications remain pending. Cornell (together with the IRCM in the case of the original Cornell agreement) can terminate a Cornell license agreement if we are in material breach of such license agreement, if we intentionally provide false reports, or if we are in default in our payment obligations, and we fail to cure such breach, false report or default within a specified period. In addition, Cornell can terminate the original Cornell agreement and certain of the other Cornell license agreements if we fail to achieve first commercial sale of a therapeutic licensed product by the date specified in the respective agreement (which, with respect to the original Cornell agreement, is December 31, 2020); however, there are a number of exceptions to Cornell's termination right, including:

- delays due to clinical development, including clinical trial enrollment challenges or data read-outs;
- delays due to regulatory matters; or
- delays due to other events over which we cannot exert direct control.

We can terminate any of the Cornell license agreements in its entirety or on a patent-by-patent, licensed product-by-licensed product or country-by-country basis if we have a reasonable basis for doing so by giving Cornell a specified number of days' prior notice. We can transfer each of the Cornell license agreements with Cornell's prior written approval (not to be unreasonably withheld) in the event of a sale of the Company, sale of assets or sale of shares, provided that such sale is not primarily for the benefit of creditors. If we fail to obtain Cornell's prior written approval for such transfer, Cornell can terminate the respective agreement and require that the transfer of such agreement be voided. We cannot assign the Cornell license agreements without Cornell's (and in the case of the original Cornell agreement, IRCM's) written consent.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies; academic institutions and governmental agencies; and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We are initially developing elamipretide for the treatment of rare primary mitochondrial diseases and common diseases of aging in which mitochondrial function is impaired. There are several companies developing treatments that target mitochondria or mitochondria-associated diseases. The majority of these efforts are in preclinical or early clinical development, are focused on gene therapy or are proposing the use of generic compounds. To our knowledge, none of these are focused on cardiolipin remodeling. Our competitors include NeuroVive Pharmaceutical AB, Reata Pharmaceuticals, Inc., LumiThera, Inc., Reneo Pharmaceuticals, Inc. and Santhera Pharmaceuticals Holding. In addition to competition from competitors who are developing treatments that seek to improve mitochondrial function or otherwise target the mitochondria, we also face competition from therapies that target the indications we are studying, particularly for diseases of aging such as GA. Such competitors who are developing or who have developed competing therapies include Apellis Pharmaceuticals Inc., Astellas Pharma Inc., Hemera Biosciences Inc., Ionis Pharmaceuticals, Inc. and IVERIC bio, Inc.

Many of the companies against which we are competing or against which we may compete in the future may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be their efficacy, safety, tolerability, convenience and price and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and associated implementing regulations. The failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions,

including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, where applicable, and post-approval studies required by the FDA.

Preclinical Studies

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

Human Clinical Trials in Support of an NDA

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

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

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease (e.g., cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.
- Phase 4: Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor or the data monitoring committee may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In general, the FDA accepts foreign safety and efficacy studies that were not conducted under an IND provided that they are well designed, well conducted, performed by qualified investigators and conducted in accordance with ethical principles acceptable to the world community. The conduct of these studies must meet at least minimum standards for assuring human subject protection. Therefore, for studies submitted in support of an NDA that were conducted outside the United States and not under an IND, the agency requires demonstration that such studies were conducted in accordance with GCP.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee and the sponsor of an approved NDA is also subject to annual program user fees. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation.

The FDA conducts a preliminary review of an NDA within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accepting an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA has agreed to specified performance goals in the review process of NDAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that FDA receives the application. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

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

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

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

Fast Track, Breakthrough Therapy, Priority Review and Regenerative Advanced Therapy Designations

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

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

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

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

Finally, with passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Accelerated Approval Pathway

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

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

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

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

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

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

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

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

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

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, as well as the Drug Supply Chain Security Act, or DSCA, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the federal level, and set minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

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

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

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity or NCE. An NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

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

Specifically, the ANDA or 505(b)(2) applicant must certify with respect to each patent whether:

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

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

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

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

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

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

Orphan Drug Designation and Exclusivity

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

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

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permit a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals from the comparable foreign regulatory authorities before we can commence clinical trials or marketing of any products in those countries or jurisdictions. The approval

process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Clinical Trial Approval in the European Union

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, or GCP, are set forth in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the European Union member states. Under this system, approval must be obtained from the competent national authority of each European Union member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new European Union clinical trials legislation was passed as a regulation that is directly applicable in all European Union member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in October 2018. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the European Union portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I is assessed jointly by all member states concerned; Part II is assessed separately by each member state concerned); strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Marketing Authorization in the European Union

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the

European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Data and Market Exclusivity

In the European Union, NCEs qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from assessing a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an NCE and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete human clinical trial database and obtain marketing approval of its product.

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for

Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Brexit and the Regulatory Framework in the United Kingdom

On January 31, 2020, the United Kingdom's decision to withdraw from the European Union, referred to as Brexit, became effective. However, significant uncertainty remains as to how the withdrawal will be effected as the United Kingdom and the European Union did not enter into a formal withdrawal agreement. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of any approved products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for products in the United States can differ significantly from payor to payor.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies, or so called health

technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense and there are high barriers to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

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

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalties laws, which provide for civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, known as the federal Physician Payments Sunshine Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, within the Department of Health and Human Services, or HHS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and local laws require the registration of pharmaceutical sales representatives and state and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that current and future business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. If operations are found to be in violation of any of these laws or any other governmental regulations that may apply to a business, the business may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of operations.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the ACA of importance to potential product candidates are:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 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;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research;

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- expansion of the entities eligible for discounts under the Public Health Service program; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current presidential administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. This includes enactment of the Tax Cuts and Jobs Act, which, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance.

In addition, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and oral arguments are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services. For example, on December 23, 2019, the Trump administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

C. Organizational structure.

Stealth BioTherapeutics Corp was incorporated in Grand Cayman, Cayman Islands as Stealth Peptides International, Inc. in April 2006. Its wholly owned subsidiary, Stealth BioTherapeutics Inc., was incorporated in Delaware as Stealth Peptides Inc. in October 2007. In addition, a wholly owned subsidiary, Stealth BioTherapeutics (HK) Limited, was incorporated in Hong Kong in September 2017. In May 2018, Stealth BioTherapeutics (Shanghai) Limited was formed as a wholly foreign owned enterprise in China. Stealth BioTherapeutics Corp, Stealth BioTherapeutics Inc., Stealth BioTherapeutics (HK) Limited, and Stealth BioTherapeutics (Shanghai) Limited are referred to herein as the "company."

D. Property, plants and equipment.

Our operations are conducted at Stealth Delaware, which is located in Newton, Massachusetts, where it occupies 17,548 square feet of office space. The lease expires November 30, 2020.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

A. Operating results.

The following discussion and analysis of our financial condition and results of operations should be read together with "Item 3.A.—Selected Financial Data" and our audited financial statements and the related notes included elsewhere in this annual report on Form 20-F. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." As a result of many factors, including those factors set forth under "Item 3.D.—Risk Factors", our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel therapies for diseases involving mitochondrial dysfunction. Mitochondria, found in nearly every cell in the body, are the body's main source of energy production and are critical for normal organ function. Dysfunctional mitochondria characterize a number of rare genetic diseases and many common age-related diseases, leading to devastating cardiac, ophthalmic and neurological symptoms. Our mission is to be the leader in mitochondrial medicine, and we have assembled a highly experienced management team, board of directors and group of scientific advisors to help us achieve this mission.

We believe our product candidates have significant potential to treat the cardiac, ophthalmic and neurological symptoms of both rare genetic and common age-related mitochondrial diseases. We are focusing our development efforts on rare cardiomyopathies, ophthalmic diseases and rare neurological diseases. Our first clinical product candidate, elamipretide, is a small peptide that targets and binds reversibly to cardiolipin, an essential structural element of mitochondria, stabilizing it under conditions of oxidative stress. This novel mechanism of action has shown potential clinical benefit in both rare genetic and common age-related cardiac and ophthalmic diseases entailing mitochondrial dysfunction. We are studying elamipretide in the following indications:

- Barth syndrome, or Barth, for which we have conducted a Phase 2/3 clinical trial and a retrospective natural history comparative control efficacy study in the United States;
- Geographic atrophy, or GA, an advanced form of dry age-related macular degeneration, for which we have conducted a Phase 1 clinical trial in the United States and in March 2019 initiated a Phase 2b clinical trial in the United States; and

- Leber's hereditary optic neuropathy, or LHON, for which we have conducted a Phase 2 clinical trial in the United States.

We are evaluating the potential for additional clinical trials in cardiomyopathy associated with Duchenne's muscular dystrophy, or DMD, and Friedreich's ataxia, or FDRA, which are phenotypically similar to the Barth cardiac phenotype assessed in our Barth program. We hope to initiate a clinical development program for elamipretide in rare cardiomyopathy by early 2021. We expect to initiate a Phase 3 global clinical trial for LHON when resources permit, but in no event earlier than 2021.

Elamipretide has been generally well tolerated in over 900 subjects exposed to it systemically and 53 subjects exposed to it topically as of December 31, 2019.

Our second clinical product candidate, SBT-272, is a novel peptidomimetic that has been shown to increase adenosine triphosphate, or ATP, production and decrease levels of reactive oxygen species, or ROS, in dysfunctional mitochondria in preclinical studies. In early experiments, SBT-272 demonstrated higher mitochondrial uptake, greater concentrations in the brain, and improved oral bioavailability relative to elamipretide. We are developing SBT-272 for rare neurological diseases involving mitochondrial dysfunction. We initiated a Phase 1 clinical trial in healthy subjects in January 2020, and we are conducting preclinical studies in amyotrophic lateral sclerosis, or ALS, and multiple system atrophy, or MSA, models to inform our decisions regarding our first Phase 2 indication.

We have discovered and own over 100 compounds, including SBT-272, SBT-259, and the SBT-550 family, that also target the mitochondria and form the basis of our broad proprietary pipeline of mitochondria-targeted product candidates. We are evaluating compounds in the SBT-259 family, including SBT-20 and SBT-259, as well as compounds in the SBT-550 family, for rare neurological indications. In addition, our internal discovery platform has generated a library of differentiated proprietary compounds which could have clinical benefit for diseases related to mitochondrial dysfunction and from which we plan to designate potential product candidates. We may also utilize certain of these compounds as part of our carrier platform, in which they could potentially serve as scaffolds to deliver other beneficial compounds to the mitochondria.

In January 2020, we adopted a strategic organizational restructuring plan, and reduced workforce by approximately 60% of our personnel. In connection with the reduction in workforce, we anticipate incurring a one-time charge totaling approximately $2.3 million related to termination benefits and other related charges in the first quarter of 2020.

Since our inception in 2006, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing our proprietary technology, identifying potential product candidates and conducting preclinical and clinical studies of our product candidates. We have not generated any product revenue and have financed our operations primarily through the private placement of Series A convertible preferred shares and convertible notes, borrowings under a term loan, and through our February 2019 initial public offering, or IPO. As of December 31, 2019, we raised an aggregate of $507.7 million in gross proceeds from the sale of Series A convertible preferred shares, the issuance of convertible promissory notes, a term loan and the sale of ordinary shares and the issuance of ADSs in our IPO, as well as gross proceeds received from Alexion Pharmaceuticals, Inc., or Alexion. In October 2019, we entered into an option agreement, or the Agreement, and the share purchase agreement, or the Equity Agreement (collectively referred to as the Alexion Arrangement), with Alexion. As of December 31, 2019, our principal source of liquidity was cash and cash equivalents, which totaled $50.8 million. Alexion terminated the Agreement in January 2020 and, as such, no there will be no further payments under the Alexion Arrangement.

As of December 31, 2019, we had an accumulated deficit of $498.0 million. Our net loss was $71.7 million, $96.7 million and $82.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. We have incurred significant net operating losses in every year since our inception and expect to continue to incur increasing net operating losses and significant expenses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly as we:

- continue to advance our clinical programs and initiate additional clinical programs;

- continue our current research programs and development activities;
- seek to identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional research, clinical and scientific personnel; and
- incur additional costs associated with operating as a public company, including expanding our operational, finance and management teams.

We believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2020. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern within one year after the issuance date of our consolidated financial statements for the year ended December 31, 2019. See Note 1 to our consolidated financial statements for additional information on our assessment. We do not expect to generate revenues from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate, which is subject to significant uncertainty. We currently use contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities, and we do not yet have a commercial organization. If we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we may seek to fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, if at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates, if developed.

Financial Overview

Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. We expect that any revenue will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our ability to generate revenues for any product candidate for which we receive regulatory approval will depend on numerous factors, including competition, commercial manufacturing capability and market acceptance of our products.

Our revenue to date was generated from the Alexion Arrangement. We received a non-refundable upfront payment of $15.0 million under the terms of the Agreement and $15.0 million under the Equity Agreement with Alexion. We recognized revenue as it relates to the Alexion Arrangement under Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, or ASC 606. In accordance with ASC 606, the Agreement and the Equity Agreement were deemed to be one arrangement, and any premium paid on the Equity Agreement was deemed to be included in the transaction price and allocated to the performance obligation identified. Alexion terminated the Agreement in January 2020 and as such, no additional revenue will be recognized under the Alexion Arrangement.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including development of our preclinical and clinical product candidates, which include:

- employee-related expenses, including salaries, benefits and share-based compensation expense;
- expenses incurred under agreements with CROs, CMOs and independent contractors that conduct research and development, preclinical and clinical activities on our behalf;
- costs of purchasing lab supplies and non-capital equipment used in our preclinical activities and in manufacturing preclinical study and clinical trial materials;

- consulting, licensing and professional fees related to research and development activities; and
- facility costs, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors such as patient enrollment or clinical site activations for services received and efforts expended.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our current development programs progress and new programs are added.

We track certain external research and development expenses for our lead product candidates. We manage certain activities, such as contract research and manufacturing of our product candidates and our discovery programs, through our third-party vendors and have captured the costs of these activities on an individual product basis from our financial records. We use our employee, consultant and infrastructure resources across our development programs and do not track and do not allocate the cost of these activities on a program-by-program basis. The following summarizes our research and development expenses:

	Year Ended December 31,		
	2019	2018	2017
		(in thousands)	
Product expenses:			
Elamipretide	$ 20,633	$ 31,961	$ 40,530
SBT-20	2	620	1,697
SBT-272	2,143	806	—
Total costs directly allocated to products	22,778	33,387	42,227
Expenses not directly allocated to products:			
Research and development programs	1,615	3,100	6,179
Consultants and professional expenses	6,547	5,756	4,457
Employee expenses including cash compensation, benefits and share-based compensation	13,664	10,819	10,357
Total expenses not directly allocated to products	21,826	19,675	20,993
Total research and development expenses	$ 44,604	$ 53,062	$ 63,220

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and investigational new drug-enabling studies;
- successful enrollment in and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of the product, if and when approved, whether alone or in collaboration with others;
- acceptance of the product, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies and treatment options;
- continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable therapeutic properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and share-based compensation for personnel in executive, finance, pre-commercial, facility operations and administrative functions. Significant costs are incurred in our pre-commercial activities including market research, public relations, patient advocacy, advisory boards and conferences and professional consulting. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to intellectual property and patent prosecution and maintenance, other legal fees and fees for accounting, tax and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses. We expect the increased costs associated with being a public company to include expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, director and officer insurance and investor and public relations costs

Other Income (Expense), Net

Other income (expense), net, primarily consists of amortization of debt discount and interest expense incurred on convertible notes payable and incurred on our term loan facility, interest income earned on a shareholder demand note receivable and on cash and cash equivalents and changes in the fair value of our derivative liability as well as our warrant liability.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with GAAP. We believe that several accounting policies are important to understanding our historical and future financial performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and we could have used different estimates which also would have been reasonable. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this annual report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our revenue to date was generated from the Alexion Arrangement. We adopted the revenue standard ASC 606 as of January 1, 2019. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases. Prior to 2019, we did not have any revenue-generating arrangements and, therefore, there was no transition impact from the adoption of ASC 606.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Upon the contract inception we determine whether the contract is within the scope of ASC 606. If the contract is within the scope of ASC 606, we assess the goods or services promised within the contract, to determine whether the promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct); and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct in the evaluation of an arrangement subject to ASC 606, we considered factors such as the research, manufacturing and commercialization capabilities of the collaboration partner or customer and the availability of the associated expertise in the general marketplace. We also consider the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, we are required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices. Determining the standalone selling prices for performance obligations requires significant judgment. However, we identified only one performance obligation and as such were not required to estimate the standalone selling price.

If an arrangement includes milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control are generally not considered probable of being achieved until those milestones have occurred.

In determining the transaction price, we adjust the consideration for the effects of the time value of money if the timing of payments provides us with a significant benefit of financing. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. We assessed our revenue-generating arrangement in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in the arrangement. We also assess if contracts entered on or near the same time with the same customer should be accounted for as a single contract, and if any portion of consideration received should be allocated to the transaction price.

We then recognize as revenue, the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time. Revenue is recognized over time if either: (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance; (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer.

In December 2019, we completed our performance obligation under the Agreement and recognized total revenue of $21.1 million in accordance with the criteria prescribed under ASC 606. See Note 2 to our 2019 consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with clinical trials;
- CMOs with respect to clinical materials, intermediates, drug substance and drug product;
- vendors in connection with research and preclinical development activities; and
- vendors related to manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. To date, there have been no material differences from our estimates to the amounts actually incurred.

Share-based Compensation

We account for share-based compensation awards in the consolidated statements of operations based on their grant-date fair value. We recognize compensation costs related to employees based on the estimated fair value of the awards on the date of grant and over the associated service periods, using the straight-line method. The options vest in accordance with the terms of the applicable agreements and expire no later than ten years after the date of grant. Compensation expense is recognized for the fair value of the consideration received, or the equity instruments issued, whichever is more reliably measurable. We measure share-based awards granted to non-employees based on the fair value of the award on the date on which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our ordinary shares and updated assumption inputs in the Black-Scholes option-pricing model, or Black-Scholes.

We estimate the fair value of our share-based awards to employees and non-employees using Black-Scholes, which requires the input of assumptions, some of which are highly subjective, including:

- expected volatility of our ordinary shares;
- expected term of the award;
- risk-free interest rate; and
- expected dividends.

Prior to our IPO, due to the lack of a public market for the trading of our ordinary shares and a lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of comparable companies that were publicly traded. For these analyses, we selected representative companies from the life sciences industry with characteristics similar to ours, including enterprise value, risk profiles, position within the industry and historical share price information, sufficient to meet the expected life of the share-based awards. We computed the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available. We use a dividend yield of 0% based on the fact that we have never declared cash dividends and have no current intention of paying cash dividends over the expected term of the option.

The expected term of options granted represents the weighted average of previously transacted awards plus the minimum and maximum expected life of the outstanding awards based on vest and expiry. For non-employee options, we have determined the expected life based on the respective contractual life. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted and with maturity dates equivalent to the expected term of the options.

We are also required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from the estimates. The estimation of the number of awards that will ultimately vest requires judgment and, to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period in which estimates are revised.

Share-based compensation totaled $3.2 million, $1.3 million and $1.3 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, 2018 and 2017, unrecognized compensation expense related to non-vested options, net of related forfeiture estimates, was $7.5 million, $2.0 million and $1.8 million, respectively. We expect to recognize our remaining share-based compensation expense as of December 31, 2019 over a weighted-average remaining vesting period of approximately 2.95 years. We expect our share-based compensation expense to increase in future periods due to the potential increase in the value of our ordinary shares and future option grants to new and current employees, directors and consultants.

Determination of the Fair Value of Ordinary Shares on Grant Dates

Following our IPO, the fair value of our ordinary shares is being determined based on the quoted market price of our ADSs. We have historically granted share options at exercise prices not less than the fair value of our ordinary shares. Prior to the IPO, our board of directors has determined the fair value of our ordinary shares considering, in part, the work of an independent valuation specialist. Prior to the IPO, our board of directors determined the estimated per share fair value of our ordinary shares at various dates considering contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-held Company Equity Securities Issued as Compensation*, or the Practice Aid.

Prior to the IPO, our ordinary share valuations were prepared using the Hybrid Method. The Hybrid Method is a hybrid between the Probability Weighted Expected Returns Method and the option-pricing method, or OPM. It is used to estimate the probability weighted value across multiple scenarios, but uses OPM to estimate the allocation of value within one or more of those scenarios. The market approach was selected to determine our enterprise value under various IPO and merger and acquisition, or M&A, scenarios, and OPM was utilized to allocate the value between the share classes under an M&A scenario, resulting in a value for the ordinary shares.

The ordinary share value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available, as well as the rights of each class of security. The estimated future value under each outcome is discounted back to the valuation date at an appropriate risk- adjusted discount rate and probability weighted to arrive at an indication of value for an ordinary share. OPM treats common and preferred shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, an ordinary share has value only if the funds available for distribution to equity holders exceeds the value of the preferred security liquidation preference at the time of the liquidity event, such as a strategic sale or a merger.

Results of Operations

Comparison of the Years Ended December 31, 2019, 2018 and 2017

The following tables summarizes our results of operations for the years ended December 31, 2019, 2018 and 2017, together with the dollar change in those items on a year over year basis:

	Year Ended December 31,		Dollar Change
	2019	2018	
	(in thousands)		
Revenue	$ 21,087	$ —	$ 21,087
Operating expenses:			
Research and development	44,604	53,062	(8,458)
General and administrative	22,315	22,217	98
Total operating expenses	66,919	75,279	(8,360)
Loss from operations	(45,832)	(75,279)	29,447
Other expense	(25,896)	(21,433)	(4,463)
Net loss	$ (71,728)	$ (96,712)	$ 24,984

	Year Ended December 31,		Dollar Change
	2018	2017	
	(in thousands)		
Operating expenses:			
Research and development	$ 53,062	$ 63,220	$ (10,158)
General and administrative	22,217	16,500	5,717
Total operating expenses	75,279	79,720	(4,441)
Loss from operations	(75,279)	(79,720)	4,441
Other income/(expense)	(21,433)	(3,190)	(18,243)
Net loss	$ (96,712)	$ (82,910)	$ (13,802)

Revenue

Revenue was $21.1 million in 2019, compared to $0 in 2018. Revenue represents non-refundable upfront payments under the Alexion Arrangement that were recognized in full in accordance with ASC 606 as we completed our performance obligation in 2019. Alexion terminated the Agreement in January 2020, and as such, no additional revenue will be recognized under the Alexion Arrangement.

Research and Development Expenses

Research and development expenses decreased by $8.5 million to $44.6 million for the year ended December 31, 2019, from $53.1 million for the year ended December 31, 2018. This decrease was primarily from a net decrease of $8.5 million in clinical trial costs due to the timing of trials that ended in 2018, a $2.8 million decrease in contract manufacturing, and a $0.9 million decrease in discovery related expenses due to timing of activities. These decreases were offset in part by increases of $3.6 million in employee and consultant related expenses driven by continued build-out of clinical, medical affairs and regulatory functions and $0.1 million in other costs.

Research and development expenses decreased by $10.2 million to $53.1 million for the year ended December 31, 2018, from $63.2 million for the year ended December 31, 2017. This decrease was primarily due to a $10.4 million decrease in clinical trial related costs as our cardiovascular clinical trials ended during early 2018, offset by an increase in costs of approximately $1.3 million for our primary mitochondrial myopathy studies, for which we incurred expenses for a full year in 2018. Manufacturing costs decreased $1.1 million as a result of the timing of production activities.

General and Administrative Expenses

General and administrative expenses increased by $0.1 million to $22.3 million for the year ended December 31, 2019, from $22.2 million for the year ended December 31, 2018. The increase in administrative expenses was primarily attributable to an increase of $3.3 million in employee related costs, a $2.3 million net increase in pre-commercial activities including building market disease awareness, and a $1.7 million increase in professional services for activities attributable to operating as a public company, offset by a decrease of $6.7 million in costs associated with our 2018 financing efforts and decrease in legal intellectual property costs of $0.5 million.

General and administrative expenses increased by $5.7 million to $22.2 million for the year ended December 31, 2018, from $16.5 million for the year ended December 31, 2017. The increase in administrative expenses was primarily attributable to an increase of $5.1 million as a result of financing efforts which were delayed due to market conditions and an increase in legal intellectual property costs of $0.6 million.

Other Expense

Other expense increased by $4.5 million to $25.9 million for the year ended December 31, 2019 from $21.4 million for the year ended December 31, 2018. The increase in other expense is primarily attributable to a $22.7 million loss on extinguishment of debt recorded in conjunction with the IPO and a $0.7 million change period over period in the fair value adjustments of the warrant liability. These increases were offset by a $3.4 million change in period over period fair value adjustments of the derivative liability associated with the convertible debt, a decrease in interest expense of $14.7 million mostly related to the convertible debt and an increase in interest income of $0.8 million.

Other expense was $21.4 million for the year ended December 31, 2018, consisting primarily of the amortization of the debt discount as a result of the exchange note with MVIL and additional debt with new investors, and interest expense incurred on the additional debt obtained during the year. Other expense was $3.2 million for the year ended December 31, 2017, consisting primarily of interest expense in connection with convertible promissory notes issued in 2017 and interest expense related to our term loan facility, which we entered into in June 2017.

Contractual Obligations

We enter into contracts in the normal course of business with CROs and clinical sites for the conduct of clinical trials, professional consultants and other vendors for clinical supply, manufacturing or other services.

We have entered into several license agreements with Cornell Research Foundation, Inc., a subsidiary of Cornell University, or Cornell, and Institut de recherches cliniques de Montréal, or the IRCM, pursuant to which Cornell and IRCM granted us an exclusive, worldwide rights under patents related to elamipretide, SBT-20 and other technology. In connection with the licenses granted under the original Cornell agreement, we issued Cornell 666,667 ordinary shares. With respect to the other Cornell license agreements, we paid Cornell upfront license fees of $60,000 and are obligated to pay Cornell royalties on net sales, if any, by us and our sublicensees of any licensed product. Subject to specified reductions and royalty offsets, such royalties are calculated as a tiered, low-to-mid single digit percentage of net sales of licensed products under each of the Cornell license agreements, except that for licensed products under the original Cornell agreement, such royalties are calculated as a tiered, low single-digit to sub-teen double-digit percentage of net sales, depending on patent coverage, amount of net sales and type of licensed product. Our obligation to pay royalties as to any licensed product extends until the later of the expiration of the last-to-expire valid claim of any licensed patent covering such licensed product or 15 years after the date of our first commercial sale of such licensed product. If a licensed product is covered by licenses granted under the original Cornell agreement and another Cornell license agreement, then, for each unit of product, royalties will only be due under the original Cornell agreement.

We are obligated to pay Cornell a low double-digit percentage of specified payments we receive in connection with granting a sublicense under the Cornell license agreements. We have also agreed to reimburse Cornell for its out-of-pocket expenses incurred in preparing, filing, prosecuting and maintaining the licensed patents, except for any licensed patents as to which we elect to waive our licensed rights. We also have agreed to pay Cornell annual license maintenance fees in dollars in the mid-five-digits for the original Cornell agreement, and mid-four-digits for each of the other Cornell license agreements starting on the date specified in each such agreement, in all cases until the first commercial sale of a specified type of licensed product under such agreement.

Recent Accounting Pronouncements

Note 2, “Summary of Significant Accounting Policies,” in the accompanying notes to the consolidated financial statements includes a discussion of recent accounting pronouncements. There were no new accounting pronouncements adopted during 2019 that had a material effect on our consolidated financial statements.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies. As a result, our financial statements may not be comparable to the financial statements of reporting companies that are required to comply with the effective dates for new or revised accounting standards that are otherwise applicable to public companies.

Quantitative and Qualitative Disclosures about Market Risk

We are minimally exposed to market risk related to changes in interest rates. As of December 31, 2019, we had cash and cash equivalents of $50.8 million, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are held in short-term money market funds. We do not believe we are materially at risk to sudden drops in interest rates based on the amounts subject to these potential changes.

Our Term Loan Facility has a floating per annum rate equal to the greater of (i) the Wall Street Journal prime rate plus 5.5% or (ii) 9.5%, which exposes us to market interest rate risk when we have outstanding borrowings. As of December 31, 2019, we had $16.5 million of outstanding borrowings under the Term Loan Facility. Assuming our outstanding debt remains constant for an entire year and the applicable annual interest rate increases or decreases by 1.0%, our annual interest expense would increase or decrease by $0.2 million.

B. Liquidity and capital resources.

Overview

We have funded our operations from inception through December 31, 2019 primarily through aggregate gross proceeds of $507.7 million from the sale of Series A convertible preferred shares, the issuance of convertible promissory notes, a term loan and the sale of ordinary shares and the issuance of ADSs in our IPO, as well as gross proceeds received under the Alexion Arrangement. As of December 31, 2019, we had cash and cash equivalents of $50.8 million.

Indebtedness

Term Loan Facility

On June 30, 2017, we entered into a loan and security agreement, or the LSA, with Hercules Capital, Inc., or Hercules, which we refer to as the Term Loan Facility. The Term Loan Facility was amended in March, July and October of 2018 and March and October of 2019. We have borrowed an aggregated principal amount of $20.0 million as of December 31, 2019.

Borrowings under the Term Loan Facility bear interest at a floating per annum rate equal to the greater of (i) the *Wall Street Journal* prime rate plus 5.5% or (ii) 9.5%. In an event of default, as defined in the LSA, the interest rate applicable to borrowings under such agreement will be increased by 4.0%. Interest payments are due monthly in arrears. Under the Term Loan Facility, as amended, we make interest only payments through January 31, 2020, at which time payments are made in monthly installments of principal and interest, continuing through the scheduled maturity date of January 1, 2021.

We may voluntarily prepay all, but not less than all, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee, which ranges from 0.5% to 3.0% of the outstanding principal depending on when the prepayment is made. A final payment of $1.3 million is due upon the earlier to occur of the maturity of the loan, the acceleration or prepayment of all outstanding principal or the termination of the Term Loan Facility.

Borrowings under the Term Loan Facility are secured by a first priority lien on all of our assets, excluding our intellectual property. We have agreed to a negative pledge on our intellectual property. The Term Loan Facility contains customary events of default and affirmative and negative covenants, including restrictions on our ability to pay dividends and incur additional debt, but does not contain any financial covenants. An event of default had not occurred as of December 31, 2019.

In connection with our entry into the Term Loan Facility, we issued to Hercules a warrant to purchase our ordinary shares. For a description of the warrant, see "Description of Share Capital and Articles of Association—Warrant" in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), which information is incorporated by reference in this annual report.

Convertible Notes

Between February and September 2017, pursuant to a note purchase agreement with MVIL, as the same was amended and restated, we issued convertible promissory notes to MVIL in an aggregate principal amount of $50.0 million, or the 2017 Shareholder Notes.

In January 2018, we entered into a note exchange agreement with MVIL pursuant to which MVIL exchanged the 2017 Shareholder Notes for a new convertible note in the principal amount of $52.4 million representing the aggregate principal amount of the 2017 Shareholder Notes plus accrued interest, or the January 2018 Shareholder Note. The January 2018 Shareholder Note accrued interest at 7% per annum, which compounded annually, and upon such compounding, was added to the outstanding principal amount.

In January 2018, we entered into a note purchase agreement with new investors pursuant to which we issued convertible promissory notes in the aggregate principal amount of $50.0 million, or the 2018 New Investor Notes. The 2018 New Investor Notes accrued interest at 7% per annum, which compounded annually, and upon such compounding, was added to the outstanding principal amount.

In October 2018, we entered into a note purchase agreement with MVIL pursuant to which we issued to MVIL three notes in the aggregate principal amount of $30.0 million in October 2018, December 2018 and January 2019, or the MVIL Notes. The MVIL Notes had substantially the same terms as the January 2018 Shareholder Note except that a qualified financing is limited to a U.S. initial public offering and that there is no change of control conversion feature.

The outstanding principal amount and accrued interest plus a 25% premium of the 2017 Shareholder Notes, the January 2018 Shareholder Note, the 2018 New Investor Notes and the MVIL Notes automatically converted into 175,210,373 ordinary shares upon the closing of our IPO on February 20, 2019.

We refer to the January 2018 Shareholder Note, the 2018 New Investor Notes, and the MVIL Notes collectively as the 2018 Notes.

Cash Flows

The following table provides information regarding our cash flows for each of the years presented:

	Year ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (47,984)	$ (72,078)	$ (69,835)
Investing activities	(130)	(12)	(173)
Financing activities	88,027	78,826	64,417
Net increase (decrease) in cash and cash equivalents	$ 39,913	$ 6,736	$ (5,591)

Net Cash Used in Operating Activities

The use of cash for operating activities in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities decreased by $24.1 million to $48.0 million during the year ended December 31, 2019, from $72.1 million year ended December 31, 2018. Cash used in operating activities during the year ended December 31, 2019, consisted of our net loss of $71.7 million, partially offset by non-cash charges of $27.3 million, which includes $22.7 million loss on extinguishment of 2018 Notes, $3.2 million in share-based compensation, $3.0 million in amortization of the debt discount, $1.7 million in non-cash interest expense and $0.6 million in other non-cash charges, offset by a $2.8 million change in fair value of derivative liability. Changes in operating assets and liabilities included $5.9 million in decreases in accounts payable, accrued expenses and other current liabilities and a $1.2 million increase in prepaid expenses and other current assets.

Net cash used in operating activities increased by $2.3 million to $72.1 million during the year ended December 31, 2018, from $69.8 million year ended December 31, 2017. Cash used in operating activities during the year ended December 31, 2018, consisted of our net loss of $96.7 million, partially offset by non-cash charges of $21.3 million, which includes $12.3 million in amortization of the debt discount as a result of the exchange note with MVIL and additional debt with new investors, $7.1 million in non-cash interest expense, $1.3 million in share-based compensation and $0.6 million in other non-cash charges. Changes in operating assets and liabilities included $4.1 million in increases in accounts payable, accrued expenses and other current liabilities and a $0.6 million decrease in prepaid expenses and other current assets.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.1 million during the year ended December 31, 2019, $12,000 during the year ended December 31, 2018 and $0.2 million during the year ended December 31, 2017.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $88.0 million during the year ended December 31, 2019, compared to $78.8 million during the year ended December 31, 2018. Cash provided by financing activities during the year ended December 31, 2019, was primarily attributable to the receipt of $78.2 million in connection with the issuance of ordinary shares in the IPO, $8.9 million in connection with the issuance of ordinary shares, $5.0 million in connection with the issuance of convertible promissory notes to a shareholder, offset in part by $2.8 million of payments made on the Term Loan Facility, $1.3 million of payments for deferred financing costs and $0.1 million related payments of debt issuance costs.

Net cash provided by financing activities was $78.8 million during the year ended December 31, 2018, compared to $64.4 million during the year ended December 31, 2017. Cash provided by financing activities during the year ended December 31, 2018, was primarily attributable to net proceeds of $25.0 million in connection with the issuance of convertible promissory notes to MVIL, $50.0 million in connection with the issuance of convertible notes payable, as well as $5.0 million related to net proceeds from the term loan facility. These proceeds were partially offset by $1.2 million related to payments on venture debt and deferred financing costs.

Funding Requirements

We expect our expenses to increase in connection with our ongoing clinical activities, particularly as we continue to develop and conduct clinical trials with respect to elamipretide and new compounds, including our ongoing and planned clinical trials; advance the development of pipeline programs; initiate new research and preclinical development efforts; and seek marketing approval for any product candidates that we successfully develop. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution and other commercial infrastructure to commercialize such products. We have incurred, and expect to continue to incur, additional costs associated with operating as a public company.

Our existing cash and cash equivalents will not be sufficient to support our clinical development of elamipretide and SBT-272 for rare cardiomyopathies and neurological indications and rare and common ophthalmic indications, our planned Phase 3 trial for LHON or any clinical development for SBT-259, SBT-550 or any other product candidates we may develop in the future. We will be required to expend significant funds in order to advance the development of elamipretide, SBT-272, SBT-259 and SBT-550, as well as any other product candidates we may develop in the future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash and cash equivalents as of December 31, 2019 will be sufficient to meet our cash commitments through the third quarter of 2020.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the research, development and commercialization of our product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, costs and results of our current and future clinical trials;
- research and preclinical development efforts for any future product candidates that we may develop;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our current and future product candidates;
- our headcount growth and associated costs if and as we expand our research and development and establish a commercial infrastructure;
- costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, that we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing investors will be diluted, and the terms of the securities we issue may include liquidation or other preferences that adversely affect the rights of holders of ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through future collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

C. Research and development, patents and licenses, etc.

Full details of our research and development activities and expenditures are given in "Item 4.B. —Business Overview" and "Item 5.A. —Operating Results" within this annual report.

D. Trend information.

See "Item 5.A. —Operating Results" and "Item 5.B. —Liquidity and Capital Resources" within this annual report.

E. Off-balance sheet arrangements.

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the applicable regulations of the SEC.

F. Tabular disclosure of contractual obligations.

Our contractual obligations relate to the lease of our office space and a term loan facility. We have summarized in the table below our fixed contractual cash obligations as of December 31, 2019.

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in thousands)		
Operating leases	$ 708	$ 708	$ —	$ —	$ —
Term loan facility[1]	17,844	14,958	2,886	—	—
Total	$ 18,552	$ 15,666	$ 2,886	$ —	$ —

(1) Represents principal amount of the outstanding term loan as of December 31, 2019 as well as an end of term charge of $1.3 million due under the LSA. The loan is subject to variable interest that will be calculated as payments become due.

G. Safe harbor.

This annual report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See the section titled "Cautionary Statement Regarding Forward-Looking Statements" at the beginning of this annual report.

Item 6. Directors, Senior Management and Employees

A. Directors and senior management.

The following table sets forth the name and position of each of the directors of Stealth BioTherapeutics Corp and of the executive officers of Stealth Delaware and their ages as of the date of this annual report. Stealth BioTherapeutics Corp does not have any executive officers other than Irene McCarthy, its Chief Executive Officer.

Name	Age	Position
Executive Officers		
Irene (Reenie) McCarthy	55	Chief Executive Officer, Director
Robert Weiskopf	69	Chief Financial Officer
Brian D. Blakey, Pharm.D.	58	Chief Business Officer
James R. Carr, Pharm.D.	57	Chief Clinical Development Officer
Non-Employee Directors		
Gerald L. Chan, Sc.D.	69	Director, Chairman of the Board
Lu Huang, M.D.(1)	46	Director
Francis W. Chen, Ph.D.(2)(3)	71	Director
Kevin F. McLaughlin(2)(3)	63	Director
Edward P. Owens(1)	73	Director
Louis Lange, M.D., Ph.D.(1)(2)	71	Director

(1) Member of Remuneration Committee
(2) Member of Audit Committee
(3) Member of Nominating Committee

Executive Officers

Irene (Reenie) McCarthy has served as a Director of Stealth BioTherapeutics Corp since June 2018 and as Chief Executive Officer of Stealth BioTherapeutics Corp since October 2018. She has served as Chief Executive Officer of Stealth Delaware since February 2016, as President and Secretary of Stealth Delaware since August 2015 and as a director of Stealth Delaware since July 2009. Prior to Stealth, Ms. McCarthy was a member of the investment team at Morningside Technology Advisory, LLC (and affiliates), a private advisory company, from January 2009 to April 2016, and she remains a director of Morningside Technology Advisory, LLC. She has served as a director for numerous private biotechnology companies developing drugs across a broad spectrum of therapeutic focus areas. She holds a J.D. from the University of Pennsylvania Law School and a B.A. in English and Political Science from Bates College. We believe that Ms. McCarthy is qualified to serve on our board of directors because of her extensive experience investing in life sciences companies, her service on several life science company boards and her decade of service to our company, as an investor, board member and officer.

Robert Weiskopf has served as Chief Financial Officer of Stealth Delaware since September 2019. Mr. Weiskopf previously served as Chief Financial Officer and Treasurer of ArQule, Inc., a biopharmaceutical company, from May 2015 to March 2019 and as Vice President of Finance, Corporate Controller, and Treasurer of ArQule, Inc. from February 2007 to May 2015. Mr. Weiskopf is a Certified Public Accountant and holds a B.S.B.A. magna cum laude and M.S.B.A. in accounting from the University of Massachusetts at Amherst.

Brian D. Blakey, Pharm.D., has served as Chief Business Officer of Stealth Delaware since February 2014. Previously, Dr. Blakey was the Chief Strategy and Operations Officer of Element Marketing Group, a medical marketing agency, from June 2010 to February 2014, and was the Vice President of Commercial Development at Salutria Pharmaceuticals, LLC (formerly AtheroGenics Inc.), a biotechnology company, from May 2006 to May 2010. He also worked in multiple roles at GlaxoSmithKline, plc, a pharmaceutical company, beginning in March 1998, ultimately serving in the position of director between July 2003 and February 2004. Dr. Blakey holds a Pharm.D. from the University of Florida.

James R. Carr, Pharm.D., has served as Chief Clinical Development Officer of Stealth Delaware since January 2017 and previously served as our Vice President, Clinical Development since March 2014. Previously, Dr. Carr was the Executive Director in the Cardiovascular Metabolic Franchise at GlaxoSmithKline plc, a pharmaceutical company, from October 2010 to March 2014 and the Vice President of Clinical Development at ARCA biopharma, Inc., a pharmaceutical company, from May 2008 to November 2010. Dr. Carr holds a Pharm.D. and a B.S. in pharmacy from the University of Minnesota.

Non-Employee Directors

Gerald L. Chan, Sc.D., was appointed as a Director of Stealth BioTherapeutics Corp and as Chairman of the Board in June 2018. He has served as a director of Stealth Delaware since October 2007. Dr. Chan co-founded the Morningside group in 1986. He has been a member of the board of directors of Hang Lung Group Limited since 1986. He served on the board of directors of Aduro Biotech Inc. (Nasdaq: ADRO) from 2014 until 2018, and currently serves as a member and the chairman of the board of Apellis Pharmaceuticals, Inc. (Nasdaq: APLS). Dr. Chan received a B.S. and M.S. in engineering from the University of California, Los Angeles, and a M.S. in medical radiological physics and an Sc.D. in radiation biology from Harvard University. He did his post-doctoral training at the Dana-Farber Cancer Institute as a fellow of the Leukemia Society of America. We believe that Dr. Chan is qualified to serve on our board of directors because of his extensive experience investing in and serving on the boards of directors of life sciences companies.

Lu Huang, M.D., was appointed as a Director of Stealth BioTherapeutics Corp in June 2018. Dr. Huang joined the Morningside group in October 2003 and leads the Morningside life science investment team in China. She has led over a dozen healthcare and life sciences investments in China and serves as a director in a number of portfolio companies including MicuRx Pharmaceuticals, Inc. Dr. Huang obtained her M.D. from Shanghai Jiao Tong University School of Medicine (formerly known as Shanghai Second Medical University) and subsequently worked at the University affiliated hospital. She holds an M.B.A. from St. John's University. We believe Dr. Huang is qualified to serve on our board of directors because of her extensive experience serving on the boards of directors of life sciences companies and her medical insights.

Francis W. Chen, Ph.D., was appointed as a Director of Stealth BioTherapeutics Corp in June 2018. He has served as a director of Stealth Delaware since April 2006. In November 2011, he founded, and currently serves as the chairman of, SinoAmerican Partners Limited, an advisory services firm that specializes in cross-border transactions involving natural resources, transportation-based assets and related financial services. Dr. Chen was also a venture partner at WI Harper Group, an early-stage venture capital firm with investment activities in Silicon Valley and China from June 2009 to December 2012. He previously served on the board of directors of SPI Energy Co., Ltd. from November 2009 to August 2013. Dr. Chen has more than 20 years of prior management experience in the healthcare industry and has served on the board of directors of several private companies. Dr. Chen holds a Ph.D. in immunology from Harvard University and an M.S. and a B.S. in chemistry from Tufts University. We believe Dr. Chen is qualified to serve on our board of directors because of his extensive experience investing in and serving on the boards of directors of life science companies.

Kevin F. McLaughlin was appointed as a Director of Stealth BioTherapeutics Corp in June 2018. He has served as a director of Stealth Delaware since March 2017. Mr. McLaughlin is currently Senior Vice President, Chief Financial Officer and Treasurer of Acceleron Pharma, Inc., a biotechnology company, and has been since November 2010. Mr. McLaughlin has also served on the board of directors of Vericel Corporation, a biopharmaceutical company, since January 2015. He previously served as Senior Vice President and Chief Financial Officer of Qteros, Inc., a cellulosic biofuels company, from 2009 through 2010 and as co-founder, Chief Operating Officer and director of Aptius Education, Inc., a publishing company, from 2007 through 2009. Mr. McLaughlin held several executive positions with PRAECIS Pharmaceuticals, Inc., a biopharmaceutical company, from 1996 through 2007, initially as Chief Financial Officer, before becoming Chief Operating Officer and eventually President and Chief Executive Officer, and he served as a member of the board of directors. Mr. McLaughlin began his career in senior financial roles at Prime Computer and Computervision Corporation. Mr. McLaughlin received a B.S. in business from Northeastern University and an M.B.A. from Babson College. We believe Mr. McLaughlin is qualified to serve on our board of directors because of his extensive experience managing and serving on the boards of directors of life science companies.

Edward P. Owens was appointed as a Director of Stealth BioTherapeutics Corp in June 2018. He has served as a director of Stealth Delaware since May 2017. Mr. Owens has been a Director of Ironwood Pharmaceuticals, Inc. (Nasdaq: IRWD) since March 2013. He is a retired Partner of Wellington Management Company LLP and the founding portfolio manager of Vanguard Health Care Fund, which he managed from 1984 until his retirement at the end of 2012. Mr. Owens holds a B.S. in Physics from the University of Virginia and an M.B.A. from Harvard Business School. We believe Mr. Owens is qualified to serve on our board of directors because of his experience in serving on the board of directors of life sciences companies, as well as his investment expertise.

Louis Lange, M.D., Ph.D., was appointed as a Director of Stealth BioTherapeutics Corp in July 2019. Dr. Lange is currently a general partner at Asset Management Ventures, an investment firm, where he has worked since June 2009. Dr. Lange was the co-founder and served as the President and Chief Executive Officer of Cardiogen Sciences, Inc., a biotechnology company, from April 2014 until it was acquired by Audentes Therapeutics, Inc. (Nasdaq: BOLD) in August 2015. Dr. Lange also co-founded CV Therapeutics, Inc. in 1990 and served as the Chairman, Chief Executive Officer and Chief Scientific Officer until it was acquired by Gilead Sciences, Inc. (Nasdaq: GILD) in 2009. Dr. Lange has also served as the Chief of Cardiology and Professor of Medicine at Jewish Hospital at Washington University. Dr. Lange has served as a member of Audentes Therapeutics, Inc.'s board of directors since August 2015 and served on the board of directors of Maxygen, Inc. from December 2005 to August 2013, CymaBay Therapeutics, Inc. (Nasdaq: CBAY) from November 2003 to October 2015, and Esperion Therapeutics, Inc. (Nasdaq: ESPR) from February 2010 to May 2014. Dr. Lange also serves as a member of the Board of Trustees at the University of Rochester, The Gladstone Foundation, is a senior advisor to Gilead and was on the board of directors of BIO (the trade organization of biotech companies) from 1998 to 2009, as well as other private companies. Dr. Lange holds a B.A. from the University of Rochester, an M.D. from Harvard Medical School and a Ph.D. from Harvard University. We believe Dr. Lange is qualified to serve on our board of directors because of his experience in serving in leadership positions at and on the board of directors of life sciences companies, as well as his investment expertise.

Family Relationships

There are no family relationships among any of our directors or executive officers.

B. Compensation.

For the year ended December 31, 2019, the aggregate compensation accrued or paid to our executive officers for services in all capacities was $2.4 million plus option awards exercisable for 8,848,750 ordinary shares at a weighted-average exercise price of $0.98 per share. Options for 8,148,750 shares expire on February 28, 2029 and options for 700,000 shares expire on September 25, 2029. The compensation that we pay to our Chief Executive Officer Reenie McCarthy, who is also a Director, is received solely in her capacity as Chief Executive Officer.

For the year ended December 31, 2019, the aggregate compensation accrued or paid to our non-employee directors for services in all capacities was $0.3 million plus option awards exercisable for 875,000 ordinary shares at a weighted-average average exercise price of $1.02 per share. Options for 725,000 shares expire on February 28, 2029 and options for 150,000 shares expire on July 23, 2029.

We have adopted a non-employee director compensation policy that provides to each non-employee director:

- $40,000 per year for his or her service as a non-employee director;
- $8,000 per year per committee for his or her service as the audit, remuneration and/or nomination committee chair;
- $5,000 per year per committee for his or her service as an audit, remuneration and/or nomination committee member (other than for the committee chair); and
- at the discretion of the board of directors, an annual grant of options or restricted share units in respect of ordinary shares.

The following table sets forth information concerning outstanding equity awards for each of our non-employee directors as of December 31, 2019:

	OPTION AWARDS			
NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Gerald L. Chan, Sc.D.	2,500,000	—	0.84	8/26/2024
	27,188	117,812	1.02	2/28/2029
Francis W. Chen, Ph.D.	50,000	—	0.45	12/13/2022
	27,188	117,812	1.02	2/28/2029
Vincent Cheung (1)	—	—	—	—
Lu Huang, M.D.	—	—	—	—
Stephen Law (1)	—	—	—	—
Kevin F. McLaughlin	34,375	15,625	1.38	03/15/2027
	27,188	117,812	1.02	2/28/2029
Edward P. Owens	32,292	17,708	1.38	5/23/2029
	27,188	117,812	1.02	2/28/2029
Louis Lange	—	150,000	1.01	7/23/2029

(1) Messrs. Cheung and Law resigned from our board in July 2019.

We also reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending our board of director and committee meetings.

Equity and Non-Equity Incentive Plans

The four equity incentive plans described in this section are our 2019 share incentive plan, as amended, or the Amended 2019 Plan, our 2020 ADS incentive plan, or the ADS Plan, our 2019 employee share purchase plan, or ESPP, and our 2006 share incentive plan, as amended to date, or the 2006 Plan.

Amended 2019 Plan

Our board of directors recently approved an amendment of our 2019 share incentive plan, which became effective on March 25, 2020 upon approval from our shareholders. The Amended 2019 Plan provides for the grant of incentive share options, non-statutory share options, share appreciation rights, awards of restricted shares, restricted share units or other share-based awards. The number of our ordinary shares that is reserved for issuance under the Amended 2019 Plan is the sum of 22,692,938 shares plus (1) the number of our ordinary shares subject to outstanding awards under our 2006 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right and (2) an annual increase, or the Evergreen Provision, to be added the first day of each fiscal year, beginning with the fiscal year ending December 31, 2020 and continuing until, and including, the fiscal year ending December 31, 2029, equal to the lowest of 31,780,518 of our ordinary shares, 4.0% of the number of ordinary shares outstanding on the first day of the fiscal year and an amount determined by our board of directors.

On January 1, 2020, prior to the amendment of our 2019 share incentive plan, 17,468,832 ordinary shares were added to the plan pursuant to the Evergreen Provision. In connection with the amendment of the plan, the number of shares reserved under the plan was reduced by 24,999,996 shares, as those shares are now reserved under the ADS Plan.

As of March 31, 2020, the total reserve under the Amended 2019 Plan is 41,700,028 shares of which 10,260,342 shares will be available for grant. Our employees, officers, directors, consultants and advisors and of any business ventures in which we have a controlling interest are eligible to receive awards under the Amended 2019 Plan; however, incentive share options may only be granted to our employees. In any calendar year, the value of awards under the Amended 2019 Plan and the ADS Plan made to any non-employee director for service as a director shall not exceed $1,000,000, unless otherwise approved by our board of directors at their discretion in extraordinary circumstances.

Pursuant to the terms of the Amended 2019 Plan, our board of directors (or a committee delegated by our board of directors) administers the Amended 2019 Plan and, subject to any limitations set forth in the Amended 2019 Plan, selects the recipients of awards and determines:

- the number of ordinary shares covered by options and the dates upon which those options become exercisable;
- the type of options to be granted;
- the exercise price of options, which price must be at least equal to the fair market value of our ordinary shares on the date of grant;
- the duration of options, which may not be in excess of 10 years;
- the methods of payment of the exercise price of options; and
- the number of our ordinary shares subject to and the terms of any share appreciation rights, awards of restricted shares, restricted share units or other share-based awards and the terms and conditions of such awards, including the issue price, conditions for repurchase, repurchase price and performance conditions (though the measurement price of share appreciation rights must be at least equal to the fair market value of our ordinary shares on the date of grant and the duration of such awards may not be in excess of ten years), if any.

In the event of any share split, reverse share split, share consolidation, share dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our ordinary shares other than an ordinary cash dividend, we are required by the Amended 2019 Plan to make equitable adjustments (or make substitute awards, if applicable), in a manner determined by our board, to:

- the number and class of securities available under the Amended 2019 Plan;
- the share counting rules under the Amended 2019 Plan;
- the number and class of shares and exercise price per share of each outstanding option;
- the share and per-share provisions and measurement price of each outstanding share appreciation right;
- the number of shares and the repurchase price per share subject to each outstanding restricted share award; and
- the share and per-share related provisions and purchase price, if any, of any outstanding restricted share unit award and other share-based award.

Upon a merger or other reorganization event (as defined in the Amended 2019 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the Amended 2019 Plan, as to some or all outstanding awards, other than restricted share awards:

- provide that all outstanding awards will be assumed or substantially equivalent awards will be substituted by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that the participant's unvested and/or unexercised awards will terminate or be forfeited immediately prior to the consummation of such transaction unless exercised by the participant;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a reorganization event pursuant to which holders of our ordinary shares will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (i) the number of shares of our ordinary shares subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (ii) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award;

- provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds (if applicable, net of exercise, measurement or purchase price thereof and any applicable tax withholdings); or
- any combination of the foregoing. Our board of directors is not obligated by the Amended 2019 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically. In the case of certain outstanding restricted share units, no assumption or substitution is permitted, and the restricted share units will instead be settled in accordance with the terms of the applicable restricted share unit agreement.

Upon the occurrence of a reorganization event other than a liquidation, winding up or dissolution, the repurchase and other rights under each outstanding restricted share award will continue for the benefit of the successor company and will, unless our board of directors may otherwise determine, apply to the cash, shares, securities or other property which our ordinary shares are converted into or exchanged for pursuant to the reorganization event, unless our board of directors provided for the termination or deemed satisfaction of such repurchase or other rights under the restricted share award agreement or any other agreement between the participant and us.

Upon the occurrence of a reorganization event involving a liquidation, winding up or dissolution, all restrictions and conditions on each outstanding restricted share award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted share award or in any other agreement between the participant and us. Our board of directors may at any time provide that any award under the Amended 2019 Plan shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

Except with respect to certain actions requiring shareholder approval under the Nasdaq Listing Rules, the Amended 2019 Plan, and our Articles of Association, our board of directors may amend, modify or terminate any outstanding award under the Amended 2019 Plan, including but not limited to, substituting therefor another award of the same or a different type, changing the date of exercise or realization, and converting an incentive share option into a nonstatutory share option, subject to certain participant consent requirements. Unless our shareholders approve such action, the Amended 2019 Plan provides that we may not (except as otherwise permitted in connection with a change in capitalization or reorganization event):

- amend any outstanding share option or share appreciation right granted under the Amended 2019 Plan to provide an exercise or measurement price per share that is lower than the then-current exercise or measurement price per share of such outstanding award;
- cancel any outstanding option or share appreciation right (whether or not granted under the Amended 2019 Plan) and grant in substitution therefor new awards under the Amended 2019 Plan (other than substitute awards permitted in connection with a merger or consolidation of an entity with us or our acquisition of property or share of another entity) covering the same or a different number of our ordinary shares and having an exercise or measurement price per share lower than the then-current exercise or measurement price per share of the cancelled award;
- cancel in exchange for a cash payment any outstanding option or share appreciation right with an exercise or measurement price per share above the then-current fair market value of our ordinary shares; or
- take any other action that constitutes a “repricing” within the meaning of the Nasdaq Listing Rules.

No award may be granted under the Amended 2019 Plan after February 14, 2029, but awards previously granted may extend beyond that date. Our board of directors may amend, suspend or terminate the Amended 2019 Plan at any time, except that shareholder approval will be required to comply with applicable law or the Nasdaq Listing Rules.

ADS Plan

In February 18, 2020, our board of directors adopted the ADS Plan, which became effective on March 25, 2020 upon approval from our shareholders.

Types of Awards

The ADS Plan provides for the grant of restricted ADSs, restricted ADS units and other ADS-based awards as described below.

Restricted ADS Awards. Restricted ADS Awards entitle recipients to acquire ADSs, subject to the right of the Company to repurchase all or part of such ADSs at their issue price or other stated or formula price (or to require forfeiture of such ADSs if issued at no cost) from the recipient in the event that the conditions specified in the applicable award are not satisfied prior to the end of the applicable restriction period established for such award. Dividends paid by the Company with respect to restricted ADSs will only be paid to the recipient if and when the ADSs become free from the restrictions on transferability and forfeitability provisions that apply to such ADSs.

Restricted ADS Unit Awards. Restricted ADS Unit Awards entitle the recipient to receive ADSs, an amount of cash equal to the fair market value of the number of ADSs set forth in the applicable award agreement, or the grant of an award under the Amended 2019 Plan to be delivered at the time such award vests or is settled pursuant to the terms and conditions established by the board of directors. Restricted ADS Unit awards may provide the recipient with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of ADSs, which amount may be settled in cash and/or ADSs and may be subject to the same restrictions on transfer and forfeitability as the Restricted ADS Units with respect to which they are paid, to the extent provided in the applicable award agreement.

Other ADS-Based Awards. Under the ADS Plan, the board of directors may grant other awards of ADSs and other awards that are valued in whole or in part by reference to, or are otherwise based on, ADSs or other property. These are referred to as Other ADS-Based Awards. Other ADS-Based Awards will be available as a form of payment in the settlement of other awards granted under the ADS Plan or as payment in lieu of compensation to which a participant is otherwise entitled. Other ADS-Based Awards may be paid in ADSs, cash or awards under the Amended 2019 Plan, as the board of directors shall determine.

Number of Shares Reserved

The number of our ordinary shares that is reserved for issuance under the ADS Plan is the sum of (1) 2,083,333 ADSs plus (2) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2030, equal to the least of (i) that number of ADSs representing 4% of the outstanding ordinary shares on such date and (ii) an amount determined by the board of directors.

If any award expires or is terminated, surrendered, canceled or forfeited in whole or in part (including as a result of ADSs subject to such award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or otherwise results in any ADSs not being issued, the unused ADSs covered by such award will again be available for grant under the ADS Plan. ADSs delivered (by actual delivery, attestation or net exercise) to the Company by a participant to satisfy tax withholding obligations with respect to awards (including ADSs retained from the award creating the tax obligation) will be added back to the number of ADSs available for the future grant of awards.

Transferability of Awards

Except as the board of directors may otherwise determine or provide in an award, awards may not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or pursuant to a qualified domestic relations order. During the life of the participant, awards are exercisable only by the participant.

Eligibility to Receive Awards

Our employees, officers, directors, consultants and advisors and of any business ventures in which we have a controlling interest are eligible to be granted awards under the ADS Plan.

Limit on Awards to Non-Employee Directors

In any calendar year, the value of awards under the Amended 2019 Plan and the ADS Plan made to any non-employee director for service as a director (calculated based on the grant date fair value of such awards for financial reporting purposes) shall not exceed $1,000,000. The board of directors may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

Administration

The ADS Plan is administered by the board of directors. The board of directors has the authority to adopt, amend and repeal the administrative rules, guidelines and practices relating to the ADS Plan and to interpret the provisions of the ADS Plan. Pursuant to the terms of the ADS Plan, the board of directors may delegate authority under the ADS Plan to one or more committees or subcommittees of the board of directors. The board of directors has authorized our Remuneration Committee to administer certain aspects of the ADS Plan, including the granting of awards to executive officers, and has authorized the Stock Option Committee of the board of directors, consisting of Ms. McCarthy to grant awards, subject to limitations set by the Board or the Remuneration Committee, to eligible participants other than members of the board of directors and executive officers. For purposes of this summary, where appropriate in the relevant context, the term "board of directors" may include the Remuneration Committee or any other committee to whom the board of directors delegates authority, as indicated in the ADS Plan.

Subject to any applicable limitations contained in the ADS Plan, the board of directors selects the recipients of awards and determines (i) the number of ADS subject to any Restricted ADS Award, Restricted ADS Unit Award or Other ADS-Based Awards and (ii) the terms and conditions of such awards, including conditions for vesting, repurchase, issue price and repurchase price, if any.

The board of directors will determine the effect on an award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a participant and the extent to which, and the period during which, the participant (or the participant's representative) may exercise rights under the award.

The board of directors may at any time provide that any award will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

Changes in Capitalization and Reorganization

We are required to make equitable adjustments (or make substitute awards, if applicable) in connection with the ADS Plan and any outstanding awards, as determined by the board of directors, to reflect share splits, share dividends, recapitalizations, spin-offs and other similar changes in capitalization or any dividends or distributions to holders of ADSs other than an ordinary cash dividend. The ADS Plan also contains provisions addressing the consequences of any reorganization event, which is defined as (a) any merger or consolidation of the Company with or into another entity as a result of which all of the ordinary shares of the Company are converted into or exchanged for the right to receive cash, securities or other property, or are cancelled, or (b) any transfer, disposition, exchange or conversion of all of the ordinary shares of the Company for cash, securities or other property pursuant to a share exchange transaction or other transaction, or (c) any liquidation or dissolution of the Company. In connection with a reorganization event, the board of directors may take any one or more of the following actions as to all or any (or any portion of) outstanding awards other than restricted ADS awards on such terms as the board of directors (except to the extent specifically provided otherwise in an applicable award agreement or another agreement between the Company and the participant):

- provide that awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice, provide that all unvested awards will be forfeited immediately prior to the consummation of such reorganization event and/or unexercised awards will terminate immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice;

- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of our ADSs will receive a cash payment for each ADS surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by a participant equal to (i) the number of shares of our ADSs subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (ii) the excess, if any, of the cash payment for each ADS surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award;
- provide that, in connection with a liquidation or dissolution of the Company, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings); and
- any combination of the foregoing.

The board of directors is not obligated by the ADS Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically. In the case of certain outstanding Restricted ADS Units, no assumption or substitution is permitted, and the Restricted ADS Units will instead be settled in accordance with the terms of the applicable Restricted ADS Unit award agreement.

In connection with a reorganization event other than a liquidation, winding up or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted ADSs will inure to the benefit of the Company's successor and will, unless the board of directors determines otherwise, apply to the cash, shares, securities or other property which the ADSs were converted into or exchanged for pursuant to the reorganization event in the same manner and to the same extent as they applied to the Restricted ADSs. The board of directors has the discretion to provide for termination or deemed satisfaction of the repurchase or other rights in the award agreement or any other agreement between the participant and the Company, either initially or by amendment. In connection with a reorganization event involving the liquidation, winding up or dissolution of the Company, except to the extent specifically provided to the contrary in the award agreement or any other agreement between a participant and the Company, all restrictions and conditions on all Restricted ADSs then outstanding will automatically be deemed terminated or satisfied.

Authorization of Sub-Plans

The board of directors may from time to time establish one or more sub-plans under the ADS Plan to satisfy applicable securities, tax or other laws of various jurisdictions. The board of directors will establish any such sub-plans by adopting supplements to the ADS Plan containing any limitations on the board of director's discretion under the ADS Plan and any additional terms and conditions not inconsistent with the ADS Plan as the board of directors deems necessary or desirable. Any supplement adopted by the board of directors will be deemed to be part of the ADS Plan but will only apply to participants within the affected jurisdiction.

Amendment or Termination

No award may be made under the ADS Plan after the expiration of 10 years from the date on which the ADS Plan was adopted by the board, but awards previously granted may extend beyond that date. The board of directors may at any time amend, suspend or terminate the ADS Plan; provided that no amendment requiring shareholder approval under any applicable legal, regulatory or listing requirement will become effective until such shareholder approval is obtained. No award will be made that is conditioned upon shareholder approval of any amendment to the ADS Plan unless the award provides that (i) it will terminate or be forfeited if shareholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (ii) it may not be exercised or settled (or otherwise result in the issuance of ADSs) prior to such shareholder approval.

Except with respect to actions requiring shareholder approval, the board of directors may amend, modify or terminate any outstanding award. A participant's consent to such amendment will be required unless the board of directors determines that the amendment, taking into account any related action, does not materially and adversely affect the participant's rights under the ADS Plan or that the change is permitted under the ADS Plan in connection with a change in capitalization or reorganization event.

2019 Employee Share Purchase Plan

In January 2019, our board of directors adopted, and our shareholders approved, the ESPP, which became effective on February 14, 2019. The ESPP is administered by our board of directors or by a committee appointed by our board of directors. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 3,972,565 ordinary shares. The number of ordinary shares reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2020 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lowest of (i) 7,945,130 ordinary shares, (ii) 1.0% of the number of ordinary shares outstanding on the first day of the fiscal year and (iii) an amount determined by our board of directors. On January 1, 2020, 4,367,208 ordinary shares were added to the ESPP pursuant to this provision.

All of our employees or employees of any designated subsidiary, as defined in the ESPP, are eligible to participate in the ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or by a designated subsidiary for at least three months prior to enrolling in the ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the ESPP.

No employee may be granted an option which permits them to purchase ordinary shares under the ESPP and any of our other employee share purchase plans to accrue at a rate which exceeds $25,000 of the fair market value of our ordinary shares in any calendar year in which the option is outstanding. In addition, no employee may purchase ordinary shares under the ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our shares.

We expect to make one or more offerings to our eligible employees to purchase shares under the ESPP beginning at such time as our board of directors or committee may determine. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our ordinary shares at the end of the offering period. Our board of directors may, at its discretion, choose a different period of not more than 12 months for an offering.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole ordinary shares that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the ESPP, the purchase price shall be determined by our board of directors for each offering period and will be at least 85% of the applicable closing price of our ordinary shares. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our ordinary shares on the first business day of the offering period or on the last business day of the offering period.

An employee may for any reason withdraw from participation in an offering prior to close of business on the fifteenth business day prior to the end of an offering period and permanently draw out the balance accumulated in the employee's account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of ordinary shares at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be made and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the number and class of securities available under the ESPP, the share limitations under the ESPP, and the purchase price for an offering period under the ESPP to reflect share splits, reverse share splits, share consolidation, share dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our ordinary shares other than ordinary cash dividends.

In connection with a merger or other reorganization event, as defined in the ESPP, our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase ordinary shares under the ESPP on such terms as our board or committee determines:

- provide that options shall be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or committee in such notice, which date shall not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our ordinary shares will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (i) the cash payment for each share surrendered in the reorganization event times the number of ordinary shares that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the acquisition price is treated as the fair market value of our ordinary shares on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the ESPP minus (ii) the result of multiplying such number of shares by the purchase price; and/or
- provide that, in connection with our liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the ESPP or any portion thereof. We will obtain shareholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the ESPP to fail to comply with Section 423 of the Code. The ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

2006 Share Incentive Plan

Our board of directors adopted and our shareholders approved previously approved the 2006 Plan. The 2006 Plan provides for the grant of options, restricted shares and other awards that are valued in whole or in part by reference to, or are otherwise based on, ordinary shares or other property. Our employees, officers, directors, consultants and advisers were eligible to receive awards under our 2006 Plan. Our board of directors administers the 2006 Plan.

The 2006 Plan expired in 2019 and no additional awards can be made under it. As of March 31, 2020, a total of 14,198,313 options remain outstanding under the 2006 Plan.

In the event of any share split, reverse share split, share dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of ordinary shares other than an ordinary cash dividend, we shall appropriately adjust, to the extent determined by the board of directors:

- the number and class of securities available under the 2006 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the repurchase price per share subject to each outstanding restricted share award; and
- the terms of each other outstanding award under the 2006 Plan.

In the event of any merger or consolidation of our company with or into another entity as a result of which all of our ordinary shares are converted into or exchanged for the right to receive cash, securities or other property or are cancelled; an exchange of all of our ordinary shares for cash, securities or other property pursuant to a share exchange transaction; or a liquidation or dissolution of our company, our board of directors shall, on such terms as our board of directors determines, take any one or more of the following actions pursuant to the 2006 Plan, as to some or all outstanding awards, except as to restricted share awards:

- provide that awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to a plan participant, provide that the participant's unexercised options or other awards shall be exercisable in full and will terminate immediately prior to the consummation of such event unless exercised by the participant within a specified period following the date of such notice;
- provide that outstanding awards shall become realizable, or deliverable, or restrictions applicable to an award shall lapse, in whole or in part prior to or upon such event;
- if under the terms of such event, holders of ordinary shares will receive upon consummation thereof a cash payment for each share surrendered in the event, make or provide for a cash payment to a plan participant in exchange for the termination of such awards;
- provide that, in connection with a liquidation of dissolution of the company, awards shall convert into the right to receive liquidation proceeds; or
- any combination of the foregoing.

401(k) Retirement Plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Code. In general, all of our employees are eligible to participate. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of the reduction contributed to the 401(k) plan. We contribute up to 3% of an employee's salary, subject to statutory limits. During the year ended December 31, 2019, we contributed $382,908.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they contract with a broker to buy or sell ordinary shares on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Insurance and Indemnification

Every director and officer is indemnified and secured harmless out of our assets and funds against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such director or officer (other than by reason of such director's or officer's own dishonesty, willful default or

fraud as determined by a court of competent jurisdiction) in or about the conduct of our affairs or in the execution of such director or officer's duties, powers, authorities or discretions, including any costs, expenses, losses or liabilities incurred by such director or officer in defending (whether successfully or otherwise) any civil proceedings concerning us or our affairs in any court whether Cayman Islands or elsewhere.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board, executive officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. Board practices.

Board Composition

Our board of directors consists of Reenie McCarthy, Gerald L. Chan, Dr. Lu Huang, Francis W. Chen, Kevin F. McLaughlin, Dr. Louis Lange and Edward P. Owens. Our directors will hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. For more information on the length of time each director has served, see "Item 6.A.—Directors and Senior Management."

Our Articles of Association provide that the minimum and maximum number of directors to be appointed shall be set by our board of directors. Our Articles of Association also provide that our directors may be removed by the affirmative vote of the holders of a majority of our ordinary shares present in person or by proxy and entitled to vote, and that our board of directors has the power to appoint a director, either as a result of a casual vacancy or as an additional director.

In accordance with the terms of our Articles of Association, our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

- the class I directors are Gerald L. Chan and Edward P. Owens, and their term will expire at the annual meeting of shareholders to be held in 2023;
- the class II directors are Dr. Louis Lange, Dr. Lu Huang and Francis W. Chen, and their term will expire at the annual meeting of shareholders to be held in 2021; and
- the class III directors are Kevin F. McLaughlin and Reenie McCarthy, and their term will expire at the annual meeting of shareholders to be held in 2022.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of shareholders in the year in which their term expires.

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, of our seven directors, five do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

Board Committees

Our board of directors has established audit, remuneration and nominating committees.

Audit Committee

During the year ended December 31, 2019, the members of our audit committee were Stephen Law (who resigned from our board in July 2019), Dr. Louis Lange, Francis W. Chen and Kevin F. McLaughlin, and Kevin F. McLaughlin serves as the chair of our audit committee. Our board of directors has determined that he is an "audit committee financial expert" as defined by applicable SEC rules. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. Our audit committee's responsibilities include:

- appointing, approving the compensation of and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function, if any;
- discussing our risk management policies;
- establishing procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our internal auditing staff, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

All audit services to be provided to us and all non-audit services to be provided to us by our registered public accounting firm must be approved in advance by our audit committee.

We believe that the composition of our committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Remuneration Committee

During the year ended December 31, 2019, the members of our remuneration committee were Edward P. Owens, Dr. Louis Lange, Stephen Law (who resigned from our board in July 2019) and Dr. Lu Huang, and Edward P. Owens serves as the chair of our remuneration committee. Our remuneration committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. Our remuneration committee's responsibilities include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our Chief Executive Officer;
- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our other executive officers;
- overseeing the evaluation of our senior executives;
- reviewing and making recommendations to our board of directors with respect to our incentive compensation and equity-based compensation plans;
- overseeing and administering our equity-based plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing with management our "Compensation Discussion and Analysis" disclosure to the extent such disclosure is required by SEC rules; and
- preparing the remuneration committee report required by SEC rules.

Nominating Committee

During the year ended December 31, 2019, the members of our nominating committee were Francis W. Chen, Kevin F. McLaughlin and Vincent Chueng (who resigned from our board in July 2019), and Francis W. Chen serves as the chair of our nominating committee. Our nominating committee's responsibilities include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board of directors' committees;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing periodic evaluations of our board of directors.

Agreements with our Executive Officers

We have entered into offer letters with each of our executive officers that set forth the terms of the executive officer's compensation, including his or her initial base salary and an annual cash bonus target percentage. The offer letters provide that the executive officers are eligible to participate in company-sponsored benefit programs that are available generally to all of our employees.

In addition, our offer letters with Dr. Blakey and Dr. Carr provide for the payment of six months' base salary in the event that we terminate their employment without cause, subject to the execution of a release of claims. Under the letters, cause is defined as one or more of (i) willful malfeasant, dishonest or grossly negligent conduct that relates to us and causes us harm or damage; (ii) a continued breach of conduct required by the invention and non-disclosure agreement, including a material breach of any non-competition, non-solicitation or confidentiality covenant or under any applicable legal principle; (iii) a material breach of duty of loyalty to us; (iv) a commission of an act of fraud, theft, misappropriation or embezzlement; (v) the commission of an act of fraud, theft, misappropriation or embezzlement; or (vi) a conviction of, or pleading nolo contendere to, a felony or any other crime involving moral turpitude. Severance payments to either of Dr. Blakey or Dr. Carr could be delayed for six months in certain circumstances for compliance with Section 409A of the Internal Revenue Code of 1986, as amended, or the Code.

Code of Business Conduct and Ethics

In December 2018, our board of directors adopted a written code of business conduct and ethics, effective as of February 14, 2019, that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on the Corporate Governance section of our website, which is located at www.stealthbt.com/investors. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a report on Form 6-K.

D. Employees.

As of December 31, 2019, we had 73 full-time employees, 45 of whom were primarily engaged in research and development activities and 25 of whom had a Ph.D. or Pharm.D. degree. All of our full-time employees are based in the United States.

In January 2020, we announced a 60% reduction in workforce as part of a strategic organizational restructuring plan, to principally align our operations around our Barth syndrome program, our Phase 2b clinical trial in GA, our Phase 1 trial of SBT-272 and our discovery programs. Consequently, as of March 31, 2020, we had 31 full time employees.

Our employees are not represented by any collective bargaining agreements.

E. Share ownership.

For information regarding the share ownership of our directors and executive officers, see "Item 6.B. — Compensation" and "Item 7.A. —Major Shareholders."

Item 7. Major Shareholders and Related Party Transactions

A. Major shareholders.

The following table sets forth information with respect to the beneficial ownership of the ordinary shares, as of February 29, 2020, except as otherwise noted, by:

- each of our directors;
- each of our executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of the ordinary shares.

The percentage ownership calculations are based on a total of 436,720,810 ordinary shares outstanding as of February 29, 2020.

The number of shares beneficially owned by each shareholder is determined under rules issued by the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, ordinary shares subject to options or other rights held by such person that are currently exercisable or will become exercisable within 60 days of February 29, 2020 are considered outstanding, although such shares subject to options or other rights are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless otherwise indicated, the address of all listed shareholders is c/o Stealth BioTherapeutics Inc., 275 Grove Street, Suite 3-107, Newton, Massachusetts 02466. Each of the shareholders listed has sole voting and investment power with respect to the shares beneficially owned by the shareholder unless noted otherwise, subject to community property laws where applicable.

NAME OF BENEFICIAL OWNER	SHARES BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED
5% Shareholders		
Morningside Venture (I) Investments Limited(1)	325,301,551	74.4%
Executive Officers and Directors		
Reenie McCarthy (2)	5,264,646	1.2%
Robert Weiskopf (3)	128,223	*%
Brian D. Blakey, Pharm.D. (4)	1,421,974	*%
James R. Carr, Pharm.D. (5)	1,017,809	*%
Gerald L. Chan, Sc.D. (6)	2,539,271	*%
Francis W. Chen, Ph.D. (7)	89,271	*%
Lu Huang, M.D.	—	*%
Louis Lange, M.D., Ph.D.	—	*%
Kevin F. McLaughlin (8)	77,812	*%
Edward P. Owens (9)	75,729	*%
All executive officers and directors as a group (10 persons) (10)	10,614,735	2.4%

* Less than 1%.

(1) Based on information set forth in Schedule 13 D/A filed with the SEC on May 24, 2019. Includes: (1), 266,701,555 ordinary shares beneficially owned by Morningside Venture (I) Investments Limited (MVIL) et al., consisting of (i) 266,101,555 ordinary shares, and (ii) 600,000 ordinary

shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020; (2) 3,255,523 ADSs, representing 39,066,276 ordinary shares, beneficially owned by Season Pioneer Investments Limited, or SPIL; and (3) 1,627,810 ADSs, representing 19,533,720 ordinary shares, beneficially owned by Equal Talent Investments Limited, or ETIL. Frances Anne Elizabeth Richard, Jill Marie Franklin, Peter Stuart Allenby Edwards and Raymond Long Sing Tang, the directors of MVIL, share voting and dispositive control over the shares held by MVIL. As a result, Ms. Richard, Ms. Franklin, Mr. Edwards and Mr. Tang may be deemed to possess voting and investment control over, and may be deemed to have indirect beneficial ownership with respect to, all shares held by MVIL. MVIL is ultimately beneficially owned by a family trust established by Madam Chan Tan Ching Fen. Each of Ms. Richard, Ms. Franklin, Mr. Edwards and Mr. Tang disclaims beneficial ownership of such shares, except to the extent of their respective pecuniary interests therein. Tracy Gia Yunn Tsoi is the sole director of SPIL and ETIL and has sole voting and dispositive power with respect to securities held by SPIL and ETIL. SPIL is ultimately wholly beneficially owned by a trust over which Mr. Edwards has sole authority to remove the trustee. ETIL is ultimately wholly beneficially owned by a trust over which Mr. Edwards has sole authority to remove the trustee. Ms. Tsoi disclaims beneficial ownership of the securities owned directly by SPIL and ETIL, except to the extent of her pecuniary interest therein. MVIL, SPIL and ETIL may act together with respect to the voting and disposition of the securities held by such entities. The principal business address for MVIL, SPIL and ETIL is 2nd Floor, Le Prince de Galles, 3-5 Avenue des Citronniers, MC 98000, Monaco.

(2) Consists of 5,047,569 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(3) Consists of 102,083 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(4) Consists of 1,386,722 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(5) Consists of 983,241 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(6) Consists of 2,539,271 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(7) Consists of 89,271 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(8) Consists of 77,812 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(9) Consists of 75,729 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

(10) Consists of 10,301,698 ordinary shares issuable upon the exercise of options exercisable within 60 days after February 29, 2020.

See “Item 3.D.—Risk Factors—Risks Related to Ownership of ADSs” for a discussion of MVIL’s controlling interest in the company.

Holdings by U.S. Shareholders

Citibank N.A., or Citibank, is the holder of record for the company’s American Depositary Receipt program, pursuant to which each ADS represents 12 ordinary shares. As of December 31, 2019, Citibank held 129,210,984 million ordinary shares representing 29.6% of the issued share capital held at that date. As of December 31, 2019, we had 14 holders of record with addresses in the United States, and such holders held 3.7% of our outstanding ordinary shares. As a result, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

B. Related party transactions.

Since January 1, 2019, we have engaged in the following transactions with our directors, executive officers or holders of more than 5% of our outstanding share capital and their affiliates, which we refer to as our related parties.

Note Issuances

As of December 31, 2019, Morningside Venture (I) Investments Limited, or MVIL, beneficially owned 61.0% of our outstanding ordinary shares.

In January 2019, we issued a convertible promissory note to MVIL in a principal amount of $5.0 million, plus accrued interest, or the January Note. The January Note accrued interest at 7% per annum, which compounded annually and, upon such compounding, was added to the outstanding principal amount. The January Note was on substantially the same terms as prior notes issued to MVIL, except that a qualified financing was limited to a U.S. initial public offering and that there was no change of control conversion feature.

The outstanding principal amount and accrued interest plus a 25% premium of the January Note and other notes held by MVIL automatically converted into 108,821,182 ordinary shares upon the closing of our IPO on February 20, 2019.

IPO Participation

Two entities associated with MVIL participated in our IPO by purchasing an aggregate of 4,883,333 ADSs in the IPO at the price to the public.

Investor Agreements

In April 2006, we entered into a Subscription and Shareholders Agreement with MVIL and certain other shareholders pursuant to which we agreed to issue ordinary shares and Series A convertible preferred shares and granted certain information rights and observer rights that remain in effect. The Subscription and Shareholders Agreement terminated upon the completion of our initial public offering in 2019. In connection with the Subscription and Shareholders Agreement, we entered into a Registration Rights Agreement with certain of our shareholders, including MVIL, in April 2006 that provided for customary registration rights to holders of our ordinary shares. The Registration Rights Agreement was terminated immediately prior to the closing of our initial public offering in 2019.

Employment Agreements

See “Item 6.C.—Board practices—Agreements with Our Executive Officers” for information about agreements between us and our executive officers.

Indemnification of Officers and Directors

As more fully described in our Articles of Association, our Articles of Association provide that our board of directors and officers shall be indemnified from and against all liability which they incur in execution of their duty in their respective offices out of our assets and funds, except liability incurred by reason of such director’s or officer’s dishonesty, willful deceit or fraud. See “Item 6.B.—Compensation” of this annual report for a further discussion of these arrangements. We have entered into indemnification agreements with each of our directors.

C. Interests of experts and counsel.

Not applicable.

Item 8. Financial Information

A. Consolidated statements and other financial information.

Our consolidated financial statements are appended at the end of this annual report, starting at page F-1, and incorporated herein by reference.

Legal Proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any material legal proceedings. We may become involved in material legal proceedings in the future.

Dividends

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future.

B. Significant changes.

Not applicable.

Item 9. The Offer and Listing

A. Offer and listing details.

Not applicable.

B. Plan of distribution.

Not applicable.

C. Markets.

Not applicable.

D. Selling shareholders.

Not applicable.

E. Dilution.

Not applicable.

F. Expenses of the issue.

Not applicable.

Item 10. Additional Information

A. Share capital.

Not applicable.

B. Memorandum and articles of association.

On March 25, 2020, at our Annual General Meeting, our shareholders approved the increase to our authorized share capital from US$225,000 divided into 750,000,000 Ordinary Shares of a nominal or par value of US$0.0003 each to US$360,000 divided into 1,200,000,000 Ordinary Shares of a nominal or par value of US$0.0003 each. Subject to the update set forth in the previous sentence, the information set forth in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), under the headings "Description of Share Capital and Articles of Association—General," "Description of Share Capital and Articles of Association—Issued Share Capital," "Description of Share Capital and Articles of Association—Articles of Association," "Description of Share Capital and Articles of Association—Differences in Corporate Law," and "Enforcement of Civil Liabilities" is incorporated herein by reference.

C. Material contracts.

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

D. Exchange controls.

There are no governmental laws, decrees, regulations or other legislation of the Cayman Islands which may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or which may affect the remittance of dividends, interest or other payments to nonresident holders of our ordinary shares or ADSs.

E. Taxation.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our ordinary shares or ADSs by U.S. Holders (as defined below). This discussion applies to U.S. Holders of our ADSs who hold such ADSs as a capital asset (generally, property held for investment). This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions and final, temporary, and proposed U.S. Treasury Regulations, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;

- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own ten percent or more of our shares; and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment or fixed base outside the United States.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the U.S. federal income tax consequences relating to an investment in such ordinary shares or ADSs will depend upon the status of the partner and the activities of the partnership.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U. S. persons have authority to control all substantial decisions of the trust or (ii) the trust has made a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

Holders of our ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of our ordinary shares or our ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for the underlying ordinary shares represented by such ADSs. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly, the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of the underlying ordinary shares.

Passive Foreign Investment Company Rules

We are a foreign corporation, within the meaning of the Code. If we are classified as a passive foreign investment company, or PFIC, in any taxable year, certain adverse U.S. federal income tax consequences could apply to a U.S. Holder as a result of that classification.

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income, or the PFIC income test; or
- on average at least 50% of the value of its assets, determined on a quarterly basis, is attributable to assets that produce passive income (or no income) or are held for the production of passive income, or the PFIC asset test.

Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents and gains from the sale or exchange of property that gives rise to passive income (or no income). Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. Generally, in determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Based on our estimated gross income and the average value of our gross assets, taking into account the price of our ADSs and the nature of our business, we do not believe that we were a PFIC for our tax year ended December 31, 2019, and do not currently expect to be a PFIC during our tax year ending December 31, 2020. However, there can be no assurance that we will not be classified as a PFIC for the current taxable year or any prior or future taxable year. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation.

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change from year to year. The total value of our assets for purposes of the PFIC asset test frequently (though not invariably) may be inferred using the market price of our ordinary shares or ADSs, which may fluctuate considerably and thereby affect the determination of our PFIC status for any given taxable year.

If we are a PFIC in any taxable year during which a U.S. Holder owns our ordinary shares or ADSs, the U.S. Holder could be liable for additional taxes and interest charges under the "PFIC excess distribution regime" upon (i) a distribution paid during a taxable year, if that distribution is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for our ordinary shares or ADSs, and (ii) any gain recognized on a sale, exchange or other disposition, including a pledge, of our ordinary shares or ADSs, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder's holding period for our ordinary shares or ADSs. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, in the amounts generally applicable to underpayments of tax over the relevant period, will be added to the tax.

If we are classified as a PFIC for any year during which a U.S. Holder holds our ordinary shares or ADSs, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds such ordinary shares or ADSs, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and the U.S. Holder makes a "deemed sale" election under the PFIC rules with respect to our ordinary shares or ADSs. If the "deemed sale" election is made, the U.S. Holder will be deemed to have sold our ordinary shares or ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's ordinary shares or ADSs would not be treated as shares of a PFIC unless we subsequently become a PFIC. If we are a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares or ADSs, and one of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Any of our non-U.S. subsidiaries that have elected to be disregarded as entities separate from us or as partnerships for U.S. federal income tax purposes would not be corporations under U.S. federal income tax law and accordingly, cannot be classified as lower-tier PFICs. However, non-U.S. subsidiaries that have not made such election may be classified as lower-tier PFICs if we are a PFIC during a U.S. Holder's holding period and the subsidiary meets the PFIC income test or PFIC asset test.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on our ordinary shares or ADSs if a valid "mark-to-market" election is made by the U.S. Holder for our ordinary shares or ADSs, provided that the ordinary shares or ADSs are "marketable." Our ordinary shares or ADSs will be considered marketable if they are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury Regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Our ADSs will be considered

marketable as long as they remain listed on The Nasdaq Global Market and are regularly traded. A mark-to-market election will not apply to our ordinary shares or ADSs for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any of our non-U.S. subsidiaries. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs notwithstanding the U.S. Holder's mark-to-market election for our ordinary shares or ADSs.

An electing U.S. Holder generally must take into account as ordinary income each year an amount equal to the excess, if any, of the fair market value of our ordinary shares or ADSs held at the end of such taxable year over the adjusted tax basis of such ordinary shares or ADSs. The U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis of such ordinary shares or ADSs over their fair market value at the end of the taxable year, but only to the extent of any net mark-to-market gains for prior years. The U.S. Holder's tax basis in our ordinary shares or ADSs would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of our ordinary shares or ADSs in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains for prior years) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC because we no longer meet the PFIC income or PFIC asset test, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the ordinary shares or ADSs would be classified as a capital gain or loss. Once made, the election cannot be revoked without the consent of the Internal Revenue Service, or the IRS, unless the ADSs cease to be marketable.

The tax consequences that would apply if we are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid qualified electing fund, or QEF, election. As we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election, U.S. holders should assume that a QEF election will not be available.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period.

Distributions

While we do not expect to pay any dividends in the near future, in the event any dividends are paid, subject to the discussion above under "Passive Foreign Investment Company Rules," a U.S. Holder that receives a distribution with respect to our ordinary shares or ADSs generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's ordinary shares or ADSs. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's ordinary shares or ADSs, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment may not apply if we are treated as a PFIC with respect to the U.S. Holder. Distributions on our ordinary shares or ADSs that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. Such dividends will not be eligible for the "dividends received'' deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations.

Dividends will be included in a U.S. Holder's income on the date of the Depositary's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss with respect to the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Sale, Exchange or Other Disposition of Our Ordinary Shares or ADSs

Subject to the discussion above under "Passive Foreign Investment Company Rules,'' a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of our ordinary shares or ADSs in an amount equal to the difference, if any, between the amount realized (i.e., the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ordinary shares or ADSs were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of our ordinary shares or ADSs will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of our ordinary shares or ADSs.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our ordinary shares or ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Passive Foreign Investment Company Rules," each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than $100,000 for our ordinary shares or ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to timely comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of our ADSs may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (i) fails to provide an accurate U.S. taxpayer identification number or otherwise establish a basis for exemption or (ii) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

Cayman Islands Taxation

Holders should consult their professional advisors on the possible tax consequences of buying, holding or selling any ADSs under the laws of their country of citizenship, residence or domicile.

The following is a discussion on certain Cayman Islands income tax consequences of an investment in the ADSs. The discussion is a general summary of present law, which is subject to prospective and retroactive change. It is not intended as tax advice, does not consider any investor's particular circumstances and does not consider tax consequences other than those arising under Cayman Islands law.

No stamp duty, capital duty, registration or other issue or documentary taxes are payable in the Cayman Islands on the creation, issuance or delivery of the ADSs. The Cayman Islands currently have no form of income, corporate or capital gains tax and no estate duty, inheritance tax or gift tax. There are currently no Cayman Islands taxes or duties of any nature on gains realized on a sale, exchange, conversion, transfer or redemption of the ADSs. Payments of dividends and capital in respect of the ADSs or ordinary shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of interest and principal or a dividend or capital to any holder of the ADSs, nor will gains derived from the disposal of the ADSs be subject to Cayman Islands income or corporation tax as the Cayman Islands currently have no form of income or corporation taxes.

Pursuant to section 6 of the Tax Concessions Law (2018 Revision) of the Cayman Islands, we have obtained an undertaking from the Governor-in-Cabinet:

- that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciation shall apply to us or our operations; and
- that no such tax or any tax in the nature of estate duty or inheritance tax shall be payable on or in respect of the ADSs or ordinary shares, debentures or other obligations of ours.

The undertaking for the Company is for a period of twenty years from April 11, 2006.

F. Dividends and paying agents.

Not applicable.

G. Statement by experts.

Not applicable.

H. Documents on display.

We previously filed with the SEC our registration statement on Form F-1 (Registration No. 333-229097), as amended, including the prospectus contained therein, to register our ADSs, each representing 12 ordinary shares, in relation to our IPO. We have also filed with the SEC a related registration statement on Form F-6 (Registration No. 333-229509), as amended, to register our ADSs.

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and file reports under those requirements with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We maintain a corporate website at www.stealthbt.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this annual report. We have included our website address in this annual report solely as an inactive textual reference.

The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. Subsidiary information.

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

We are minimally exposed to market risk related to changes in interest rates. As of December 31, 2019, we had cash and cash equivalents of $50.8 million, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are held in short-term money market funds. We do not believe we are materially at risk to sudden drops in interest rates based on the amounts subject to these potential changes.

Our Term Loan Facility has a floating per annum rate equal to the greater of (i) the Wall Street Journal prime rate plus 5.5% or (ii) 9.5%, which exposes us to market interest rate risk when we have outstanding borrowings. As of December 31, 2019, we had $16.5 million of outstanding borrowings under the Term Loan Facility. Assuming our outstanding debt remains constant for an entire year and the applicable annual interest rate increases or decreases by 1.0%, our annual interest expense would increase or decrease by $0.2 million.

Item 12. Description of Securities Other than Equity Securities

A. Debt securities.

Not applicable.

B. Warrants and rights

Not applicable.

C. Other securities

Not applicable.

D. American depositary shares.

Citibank, N.A., as depositary bank, registers and delivers our American Depositary Shares, also referred to as ADSs. Each ADS represents 12 ordinary shares (or a right to receive 12 ordinary shares) deposited with Citibank, N.A.—Hong Kong, located at 9/F, Citi Tower, One Bay East, 83 Hoi Bun Road, Kwun Tong, Kowloon, Hong Kong, or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate office at which our ADSs are administered is located at 388 Greenwich Street, New York, New York 10013. A deposit agreement among us, the depositary and the ADS holders sets out ADS holder rights as well as the rights and obligations of the depositary. A form of the deposit agreement is incorporated by reference as an exhibit to this annual report.

Fees and Charges Payable by ADS Holders

The table below summarizes the fees and charges that a holder of our ADSs may have to pay, directly or indirectly, to our depositary, Citibank, N.A., pursuant to the deposit agreement and the types of services and the amount of the fees or charges paid for such services. The actual fees payable by us and the holders of ADSs are negotiated between the depositary and us. In connection with these arrangements, we have agreed to pay various fees and expenses of the depositary. Currently, ADS holders are responsible for paying a fee upon the delivery of ordinary shares against the surrender of ADSs.

The fees and charges that an ADS holder may be required to pay can be changed in the future upon mutual agreement between the depositary and us and may include:

SERVICE	FEE
Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio), excluding ADS issuances as a result of distributions of ordinary shares	Up to $5.00 per 100 ADSs (or fraction thereof) issued
Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio)	Up to $5.00 per 100 ADSs (or fraction thereof) cancelled
Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to $5.00 per 100 ADSs (or fraction thereof) held
Distribution of ADSs pursuant to (i) share dividends or other free share distributions, or (ii) exercise of rights to purchase additional ADSs	Up to $5.00 per 100 ADSs (or fraction thereof) held
Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to $5.00 per 100 ADS (or fraction thereof) held
ADS Services	Up to $5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the depositary

In addition, ADS holders are responsible for certain fees and expenses incurred by the depositary and certain taxes and governmental charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary in the conversion of foreign currency;
- the fees and expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary, the custodian or any nominee in connection with the servicing or delivery of deposited property.

Depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary and by the brokers (on behalf of their clients) delivering our ADSs to the depositary for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed. In the case of distributions other than cash (e.g., stock dividend, rights), the depositary charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor, the depositary sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of our ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary.

In the event of refusal to pay taxes or other governmental charges by the holder of an ADS, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of such tax or other governmental charge from any distribution to be made to the ADS holder, and the ADS holder would remain liable for any deficiency.

The disclosure under this heading "Fees and Charges Payable by ADS Holders" is subject to and qualified in its entirety by reference to the full text of the deposit agreement.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Not applicable

The information set forth in our prospectus dated February 14, 2019, filed with the SEC pursuant to Rule 424(b), under the headings "Use of Proceeds" is incorporated herein by reference.

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer (our principal executive officer and principal financial officer). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

B. Management's annual report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed, under the supervision of our Chief Executive Officer (our principal executive officer and principal financial officer), to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with accounting principles generally accepted in the United States of America.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Moreover, projections of any evaluation of the effectiveness of internal control to future periods are subject to a risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2019, based on the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2019, was effective.

C. Attestation report of the registered public accounting firm.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

D. Changes in internal control over financial reporting.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Mr. Kevin McLaughlin, an independent director and member of the Audit Committee, qualifies as an "audit committee financial expert," as defined in Item 16A of Form 20-F.

Item 16B. Code of Ethics

In December 2018, our board of directors adopted a written code of business conduct and ethics, effective as of February 14, 2019, that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on the Corporate Governance section of our website, which is located at www.stealthbt.com/investors. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a report on Form 6-K.

Item 16C. Principal Accountant Fees and Services

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by Deloitte & Touche LLP, our independent registered public accounting firm, as well as Deloitte Tax LLP, Deloitte Touche Tohmatsu LLC and Deloitte Advisory Limited for the periods indicated.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Audit fees(1)	$ 455	$ 2,389
Audit-related fees	—	—
Tax fees(2)	15	—
All other fees	—	—
Total	$ 470	$ 2,389

(1) Audit fees totaled approximately $0.5 million for Deloitte & Touche LLP in 2019 and $0.5 million, $1.7 million and $0.2 million for Deloitte & Touche LLP, Deloitte Touche Tohmatsu LLC and Deloitte Advisory Limited, respectively, in 2018.

(2) Tax fees consist of fees for professional services with respect to tax advisory services.

The policy of our audit committee or our board of directors is to pre-approve all auditing services and permitted non-audit services to be performed for us by our independent auditor, Deloitte & Touche LLP, including the fees and terms thereof for audit services, audit-related services, tax services and other non-audit services as described in Section 10A(i)(l)(B) of the Exchange Act.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with the rules and regulations of Nasdaq, we will comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions afforded to foreign private issuers:

- exemption from the requirement to have independent director oversight of director nominations;
- exemption from the requirements that our board of directors have a compensation committee that is composed entirely of independent directors; and
- exemption from the requirement that our board of directors shall have regularly scheduled meetings at which only independent directors are present as set forth in Nasdaq Rule 5605(b)(2).

We intend to follow our home country practices in lieu of the foregoing requirements. Although we may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), we must comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we currently intend to comply with the applicable Nasdaq corporate governance rules other than as noted above, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules.

In addition, as a foreign private issuer, we expect to take advantage of the following exemptions from SEC reporting obligations:

- exemption from filing quarterly reports on Form 10-Q or current reports on Form 8-K, disclosing significant events within four days of their occurrence; and
- exemption from Section 16 rules regarding sales of common shares by insiders, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq and the domestic reporting requirements of the SEC. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

See pages beginning on F-1 of this annual report on Form 20-F.

Item 18. Financial Statements

The financial statements are filed as part of this annual report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Description
1.1*	Amended and Restated Memorandum and Articles of Association of the Company
2.1	Deposit Agreement among the Company, Citibank, N.A., as depositary, and all Owners and Holders of ADSs issued thereunder (incorporated by reference to Exhibit 99.3 of our Report on Form 6-K (File No. 001-38810), filed with the Securities and Exchange Commission on March 5, 2019)
2.2	Form of American Depository Receipt (included in Exhibit 2.1)
2.3*	Description of the Registrant's Securities pursuant to Section 12 of the Securities Exchange Act of 1934
4.1	Warrant Agreement, dated June 30, 2017, by and between the Company and Hercules Capital Inc., as amended and restated on June 7, 2018 (incorporated by reference to Exhibit 4.3 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28 2018)
4.2	2006 Share Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.3	Form of Incentive Option Agreement under 2006 Share Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.4	Form of Nonstatutory Option Agreement under 2006 Share Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.5*	2019 Share Incentive Plan, as amended
4.6	Form of Share Option Agreement under 2019 Share Incentive Plan (incorporated by reference to Exhibit 10.5 of our Registration Statement on Form F 1, as amended, filed with the Securities and Exchange Commission January 30, 2019)
4.7	Form of Restricted Share Agreement under 2019 Share Incentive Plan (incorporated by reference to Exhibit 10.6 of our Registration Statement on Form F-1, as amended, filed with the Securities and Exchange Commission January 30, 2019)
4.8	Form of Director and Officer Indemnification Agreement by and between the Registrant and each of its officers and directors (incorporated by reference to Exhibit 10.7 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)

Exhibit Number	Description
4.9†	Exclusive License Agreement, dated April 20, 2006, among the Company, Cornell Research Foundation, Inc. and Institut de recherches cliniques de Montréal, as amended by First Amendment to Exclusive License Agreement dated October 7, 2010 (incorporated by reference to Exhibit 10.8 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.10†	Exclusive License Agreement, dated November 22, 2010, between the Company and Cornell University (incorporated by reference to Exhibit 10.9 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.11†	Exclusive License Agreement, dated November 3, 2011, by and between the Company and Cornell University (incorporated by reference to Exhibit 10.10 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.12†	Exclusive License Agreement, dated December 27, 2012, by and between the Company and Cornell University (incorporated by reference to Exhibit 10.11 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.13†	Exclusive License Agreement, dated August 12, 2013, by and between the Company and Cornell University (incorporated by reference to Exhibit 10.12 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.14	Office Lease Agreement, dated October 31, 2014, by and between the Company and Hines Global REIT Riverside Center, LLC (incorporated by reference to Exhibit 10.13 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.15	Amendment Agreement by and between the Company and Danforth Advisors, LLC, dated as of June 13, 2018 (incorporated by reference to Exhibit 10.14 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.16	Loan and Security Agreement, dated June 30, 2017, by and between the Company and Hercules Capital Inc., as amended on March 12, 2018, July 26, 2018 and October 10, 2018 (incorporated by reference to Exhibit 10.15 of our Registration Statement on Form F-1 filed with the Securities and Exchange Commission December 28, 2018)
4.17	2019 Employee Share Purchase Plan (incorporated by reference to Exhibit 10.16 of our Registration Statement on Form F-1, as amended, filed with th Securities and Exchange Commission January 30, 2019)
4.18	First Amendment to Lease dated as of January 31, 2019 by and between the Company and Hines Global REIT Riverside Center LLC (incorporated by reference to Exhibit 10.17 of our Registration Statement on Form F-1, as amended, filed with the Securities and Exchange Commission February 14, 2019)
4.19	Fourth Amendment to Loan and Security Agreement dated as of March 29, 2019, by and between Hercules Capital Inc. and the Company (incorporate by reference to Exhibit 4.19 of our Annual Report on Form 20-F (File No.001-38810) filed on April 4, 2019)
4.20*	2020 ADS Incentive Plan
4.21*	Form of Restricted ADS Unit Award Agreement under 2020 ADS Incentive Plan
8.1*	Subsidiaries of the Registrant
12.1*	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 90 of the Sarbanes-Oxley Act of 2002

Exhibit Number	Description
15.1*	Consent of Deloitte & Touche, LLP, independent registered public accounting firm
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Confidential treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Stealth BioTherapeutics Corp

Date: April 1, 2020

By: /s/ Irene P. McCarthy
Name: Irene P. McCarthy
Title: Chief Executive Officer

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Index to Consolidated Financial Statements as of December 31, 2019 and 2018 and for the Years Ended December 31, 2019, 2018 and 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Stealth BioTherapeutics Corp

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Stealth BioTherapeutics Corp and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, convertible preferred shares and shareholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

April 1, 2020

We have served as the Company's auditor since 2014.

STEALTH BIOTHERAPEUTICS CORP
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 50,768	$ 10,855
Prepaid expenses and other current assets	1,630	2,438
Total current assets	52,398	13,293
Property and equipment, net	345	499
Deferred offering costs	—	1,325
Other non-current assets	—	406
Total assets	$ 52,743	$ 15,523
Liabilities, convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 9,520	$ 11,023
Accrued expenses and other current liabilities	8,495	13,826
Accrued interest payable	1,219	7,297
Current portion of long-term debt	14,716	8,465
Total current liabilities	33,950	40,611
Convertible notes payable	—	103,257
Long-term debt, less current portion	1,526	10,317
Derivative liability	—	36,567
Warrant liability	—	100
Total liabilities	35,476	190,852
Commitments and contingencies (Note 14)		
Series A convertible preferred shares, $0.0003 par value; no shares authorized, issued and outstanding at December 31, 2019; 106,666,667 shares authorized; 91,600,398 issued and outstanding at December 31, 2018; liquidation preference of $211,377 at December 31, 2018	—	211,377
Shareholders' equity (deficit):		
Ordinary shares, $0.0003 par value;750,000,000 shares authorized and 436,720,810 shares issued and outstanding at December 31, 2019; 203,333,333 shares authorized and 68,487,948 shares issued and outstanding at December 31, 2018;	131	21
Additional paid-in capital	515,133	39,542
Accumulated deficit	(497,997)	(426,269)
Total shareholders' equity (deficit)	17,267	(386,706)
Total liabilities, convertible preferred shares and shareholders'equity (deficit)	$ 52,743	$ 15,523

See the accompanying notes to these audited consolidated financial statements.

STEALTH BIOTHERAPEUTICS CORP
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenue	$ 21,087	$ —	$ —
Operating expenses:			
Research and development	$ 44,604	$ 53,062	$ 63,220
General and administrative	22,315	22,217	16,500
Total operating expenses	66,919	75,279	79,720
Loss from operations	(45,832)	(75,279)	(79,720)
Other income (expense):			
Interest income	988	195	57
Interest expense	(6,666)	(21,357)	(3,282)
Change in valuation of derivative liability	2,782	(684)	—
Change in valuation of warrant liability	(300)	413	35
Loss on extinguishment of debt	(22,700)	—	
Total other income (expense), net	(25,896)	(21,433)	(3,190)
Net loss attributable to ordinary shareholders	$ (71,728)	$ (96,712)	$ (82,910)
Net loss per share attributable to ordinary shareholders — basic and diluted	$ (0.19)	$ (1.41)	$ (1.21)
Weighted average ordinary shares used in net loss per share attributable to ordinary shareholders — basic and diluted	375,669,759	68,476,149	68,472,262

See the accompanying notes to these audited consolidated financial statements

STEALTH BIOTHERAPEUTICS CORP

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)

(in thousands, except share amounts)

	SERIES A CONVERTIBLE PREFERRED SHARES		ORDINARY SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	SHAR
	SHARES	AMOUNT	SHARES	AMOUNT			
Balance at January 1, 2017	91,600,398	$ 211,377	68,458,475	$ 21	$ 36,796	$ (246,647)	$
Exercise of share options	—	—	16,139	—	10	—	
Share-based compensation expense	—	—	—	—	1,287	—	
Issuance of warrant for ordinary shares	—	—	—	—	157	—	
Net loss	—	—	—	—	—	(82,910)	
Balance at December 31, 2017	91,600,398	$ 211,377	68,474,614	$ 21	$ 38,250	$ (329,557)	$
Exercise of share options	—	—	13,334	—	15	—	
Share-based compensation expense	—	—	—	—	1,277	—	
Net loss	—	—	—	—		(96,712)	
Balance at December 31, 2018	91,600,398	$ 211,377	68,487,948	$ 21	$ 39,542	$ (426,269)	$
Issuance of ordinary shares from initial public offering, net of underwriting fees and issuance costs of $8,482	—	—	85,058,784	26	76,482	—	
Conversion of convertible preferred shares into ordinary shares	(91,600,398)	$ (211,377)	91,600,398	27	211,349	—	
Conversion of convertible notes	—	—	175,210,373	52	175,158	—	
Issuance of ordinary shares	—	—	16,304,347	5	8,908	—	
Exercise of share options	—	—	58,960	—	50	—	
Share-based compensation expense	—	—	—	—	3,244	—	
Reclassification of warrant liability to equity	—	—	—	—	400	—	
Net loss			—	—	—	(71,728)	
Balance at December 31, 2019	—	$ —	436,720,810	$ 131	$ 515,133	$ (497,997)	$

See the accompanying notes to these audited consolidated financial statements

STEALTH BIOTHERAPEUTICS CORP

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net loss	$ (71,728)	$ (96,712)	$ (82,910)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	284	309	347
Change in fair value of derivative liability	(2,782)	684	—
Change in fair value of warrant liability	300	(413)	(35)
Loss on extinguishment of debt	22,700	—	—
Issuance of warrant for ordinary shares	—	—	157
Amortization of debt discount	3,006	12,278	192
Write-off of deferred offering costs	—	—	458
Non-cash interest expense	1,731	7,070	2,526
Share-based compensation	3,244	1,277	1,287
Loss on disposal of asset	—	—	18
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,214	(625)	(73)
Accounts payable	(1,503)	3,568	4,545
Accrued expenses, accrued interest payable and other current liabilities	(4,450)	486	3,653
Net cash used in operating activities	(47,984)	(72,078)	(69,835)
Cash flows from investing activities:			
Purchase of property and equipment	(130)	(12)	(161)
Changes in other assets	—	—	(12)
Net cash used in investing activities	(130)	(12)	(173)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable to MVIL	—	25,000	50,000
Proceeds from issuance of convertible notes payable	5,000	50,000	—
Proceeds from term debt issuance	—	5,000	14,633
Proceeds from issuance of ordinary shares	8,913	—	—
Proceeds from issuance from the IPO, net of commissions	79,105	—	—
Payment of term debt issuance costs	(85)	—	(226)
Payment of convertible debt issuance costs	—	(56)	—
Payment of offering costs	(2,151)	(446)	—
Principal payments on term debt	(2,805)	(687)	—
Proceeds from exercise of share options and warrant	50	15	10
Net cash provided by financing activities	88,027	78,826	64,417
Net increase (decrease) in cash and cash equivalents	39,913	6,736	(5,591)
Cash and cash equivalents, beginning of period	10,855	4,119	9,710
Cash and cash equivalents, end of period	$ 50,768	$ 10,855	$ 4,119
Supplemental disclosure of noncash investing and financing activity:			
Noncash items:			
Fair value of warrants issued in connection with term loan	$ —	$ —	$ 548
Fair value of derivatives recorded in connection with the 2018 MVIL Note and 2018 New Investor Notes	$ 1,256	$ 35,884	$ —
Conversion of convertible preferred shares into ordinary shares	$ 211,377	$ —	$ —
Conversion of convertible notes and accrued interest into ordinary shares	$ 175,210	$ —	$ —
Reclassification of deferred offering cost to additional paid-in capital	$ 447	$ —	$ —
Reclassification of warrant liability to equity	$ 400	$ —	$ —
Noncash conversion of accrued interest due to MVIL into new convertible notes payable to MVIL	$ —	$ 2,357	$ —
Deferred offering costs included in accrued expenses	$ —	$ 879	$ —
Supplemental cash flow information-cash paid for interest	$ 1,918	$ 1,950	$ 564

See the accompanying notes to these audited consolidated financial statements.

1. Organization and Operations

The Company

Stealth BioTherapeutics Corp was incorporated in Grand Cayman, Cayman Islands as Stealth Peptides International, Inc. in April 2006. Its wholly owned subsidiary, Stealth BioTherapeutics Inc., was incorporated in Delaware as Stealth Peptides Inc. in October 2007. In addition, a wholly owned subsidiary, Stealth BioTherapeutics (HK) Limited, was incorporated in Hong Kong in September 2017. In May 2018, Stealth BioTherapeutics (Shanghai) Limited was formed as a wholly foreign owned enterprise in China. Hereinafter, Stealth BioTherapeutics Corp, Stealth BioTherapeutics Inc., Stealth BioTherapeutics (HK) Limited, and Stealth BioTherapeutics (Shanghai) Limited are referred to as the "Company." The Company is a clinical stage biotechnology company focused on the discovery and development of novel pharmaceutical agents to treat patients suffering from diseases involving mitochondrial dysfunction through its mitochondrial medicine platform. The consolidated financial statements include the assets and liabilities and operating results of the Company and its wholly owned subsidiaries. Since inception, the Company has devoted substantially all of its efforts to research and development, business planning, acquiring operating assets, seeking intellectual property protection for its technology and product candidates, and raising capital.

The Company has entered into numerous debt and equity issuances with Morningside Venture Investments Limited ("MVIL"). As of December 31, 2019, MVIL and certain entities associated with MVIL together held approximately 74.4% of the Company's outstanding shares. See Notes 8 and 9.

The Company has incurred net losses and negative cash flows from operations in each year since inception and had an accumulated deficit of $498.0 million as of December 31, 2019. The Company has financed its operations to date with proceeds from the issuance of preferred shares, initial public offering ("IPO"), convertible debt and long term debt.

On February 20, 2019, the Company closed its IPO, in which it issued and sold 6,500,000 American depositary shares ("ADS"), each representing 12 ordinary shares, for a total of 78,000,000 ordinary shares. The price to the public was $12.00 per ADS. The Company received gross proceeds of $78.0 million from the IPO. On March 4, 2019, the Company issued an additional 588,232 ADSs in connection with the underwriters' partial exercise of their over-allotment option, pursuant to which the Company raised additional gross proceeds of $7.1 million. Net proceeds received in 2019 after deducting underwriting discounts and commissions of $6.0 million and offering expenses of approximately $2.2 million were $76.9 million. Upon closing of the IPO, all shares of the Company's outstanding Series A convertible preferred shares ("Series A preferred shares") automatically converted into 91,600,398 ordinary shares and the outstanding convertible notes payable, including principal, interest and premium thereon, converted into 175,210,373 ordinary shares. See Notes 8 and 9 regarding the terms of the convertible notes payable and Series A preferred shares.

Liquidity and Going Concern

These consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Since its inception, the Company has incurred recurring losses, including net losses of $71.7 million for the year ended December 31, 2019. The Company expects to continue to incur operating losses in the foreseeable future.

Management believes that cash and cash equivalents of $50.8 million at December 31, 2019 will be sufficient to fund operating expenses through the third quarter of 2020. The Company may seek to obtain financing through equity and debt issuances, collaborative agreements, and grants from government and private sponsors. Because the ability to obtain additional financing is outside of the Company's control, the foregoing conditions raise substantial doubt in regard to the Company's ability to continue as a going concern. If the Company is unable to obtain additional funding when needed, or to the extent needed, it may be necessary to scale back operations or halt certain research and development activities, which could prevent the Company from successfully executing on its operating plan. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded assets or liabilities that might be necessary should the Company be unable to continue its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to authoritative GAAP, as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates related to, but not limited to, estimates related to the fair value of ordinary shares, share-based compensation expense, recoverability of the Company's net deferred tax asset-related valuation allowances, and certain prepaid expenses and accrued expenses. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

The Jumpstart Our Business Startups Act of 2012 ("JOBS Act") permits an "emerging growth company" such as the Company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected to avail itself of this exemption from new or revised accounting standards and, therefore, the Company will not be subject to the same new or revised accounting standards as other public companies. As a result, the Company's financial statements may not be comparable to the financial statements of reporting companies that are required to comply with the effective dates for new or revised accounting standards that are otherwise applicable to public companies.

Principles of Consolidation

All intercompany balances and transactions have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and assess performance. Management views the Company's operations and manages its business as a single operating segment.

Cash Equivalents

Cash equivalents include highly liquid investments maturing within 90 days from the date of purchase. Cash equivalents consist primarily of money market funds at December 31, 2019 and 2018 and are valued at cost, which approximates fair value.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of money market funds. The Company places these investments in highly rated financial institutions and limits the amount of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds.

Fair Value

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting

standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1—Quoted prices in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial instruments consist of cash equivalents, principally U.S. government securities, accounts payable, accrued expenses, term debt, a derivative liability and a warrant liability.

Management believes that the carrying amounts of the Company's cash equivalents, accounts payable and accrued expenses approximate the fair value due to the short term nature of those instruments. The Company has classified these financial instruments as Level I. Cash equivalents as of December 31, 2019 and 2018 were $50.6 million and $10.7 million, respectively.

As of December 31, 2019 and 2018, the Company had a term loan outstanding (see Note 7), the fair value of which is measured using Level 2 inputs. The Company believes that its debt obligations bear interest at rates which approximate prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximate fair value.

The Company's warrant liability as of December 31, 2018 was carried at fair value determined according to the fair value hierarchy described above and classified as a Level 3 measurement.

The Company's derivative liability as of December 31, 2018 was carried at fair value determined according to the fair value hierarchy described above and classified as a Level 3 measurement.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the years ended December 31, 2019 and 2018. The change in fair value of the derivative and warrant liability is included in other income (expense).

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Major improvements are capitalized as additions to property and equipment, whereas expenditures for maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operating expenses as incurred.

Depreciation and amortization is recorded using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

Asset	Estimated useful life
Computer equipment and software	3 years
Furniture, fixtures, and other	5 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of useful life or term of lease

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to the undiscounted expected future cash flows the assets are expected to generate

and recognizes an impairment loss equal to the excess of the carrying value over the fair value of the related asset. For the years ended December 31, 2019 and 2018, no impairments have been recorded.

Operating Leases

The Company leases facilities under a non-cancelable operating lease agreement. The lease agreement contains free or escalating rent payment provisions. The Company recognizes rent expense under such leases on a straight-line basis over the term of the lease with the difference between the expense and the payments recorded as deferred rent on the consolidated balance sheets. Any reimbursements by the landlord for tenant improvements are considered lease incentives, the balance of which is recorded as a lease incentive obligation within deferred rent on the consolidated balance sheets and amortized over the life of the lease. Lease renewal periods are considered in determining the lease term.

Convertible Preferred Shares

The Company classifies convertible preferred shares as temporary equity in the consolidated balance sheets due to certain change in control clauses that are outside of the Company's control, including liquidation, sale, or transfer of control of the Company, as holders of the convertible preferred shares could cause redemption of the shares in these situations.

Revenue Recognition Policy

Revenues consist mainly of research and development services performed under a contract with a customer. Effective January 1, 2019, the Company adopted ASC 606, *Revenue from Contracts with Customers (Topic 606)* ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases. Prior to 2019, the Company did not have any revenue-generating arrangements and, therefore, there was no transition impact from the adoption of ASC 606.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company assesses the goods or services promised within each contract, to determine whether the promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct); and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct in the evaluation of an arrangement subject to ASC 606, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner or customer and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices. Determining the standalone selling prices for performance obligations requires significant judgment. However, the Company identified only one performance obligation and as such was not required to estimate the standalone selling price.

If an arrangement includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone

value is included in the transaction price. Milestone payments that are not within the Company's control are generally not considered probable of being achieved until those milestones have occurred.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. The Company assessed its revenue-generating arrangement in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in the arrangement. The Company also assesses if contracts entered on or near the same time with the same customer should be accounted for as a single contract, and if any portion of consideration received should to be allocated to the transaction price.

The Company then recognizes as revenue, the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time. Revenue is recognized over time if either: (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance; (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer.

Alexion Arrangement

In October 2019, the Company entered into an option agreement ("Agreement") with Alexion Pharmaceuticals Inc. ("Alexion"), under which Alexion had an option to negotiate a license, co-development and co-promotion arrangement for primary mitochondrial myopathy ("PMM") and the Company was required to perform certain services for Alexion. Under the terms of the Agreement, the Company is responsible for all costs to be incurred in the performance of these services, and as such, the arrangement falls in scope of ASC 606 and Alexion is the customer in the arrangement.

Simultaneously with the entry into the Agreement, the Company entered into a share purchase agreement (the "Equity Agreement", and collectively with the Agreement, the "Alexion Arrangement"). Pursuant to the terms of the Equity Agreement, Alexion purchased 16,304,347 of the Company's ordinary shares at a purchase price of $0.92 per share, for an aggregate purchase price of $15.0 million. The purchase price represented a 41% premium over the average closing price of the Company's American Depositary Shares prior to the Alexion Arrangement. The estimated fair market value of the ordinary shares purchased of $8.9 million was recognized as equity and the premium over the fair market value in the amount of $6.1 million was recognized as a contract liability upon receipt of payment and allocated to the transaction price.

Under the Agreement, the Company was obligated to provide topline data for its Phase 3 clinical trial ("PMM Topline Data") in PMM. Upon the receipt of the PMM Topline Data, Alexion would have the opportunity to exercise its option to negotiate a license and co-promote agreement. In connection with its entry into the Alexion Arrangement, the Company received an upfront non-refundable payment of $15.0 million, which together with the $6.1 million premium received from the issuance of shares, resulted in $21.1 million of transaction price recorded as a contract liability at contract inception.

The Company identified the following promises under the arrangement: (i) research and development services for completion of its Phase 3 clinical trial; (ii) regulatory responsibilities for its Phase 3 clinical trial; (iii) manufacturing responsibilities for its Phase 3 clinical trial; and (iv) the option to negotiate a license and co-promote agreement for PMM. The research and development services, manufacturing and regulatory responsibilities for PMM were deemed not capable of being distinct and not distinct in the context of the contract. The Company provides a significant service of integrating these services promised in the contract into a bundle of services that were combined into a single performance obligation. The Company determined that the option to negotiate for a license agreement was not deemed to be a performance obligation, as it represents the right of first offer, which the Company is not contractually or economically compelled to accept.

Accordingly, the Company identified one performance obligation for the Agreement. The transaction price of $21.1 million was allocated to the performance obligation identified. As of December 31, 2019, the Company satisfied its performance obligation under the Agreement and the revenue associated with the performance obligation was recognized in full.

Alexion terminated the Agreement in January 2020 and, as such, no additional revenue will be recognized under the Alexion Arrangement.

Research and Development Costs

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense; (ii) external research and development expenses incurred under arrangements with contract research organizations and contract manufacturing organizations, investigational sites and consultants, including share-based compensation expense for consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; and (iv) costs associated with preclinical and clinical activities and regulatory operations. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and recorded in the accompanying consolidated balance sheets as prepaid research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed. If expectations change such that the Company does not expect it will need the goods to be delivered or the services to be rendered, capitalized non-refundable advance payments would be charged to expense.

The Company enters into consulting, research and other agreements with commercial entities, researchers, universities and others for the provision of goods and services. Under such agreements, the Company may pay for services on an hourly, monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Share-based Compensation

The Company accounts for share-based compensation awards as compensation expense based on their grant date fair values. For share-based awards granted to employees, the Company allocates share-based compensation expense on a straight-line basis over the associated service or vesting period. For non-employees the compensation expense is generally recognized during the period in which services are rendered. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then current fair value of the Company's ordinary shares and updated assumption inputs in the Black-Scholes option-pricing model ("Black-Scholes"). The Company recognizes compensation expense for the portion of awards that have vested each period. Share-based compensation is classified in the accompanying consolidated statements of operations within research and development or general and administrative operating expenses depending on where the related services are provided.

The Company estimates the fair value of its share options using Black-Scholes, which requires the input of subjective assumptions, including (a) expected share price volatility, (b) expected term of the award, (c) risk-free interest rate, (d) expected dividends and (e) estimated fair value of its ordinary shares on the measurement date. Due to the lack of a public market for the trading of its ordinary shares and a lack of Company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies, which are publicly traded. When selecting these public companies on which it has based its expected share price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the share-based awards. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based awards. The expected term of options granted represents the weighted average of previously transacted awards plus the minimum and maximum expected life of the outstanding awards based on vesting and expiry. The expected term for nonemployee awards is the remaining contractual term of the option. The risk-free interest rates are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid and does not expect to pay dividends in the foreseeable future.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical plan data to estimate forfeitures and records share-based compensation expense only for those awards that are expected to vest. Share-based compensation expense recognized in the consolidated financial statements is based on awards that are ultimately expected to vest.

Income Taxes

Deferred income taxes are recorded using an asset and liability approach. The Company records deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized, which is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2019 and 2018, the Company does not have any material uncertain tax positions.

Guarantees and Indemnification

The Company indemnifies its officers and directors for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. The Company has not experienced any losses related to these indemnification obligations, and no claims are outstanding.

Net Loss Per Share Attributable to Ordinary Shareholders

Basic net loss per share attributable to ordinary shareholders is calculated by dividing net loss attributable to ordinary shareholders by the weighted average shares outstanding during the period, without consideration for ordinary share equivalents. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average ordinary shares and participating securities (the "two-class method"). The Company's convertible preferred shares participate in any dividends declared by the Company and are, therefore, considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. Diluted net loss per share attributable to ordinary shareholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of ordinary share equivalents outstanding for the period, determined using the treasury-share and if-converted methods. For purposes of the diluted net loss per share attributable to ordinary shareholders' calculation, convertible preferred shares, share options, warrants and convertible notes are considered to be ordinary share equivalents, but have been excluded from the calculation of diluted net loss per share attributable to ordinary shareholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share are the same for all periods presented.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in shareholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations.

During 2018, the Company deferred offering costs of $1.3 million related to the IPO that closed in 2019. Upon the closing of the IPO, these costs were recorded in shareholders' equity as a reduction of additional paid-in capital.

Recent Accounting Pronouncements

Recently issued accounting pronouncements not yet adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The new guidance most significantly impacts lessee accounting and disclosures but also requires enhanced disclosures for lessors. The

guidance requires lessees to identify arrangements that should be accounted for as leases. For lease arrangements exceeding a 12-month term, a right-of-use asset and lease obligation is recorded by the lessee for all leases, whether operating or financing, while the statement of operations reflects lease expense for operating leases and amortization and interest expense for financing leases. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The Company will adopt the new standard effective January 1, 2021. The Company is evaluating the impact of this new standard on its consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"). These amendments expand the scope of Topic 718, Compensation—Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The Company will adopt the new standard effective January 1, 2020. The Company believes the impact of this new standard will not have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Changes to Disclosure Requirements for Fair Value Measurements*, which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies and adds certain disclosure requirements, and is effective for the Company beginning on January 1, 2020. The Company does not expect that this standard will have a material effect on the Company's consolidated financial statements.

Recently adopted accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), a new revenue recognition standard which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. The Company adopted the new accounting standard effective January 1, 2019. Prior to 2019, the Company did not have any revenue-generating arrangements and, therefore, there was no transition impact from the adoption of ASC 606.

3. Fair Value of Financial Assets and Liabilities

Fair Value Hierarchy

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2019 and December 31, 2018:

	Fair Value Measurements as of December 31, 2019 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Short-term money market funds	$ 50,622	$ —	$ —	$ 50,622
Total financial assets	$ 50,622	$ —	$ —	$ 50,622

	Fair Value Measurements as of December 31, 2018 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Short-term money market funds	$ 10,710	$ —	$ —	$ 10,710
Total financial assets	$ 10,710	$ —	$ —	$ 10,710
Liabilities:				
Derivative liability	$ —	$ —	$ 36,567	$ 36,567
Warrant liability	—	—	100	100
Total financial liabilities	$ —	$ —	$ 36,667	$ 36,667

As of December 31, 2019, and 2018, the carrying amounts of cash, accounts payable, and accrued expenses approximated their estimated fair values because of the short-term nature of these financial instruments. The Company's cash equivalents, which are in money market funds, are classified within Level 1 of the fair value hierarchy because they are valued using quoted prices as of December 31, 2019 and 2018.

Upon the Company's IPO, the underlying warrants became exercisable for ordinary shares instead of Series A preferred shares and the related fair value of the warrant liability immediately prior to the IPO was recorded as additional paid in capital with reclassification of the warrant liability as equity. The underlying convertible debt obligations for the derivative liability were automatically converted into ordinary shares upon the IPO and the difference between the fair value of the shares issued in exchange for the convertible notes and the net carrying amount of the convertible notes was recorded as an extinguishment loss. As such, there were no liabilities to be remeasured at fair value on a recurring basis as of December 31, 2019.

As of December 31, 2018, the outstanding debt from the Term Loan (Note 7) and convertible debt obligations (Note 8) bear interest at rates which approximate prevailing market rates for instruments with similar characteristics and, accordingly, the carrying values for these instruments approximate fair value. Upon the IPO, the convertible debt obligations were converted to ordinary shares. As of December 31, 2019, the outstanding debt from the Term Loan bears interest at a rate which approximates prevailing market rates for an instrument with similar characteristics and, accordingly, the carrying value for this instrument approximates fair value.

Warrant Liability

As consideration for the Company's Loan (see Note 7), the Company and the lender entered into a warrant agreement. The warrant was recorded as a liability at fair value upon issuance. The warrant was recorded at fair value on the Company's consolidated balance sheet as a liability and discount to the Loan. It was subject to revaluation at each balance sheet date, and any changes in value were recorded as a component of gain or loss from valuation of warrant liability, until the earlier of their exercise or expiration or upon the completion of a liquidation event.

In December 2018, the Company used a Black-Scholes model which incorporates assumptions and estimates, to value the warrant under various liquidity scenarios. The estimated fair value of the warrant as of December 31, 2018, used the following assumptions: average volatility of 65%, expected term of 7.1 years, average risk-free interest rate of 2.6%, fair value of ordinary shares of $1.05, fair value of Series A preferred shares of $2.31 and a zero dividend yield. The resulting estimated fair value of the warrant liability was $0.1 million.

In 2019, upon the completion of the IPO and the resulting conversion of the Series A preferred shares, the outstanding Warrant became exercisable into 500,000 ordinary shares at $1.00 per share. Upon the completion of the IPO, the Warrant met the criteria for equity classification as it was indexed to the Company's shares and therefore the Warrant was reclassified from a liability to an equity instrument and was included in additional paid-in capital. The following assumptions were used to measure the final fair value of the warrant liability prior to the IPO: average volatility of 61.1%, expected term of 8.36 years, average risk-free interest rate of 2.6%.

The following table presents the Warrant liability measured at fair value using unobservable inputs (Level 3) as of the year ended December 31, 2019 and 2018 (in thousands):

Fair value at January 1, 2018	$	513
Change in fair value of warrant liability		(413)
Fair value at December 31, 2018	$	100
Change in fair value of warrant liability		300
Reclassification of warrant liability		(400)
Fair value at December 31, 2019	$	—

Derivative Liability

During 2018, the Company entered into a number of note purchase agreements (see Note 8) in which it concluded that certain of the redemption and conversion features within the agreements met the bifurcation criteria under ASC 815*, Derivatives and Hedging*, and therefore should be accounted for separately from the debt ("Derivative Liability"). The Derivative Liability is recorded at fair value on the Company's consolidated balance sheet as a liability and subject to revaluation at each balance sheet date, and any changes in value are recorded as a component of gain or loss in the change in valuation of derivative liability on the statements of operations.

In January 2018, upon the issuance of the first note in the amount of $15.0 million as well as the exchange note of $52.4 million, the identified embedded derivatives were initially valued using a Monte Carlo simulation. The simulation took into consideration the probability of four scenarios: subsequent financing at 10% probability, short term IPO at 20% probability, long term IPO at 50% probability, and change of control at a 20% probability. Other assumptions included a forecast horizon of 2.0 years, the present value of the Company's equity, and expected volatility of 82%. The resulting fair value of the derivatives was $19.3 million.

In April 2018, upon the issuance of the second note in the amount of $5.0 million, the embedded derivative was initially valued using a Monte Carlo simulation. The simulation took into consideration the probability of four scenarios: subsequent financing at 10% probability, short term IPO at 30% probability, long term IPO at 40% probability, and change of control at a 20% probability. Other assumptions included a forecast horizon of 1.8 years, the present value of the Company's equity, and expected volatility of future equity of 83%. The resulting derivative fair value was $1.4 million.

In May 2018, upon the issuance of additional notes in the amount of $30.0 million, the embedded derivatives were initially valued using a Monte Carlo simulation. The simulation took into consideration the probability of four scenarios: subsequent financing at 10% probability, short term IPO at 40% probability, long term IPO at 30% probability, and change of control at a 20% probability. Other assumptions included a forecast horizon of 1.6 years, the present value of the Company's equity, and expected volatility of future equity of 79%. The resulting derivative fair value was $11.2 million.

As of December 31, 2018, the fair value of the total Derivative Liability for the January through May notes totaling $102.4 million was re-measured using the Monte Carlo simulation. The simulation took into consideration the probability of four scenarios: subsequent financing at 10% probability, short term IPO at 50% probability, long term IPO at 20% probability, and change of control at a 20% probability. Other assumptions included the present value of the Company's equity, the expected volatility of future equity at 64%, an annualized risk free rate of 2.7% and a forecast horizon of 1.75 years. The resulting fair value of the derivative was $32.8 million.

In October 2018, upon the issuance of additional notes in the amount of $15.0 million, the embedded derivatives were initially valued using the ordinary share value of the Company of $1.53. This alternative method was utilized because the new note did not contain subsequent financing or change of control conversion features. The probabilities and timing of three IPO scenarios were as follows: no IPO at 30% probability, short term IPO at 20% probability with time to IPO of 0.17 years and long term IPO at 50% probability with a time to IPO of 0.41 years. The resulting derivative fair value was $2.4 million.

In December 2018, upon the issuance of additional notes in the amount of $10.0 million, the embedded derivatives were initially valued using the ordinary share value of the Company of $1.05 and the probabilities and

timing of three scenarios: no IPO at 30% probability, short term IPO at 40% probability with time to IPO of 0.16 years and long term IPO at 30% probability with time to IPO of 1.4 years. The resulting derivative fair value was $1.5 million.

As of December 31, 2018, the fair value of the total Derivative Liability for the October through December notes totaling $25.0 million was re-measured using the fair value of the Company's ordinary shares of $1.05 and the probabilities and timing of three scenarios: no IPO at 30% probability, short term IPO at 50% probability with time to IPO of 0.16 years and a long term IPO at 20% probability with time to IPO of 1.40 years. The resulting fair value of the derivative was $3.8 million.

In 2019, upon closing of the IPO, all the Company's outstanding convertible notes payable, including principal, interest and premium thereon, converted into 175,210,373 ordinary shares. The automatic conversion upon the IPO was a settlement of the debt and the difference between the fair value of the shares issued in exchange for the convertible notes and the net carrying amount of the convertible notes was recorded as a loss on extinguishment of debt. See Notes 8 and 9 regarding the terms of the convertible notes payable and Series A preferred shares, respectively.

The following table presents the Derivative Liability measured at fair value using Level 3 inputs as of the year ended December 31, 2019 and 2018 (in thousands):

Fair value at January 1, 2018	$ —
Issuance of debt	35,883
Change in fair value of derivative liability	684
Fair value at December 31, 2018	$ 36,567
Issuance of debt	1,256
Change in fair value of derivative liability	(2,782)
Conversion of debt- derivative liability	(35,041)
Fair value at December 31, 2019	$ —

There have been no transfers between fair value measure levels during the years ended December 31, 2019 and 2018.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	As of December 31,	
	2019	2018
Research and development	$ 387	$ 2,085
Prepaid insurance	280	95
Other	963	258
Total	$ 1,630	$ 2,438

5. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	As of December 31,	
	2019	2018
Computer equipment and software	$ 373	$ 367
Furniture, fixtures and other	768	719
Laboratory equipment	377	377
Leasehold improvements	449	374
	1,967	1,837
Accumulated depreciation	(1,622)	(1,338)
Property and equipment, net	$ 345	$ 499

Depreciation expense was $0.3 million for each of the years ended December 31, 2019, 2018 and 2017.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of December 31,	
	2019	2018
Research and development	$ 3,403	$ 7,830
Employee compensation costs	2,020	2,485
Consulting and professional services	2,252	2,335
Legal expenses	651	742
Deferred rent	72	122
Other	97	312
Total	$ 8,495	$ 13,826

7. Debt

Term Loan

In June 2017, the Company entered into a Loan and Security Agreement (the "LSA") with a lender that permitted the Company to borrow up to an aggregate principal amount of $40.0 million through a multiple tranche term loan (the "Term Loan"). The tranche advances are based on the Company achieving certain performance milestones as defined in the LSA. Upon closing of the Term Loan, the Company drew the first tranche less expenses, which resulted in net proceeds of $12.1 million. In September 2017, the Company drew the second tranche advance of $2.5 million upon achieving the first milestone. In March 2018, the Company drew the third tranche advance of $5.0 million upon achieving a second milestone, bringing the total gross amount borrowed to $20.0 million as of December 31, 2019.

The Term Loan included a $0.2 million facility charge, which was paid to the lender on the closing date. The Company paid a $30,000 due diligence fee prior to the Term Loan closing, and the Company incurred additional cash expenses of $0.4 million related to the Term Loan. These three amounts were all recorded as a debt discount and are being amortized as interest expense using the effective interest method over the life of the Term Loan. The Term Loan also includes an end of term charge equal to the greater of $750,000 or 5% of the aggregate principal amount of all advances. The end of term charge is being accrued and recorded to interest expense over the life of the Term Loan using the effective interest method.

The Term Loan bears interest at the greater of (i) the prime rate plus 5.5% or (ii) 9.5%. As of December 31, 2019, the interest rate was 10.25%. Interest accrues from the closing date and interest payments are due monthly in arrears on the first of the month. Payments under the Term Loan were interest only for the first twelve months after closing followed by a 30-month amortization period of principal and interest payments that were scheduled to begin on August 1, 2018 and continue through the scheduled maturity date of January 1, 2021. During 2018, the Term Loan was amended to, among other things, postpone the principal payments to December 1, 2018. In March 2019, the Term Loan was amended to postpone principal payments to October 1, 2019. These amendments to the Term Loan were accounted for as a debt modification. For consideration of the amendments, the Company agreed to pay an additional end of term charge of $0.3 million at maturity which is being accrued and recorded to interest expense over the life of the loan using the effective interest method. In October 2019, subsequent to the October principal payment, the principal payments on the Term Loan were deferred to February 1, 2020, based on achievement of certain performance milestones.

The Company's obligations to the lender are secured by a first priority security interest in substantially all of its assets, excluding intellectual property ("IP"). The lender maintains a negative pledge on IP with a security interest in the proceeds of the sale of the IP. The Term Loan contains certain covenants related to restrictions on payments for certain investments, additional debt, distributions and transfers. In connection with the LSA, the Company was required to enter into separate deposit account control agreements with the lender in order to perfect the lender's security interest in the cash collateral in the Company's operating accounts. In the event of a default under the LSA, the lender would have the right to take control of the operating account(s) and restrict the Company's access to the operating account(s) and the funds therein.

As consideration for the Term Loan, the Company and the lender entered into a warrant agreement pursuant to which the lender, as Warrant holder, has the right to purchase a quantity of shares equal to the quotient derived by dividing (a) the Warrant coverage by (b) the exercise price. Warrant coverage means the greater of (a) $312,500 plus 2.5% of future tranche advances in the event all or part of the tranches are funded or (b) $375,000. The exercise price is (a) the purchase price of Series A preferred shares, $2.30769 per share, or (b) the price per share paid in the next equity round of financing of ordinary shares or preferred shares, which results in aggregate gross proceeds of at least $30 million. Upon the closing of the IPO, the Warrant became exercisable for 500,000 ordinary shares at an exercise price of $1.00 per ordinary share. The Warrant was exercisable beginning in June 2017, in whole or in part, and expires in ten years. The Warrant was originally recorded as a liability and the discount on the debt was being amortized through interest expense using the effective interest rate method over the remaining term of the Term Loan. Upon the completion of the IPO, the Warrant met the criteria for equity classification as it was indexed to the Company's shares and as such was reclassified to an equity instrument and was included in additional paid-in capital. See Note 3 for fair value considerations and disclosures.

In addition, the lender can declare a material adverse effect while monitoring our business, operations, properties, assets or financial condition. A material adverse effect is considered an event of default under the LSA. In the event of default, repayment of amounts due under the Loan may be accelerated by the lender.

Future principal payments under the Loan as of December 31, 2019 are as follows (in thousands):

2020	$	14,958
2021		1,551
Total future principal payments		16,509
Less unamortized debt discount		(267)
Total balance, balance sheet	$	16,242
Term loan—current portion	$	14,716
Term loan—non-current portion		1,526
Total balance, balance sheet	$	16,242

Interest expense related to the Loan for the year ended December 31, 2019, 2018 and 2017 was $2.7 million, $2.9 million and $1.0 million, respectively. Accrued interest as of December 31, 2019 and 2018 was $1.2 million and $0.8 million, respectively.

8. Convertible Notes Payable and MVIL Demand Note Receivable

Upon the closing of the IPO, the outstanding convertible notes payable referenced above, including principal, interest and premium thereon, converted into 175,210,373 ordinary shares. Interest expense relating to the convertible notes referenced above for the year ended December 31, 2019, 2018 and 2017 was $1.3 million, $6.6 million, $2.2 million, respectively.

Interest expense related to the debt discount amortization was $2.7 million and $11.9 million for the year ended December 31, 2019 and 2018, respectively.

During 2017, the Company issued six convertible promissory notes payable to MVIL, resulting in proceeds of $50.0 million (the "2017 MVIL Notes"). The notes accrued interest at 8% per annum. Effective upon the closing of a qualified financing, as defined, the outstanding principal and accrued interest automatically convert into shares of the same class and series of our shares issued to other investors in the qualified financing. MVIL also had the right to convert some or all of the outstanding amount into shares of Series A preferred shares at a conversion price of $2.30769 after December 31, 2018. In January 2018, the Company entered into a note exchange agreement with MVIL in the amount of $52.4 million, which represents the total principal and accrued interest of the 2017 MVIL Notes at the time of the execution of the note exchange agreement. The exchange terminated the 2017 MVIL Notes and created a new convertible note under substantially the same terms as the notes described in the following paragraph. The note exchange agreement was accounted for as a debt extinguishment and resulted in no gain or loss upon recognition of the new debt.

In January 2018, the Company entered into a note purchase agreement with investors (as amended, the "2018 Agreement"), whereby the Company was eligible to borrow an aggregate principal amount of $30.0 million in exchange for notes convertible into ordinary shares of the Company. In April 2018, the note purchase agreement was amended to allow the Company to borrow up to $65.0 million in the aggregate. Between January and May 2018, the Company issued notes in an aggregate principal amount of $50.0 million (the "2018 New Investor Notes"). The 2018 New Investor Notes accrued interest at 7% per annum. Accrued interest on the 2018 New Investor Notes compounded annually. The 2018 New Investor Notes, as amended, were convertible upon (i) the closing of an initial public offering or (ii) a subsequent financing occurring after January 10, 2019. Effective upon the closing of a qualified financing, as defined, the outstanding principal and accrued interest plus a 25% premium, defined as the sum of principal plus interest multiplied by 25%, automatically convert into shares of the same class and series of our shares issued to other investors in the qualified financing. The 2018 Investor Notes converted in accordance with their terms upon the closing of the IPO.

The Company evaluated the 2018 New Investor Notes as well as the exchange agreement and concluded that certain of the redemption and conversion features met the bifurcation criteria under ASC 815, *Derivatives and Hedging* and should be accounted for separately from the debt.

The derivative liability was recorded at fair value on the Company's consolidated balance sheet as a liability and subject to revaluation at each balance sheet date, and any changes in value were recorded as a component of gain or loss in the change in valuation of derivative liability on the statements of operations. The initial values of the derivative, along with legal fees, were recorded as a debt discount and are being amortized as interest expense using the effective interest method over the life of the note. See Note 3 for fair value considerations and disclosures.

In October 2018, the Company entered into the 2018 MVIL Note, under which the Company borrowed $30.0 million, of which it has borrowed $25.0 million as of December 31, 2018. In January 2019, the Company borrowed the remaining $5.0 million. The notes contain similar terms as the notes described in the paragraph above describing the 2018 New Investor Notes except that a qualified financing is limited to a U.S. IPO and that there was no change of control conversion feature. The 2018 MVIL Note was convertible upon a qualified initial public offering of the Company's ordinary shares in the United States at the initial public offering price per share. Effective upon the closing of a qualified financing, the outstanding principal and accrued interest plus a 25% premium of such principal and interest automatically converts into shares of the same class and series of our shares issued to other investors in the qualified financing. The automatic conversion upon the IPO was a settlement of the debt and the difference between the fair value of the shares issued in exchange for the convertible notes and the net carrying amount of the convertible notes was recorded as a loss on extinguishment of debt. The 2018 MVIL Note accrued interest at 7% per annum and accrued interest compounded annually, and upon such compounding, was added to the outstanding principal amount. The 2018 MVIL Note converted in accordance with its terms upon the closing of the IPO.

9. Convertible Preferred Shares

Upon the closing of the IPO in February 2019, all shares of the Company's outstanding Series A preferred shares automatically converted into 91,600,398 ordinary shares. At December 31, 2019, the Company has no Series A convertible preferred shares authorized or outstanding.

At December 31, 2018, the Company had authorized 106,666,667 shares of Series A preferred shares, $0.0003 par value, and there were 91,600,398 shares issued and outstanding. The rights and preferences of the Series A preferred shares were as follows:

Conversion—At any time at the holder's request and automatically upon the closing of a qualified IPO or sale of the Company, Series A preferred shares were convertible into ordinary shares at a ratio which was computed by dividing the original issue price by the applicable conversion price. A qualified IPO was defined under our articles of association as a fully underwritten public offering of ordinary shares in which aggregate gross proceeds equal or exceed $35.0 million pursuant to an effective registration statement under the Securities Act or in a jurisdiction outside of the United States. The initial conversion price of $2.30769 was subject to adjustment if the Company subsequently issued or sold ordinary shares or Series A preferred shares at a per share price that was less than the conversion price in effect at that time. At December 31, 2018, the applicable conversion ratio was 1:1.

Dividends—Series A preferred shares were entitled to receive, when and as declared by the board of directors, preferential cash dividends at a rate at least equal to 8% of the original issue price. Such dividends were not cumulative. No dividends were declared.

Redemption Rights—Series A preferred shares did not have any stated redemption rights.

Liquidation Rights—In the event of a liquidation, dissolution, or winding-up of the Company, Series A preferred shares were entitled to be paid an amount first out of legally available funds available for distribution to holders of the Company's capital share an amount equal to $2.30769 per share, plus all declared but unpaid dividends with respect to each such shares, as adjusted for any share dividend, share split, recapitalization, or other similar event. After payment of all preferential amounts, any assets and funds of the Company that remain available would have been distributed on a pro rata basis among the holders of ordinary shares.

Voting Rights—Series A preferred shares were entitled to the number of votes equal to the number of ordinary shares into which the Series A preferred shares were convertible. Preferred and ordinary shareholders voted together as a single class except for the election of the Company's board of directors. For such election, holders of Series A preferred shares had the right to elect two directors and the holders of ordinary shares had a right to appoint one director.

10. Shareholders' Equity

Ordinary Shares

At December 31, 2019 and 2018, 750,000,000 and 203,333,333 ordinary shares, $0.0003 par value, were authorized for issuance, and 436,720,810 and 68,487,948 ordinary shares were issued and outstanding, respectively.

In January 2017, the Company issued a warrant to purchase 231,989 ordinary shares to an affiliate of the Company's then-serving interim Chief Financial Officer of Stealth BioTherapeutics Inc. at an exercise price of $1.38 per share. The warrant was fully vested as of December 31, 2017 and expires in January 2022. The Company recorded an expense of $0.2 million within general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2017. In June 2018, the warrant was amended and restated to be treated as an option agreement under the Company's 2006 Share Incentive Plan (the "2006 Plan").

Prior to the Company's IPO, the voting, dividend and liquidation rights of holders of ordinary shares were subject to and qualified by the rights, powers and preferences of holders of Series A preferred shares. The rights and preferences of ordinary shares are as follows:

Voting—Holders are entitled to one vote for each ordinary share held at all meetings of shareholders and written action in lieu of meetings; there is no cumulative voting.

Dividends—Holders are entitled to receive dividends, if and when declared by the board of directors. Cash dividends may not be declared or paid to holders until paid on Series A preferred shares in accordance with its terms. No dividends have been declared.

Liquidation—The holders of ordinary shares are entitled to share in the Company's assets available for distribution on a pro rata basis, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

The Company has reserved for future issuance the following number of ordinary shares as of December 31, 2019:

2019 Share Incentive Plan	63,429,506
Employee Share Purchase Plan	3,972,565
Conversion of ordinary share warrant	500,000
Total	67,902,071

11. Share Incentive Plan

The Company's 2006 Plan provides for the grant of share options or other awards to employees, directors, advisors and consultants for the purchase of up to 25,544,054 ordinary shares. Share options vest over varying schedules as determined by the Company's board of directors and typically expire 10 years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2006 Plan.

Prior to the IPO, in determining the exercise prices for options granted, the board of directors considered the fair value of ordinary shares as of the grant date, based upon a variety of factors, including the results obtained from a third-party valuation, the Company's financial position and financial performance, the status of technological developments of the Company's proposed products, the composition and ability of the current scientific and management team, an evaluation or benchmark of the Company's competition, the illiquid nature of the ordinary shares, sales of capital share including convertible preferred shares, the effect of the rights and preferences of Series A preferred shares, and the prospects of a liquidity event. Following the IPO, the fair value of the ordinary shares was determined based on the quoted market price of the ADSs. The Company has historically granted share options at exercise prices not less than the fair value of our ordinary shares.

In January 2019, the Company adopted the 2019 Share Incentive Plan ("2019 Plan") and as a result no further awards will be made under the 2006 Plan. In addition, any ordinary shares subject to awards under the 2006 Plan that expire, are forfeited, or are otherwise surrendered, without having been fully exercised or resulting in any ordinary shares being issued will become available for issuance under the 2019 Plan, up to an additional 15,794,199 shares, which is the number of shares issuable pursuant to outstanding awards granted under the 2006 Plan. The 2019 Plan provides for the grant of shares or other awards to employees, directors, advisors and consultants for the purchase of up to 63,487,133 ordinary shares. Share options vest over varying schedules as determined by the Company's board of directors and typically expire 10 years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2019 Plan.

At December 31, 2019, there were 27,303,135 ordinary shares available for future grant under the 2019 Plan.

Total share-based compensation expense is as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 1,195	$ 603	$ 722
General and administrative	2,049	674	565
Total	$ 3,244	$ 1,277	$ 1,287

As of December 31, 2019, total unrecognized compensation expense related to non-vested share options, net of related forfeiture estimates, was $7.5 million. The Company expects to recognize its remaining unrecognized share-based compensation expense over a weighted-average period of approximately 2.95 years.

The fair value of each share option granted to employees and directors was estimated on the date of grant using the following assumptions:

	Year Ended December 31,		
	2019	2018	2017
Risk free interest rate	1.43% - 2.61%	2.65% - 3.12%	1.89% - 2.83%
Expected dividend yield	—	—	—
Expected term (in years)	5.4 - 6.4	6.0	6.0
Expected volatility	55% - 58%	59%	57%

The following table summarizes share option plan activity for the year ended December 31, 2019:

	Number of Shares	Weighted-Average Exercise Price	Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	15,871,228	$ 1.06	6.7	$ 3,580,527
Granted	22,228,741	$ 0.96		
Exercised	(58,960)	$ 0.84		
Cancelled or forfeited	(1,914,638)	$ 1.11		
Outstanding at December 31, 2019	36,126,371	$ 0.99	7.8	$ -
Exercisable at December 31, 2019	15,869,209	$ 0.99	6.1	$ -
Vested and expected to vest at December 31, 2019	30,523,472	$ 0.99	7.5	$ -

The weighted average grant date fair value per share for awards granted during the year ended December 31, 2019, 2018 and 2017, was $0.53, $0.82 and $0.74, respectively.

12. 401(k) Savings Plan

In 2014, the Company adopted a tax-qualified employee savings and retirement 401(k) Plan, covering all qualified employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits.

The Company contributes up to 3% of an employee's annual salary, within statutory limits. During the years ended December 31, 2019, 2018 and 2017, the Company contributed $0.4 million, $0.3 million and $0.3 million, respectively.

13. License Agreements

In 2006, the Company entered into a license agreement, as amended, with Cornell Research Foundation, Inc. ("Cornell") and a research institute (collectively "licensor") for certain intellectual property rights and, subsequently, entered into four additional license agreements with Cornell. Under the terms of the original license agreement, the Company issued an aggregate of 666,667 ordinary shares to Cornell between 2006 and 2009. The Company has also paid $60,000 in license fees. The Company is also required to pay royalties on the commercial sale of products that result from the licensed intellectual property, as well as a percentage of any sublicensing revenue. Subject to specified reductions and royalty offset, such royalties are calculated as a tiered, low-to-mid single digit percentage of net sales of licensed products under each of the license agreements, except that for licensed products under the original agreement, such royalties are calculated as a tiered, low single-digit to sub-teen percentage of net sales, depending on patent coverage, amount of net sales and type of licensed product. Under this license agreement, if the Company fails to commercialize a product by December 31, 2020, the licensor may terminate the license, subject to specified exceptions for causes due to scientific, regulatory and other events over which the Company cannot exert direct control.

14. Commitments and Contingencies

Lease commitments

The Company's U.S. subsidiary currently leases office space in Newton, Massachusetts under a lease that expires in November 2020 and made a security deposit of $0.3 million, which is classified in other assets on the accompanying consolidated balance sheets. In 2019, the security deposit was reduced by $75,000 and the remaining balance was classified as prepaid and other current assets for the year ended December 31, 2019.

The Company has accounted for the lease as an operating lease. The lease was amended in January 2019 to include the additional adjacent office space beginning May 2019. Rent expense was $0.6 million for each of the years ended December 31, 2019, 2018 and 2017. The expense is being recorded on a straight-line basis over the term of the lease. Incentives received from the landlord related to the operating lease are recorded as deferred rent. As of December 31, 2019 and 2018, the Company recorded deferred rent of $72,579 and $0.1 million, respectively, which is included in accrued expenses and other current liabilities on the accompanying consolidated balance sheet.

Future minimum payments payable under all operating leases as of December 31, 2019 are as follows (in thousands):

Year Ending December 31,	
2020	708
Total minimum lease payments	$ 708

15. Income Taxes

As a Cayman Islands entity, Stealth BioTherapeutics Corp is not currently subject to taxation. Stealth BioTherapeutics Inc. is subject to U.S. income tax and certain state income taxes.

The following table presents domestic and foreign components of loss before income tax benefit for the periods presented (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Domestic	$ 3,633	$ 3,116	$ 1,599
Foreign	68,095	93,596	81,311
Loss before income tax benefit	$ 71,728	$ 96,712	$ 82,910

A reconciliation setting forth the differences between the Company's effective tax rate and the U.S. statutory tax rate is as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Income tax benefit at federal statutory rate	$ 763	$ 654	$ 557
State and local income taxes net of federal tax benefit	247	522	255
Federal credits	2,454	1,267	1,299
Federal rate change	—	—	(280)
Nondeductible/nontaxable permanent items	(89)	77	(12)
Other	—	(56)	1
Change in valuation allowance	(3,376)	(2,464)	(1,820)
Income tax benefit	$ —	$ —	$ —
Effective tax rate	0.0%	0.0%	0.0%

The significant components of the Company's deferred tax assets are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 832	$ 663
Credits	7,522	4,585
Deferred rent	17	30
Other accrued liabilities	84	754
Depreciation	47	22
Deferred interest	1,264	—
Total deferred tax assets	9,766	6,054
Deferred tax liabilities:		
Other accrued liabilities	—	—
Depreciation	—	—
Total deferred tax liabilities	—	—
Valuation allowance	9,766	6,054
Net deferred tax liability	$ —	$ —

As of December 31, 2019, Stealth BioTherapeutics Inc. had federal and state net operating loss carryforwards of $3.7 million and $1.0 million, respectively. The net operating loss carryforwards expire at various dates beginning in 2034 through 2039 for U.S. and state tax purposes. As of December 31, 2019, the Company had federal and state research and development credit carryforwards of approximately $4.0 million and $1.6 million, respectively, which, if unused, will expire in years 2035 through 2039 (federal) and 2030 through 2034 (state). As of December 31, 2019, the Company also had an orphan drug credit of $2.2 million, which, if unused, will expire in year 2037 through 2039.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. As of December 31, 2019, the Company maintains a full valuation allowance for its deferred tax assets due to uncertainty regarding their realization. Adjustments could be required in the future if the Company estimates that the amount of deferred tax assets to be realized is more or less than the net amount the Company has recorded. The valuation allowance increased $3.4 million and $2.5 million during the years ended December 31, 2019 and 2018, respectively, due primarily to the generation of net operating losses during the period and the recognition of potential research and development tax credits.

The Company is not currently under any income tax examinations. Due to the Company's net operating losses, all tax years generally remain open in each jurisdiction. No interest or penalties have been recorded on any

unrecognized tax benefits since its inception. The Company does not believe material uncertain tax positions have arisen to date.

Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards and tax credits, which could be used annually to offset future taxable income.

On December 22, 2017, The Tax Cuts and Jobs Act (the "Act)" was enacted. The Act significantly revised the U.S. corporate income tax law by lowering the corporate Federal income tax rate from 35% to 21%. As of December 31, 2017, the Company has assessed the effects of the corporate rate reduction on its existing deferred tax balances which resulted in a $0.3 million reduction in the deferred tax assets. Since the Company maintains a full valuation allowance on its deferred tax assets, a corresponding reduction in the valuation allowance equal to the effect of the rate reduction on the ending deferred tax asset was also reflected. In addition to the rate reduction, the Act also requires companies with foreign subsidiaries to pay a one-time transition tax on earnings that were previously tax deferred. As of December 31, 2019 and 2018, the Company does not have previously deferred foreign earnings subject to the transition tax.

16. Net Loss Per Share Attributable to Ordinary Shareholders

Basic and diluted net loss per ordinary share are calculated as follows (in thousands, other than share and per share data):

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss attributable to ordinary shareholders—basic and diluted	$ (71,728)	$ (96,712)	$ (82,910)
Denominator:			
Weighted-average ordinary shares used in net loss per share attributable to ordinary shareholders—basic and diluted	375,669,759	68,476,149	68,472,262
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.19)	$ (1.41)	$ (1.21)

The following ordinary share equivalents, presented on an as converted basis, were excluded from the calculation of net loss per share for the periods presented, as their effect is anti-dilutive:

	Year Ended December 31,		
	2019	2018	2017
Series A preferred shares	—	91,600,398	91,600,398
Series A preferred shares warrants	—	216,667	162,500
Ordinary share warrants	500,000	—	231,989
Convertible notes payable and accrued interest from MVIL	—	—	22,640,052
Outstanding share options	36,126,371	15,871,228	14,789,031
Total	36,626,371	107,688,293	129,423,970

17. Related Party

For the years ended December 31, 2019, 2018 and 2017, the Company paid $96,528, $0.2 million and $0.2 million, respectively, for consulting services provided by an entity affiliated with its former interim Chief Financial Officer.

Except as disclosed elsewhere in the notes to the accompanying consolidated financial statements, there were no other material transactions with related parties.

18. Subsequent Events

On December 31, 2019, the Company's Chief Scientific Officer, Mark Bamberger, submitted notice of his resignation from the Company, effective December 31, 2019. In connection with his resignation, Dr. Bamberger entered into a separation agreement with the Company. On January 1, 2020, the Company also entered into a consulting agreement with Dr. Bamberger, by which he will be compensated for discovery-related consulting services on an as-needed basis.

On January 7, 2020, the Company adopted a strategic organizational restructuring plan, and reduced the workforce by approximately 60% of its personnel. In connection with the reduction in workforce, the Company anticipates incurring a one-time charge totaling approximately $2.3 million related to termination benefits and other related charges in the first quarter of 2020.

In 2020, the board of directors approved a new equity compensation plan, the 2020 ADS incentive plan ("the ADS Plan"), and amended the current 2019 Plan ("the Amended 2019 Plan"), and in March 2020, the shareholders approved the ADS Plan and the Amended 2019 Plan. The amendment of the 2019 plan reduced the number of ordinary shares reserved thereunder by 24,999,996, as those shares are now available under the ADS Plan.

On March 25, 2020, the shareholders approved the increase to the Company's authorized share capital from 750,000,000 ordinary shares of a nominal or par value of US$0.0003 each to 1,200,000,000 ordinary shares of a nominal or par value of US$0.0003 each.

In March 2020, the COVID-19 pandemic, which began in December 2019 in China and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The Company has taken a series of actions aimed at safeguarding the Company's employees and business associates, including implementing a work-at-home policy. These disruptions could result in increased costs of execution of operational plans or may negatively impact the quality, quantity and regulatory usability of data that the Company would otherwise be able to collect. While these disruptions are currently expected to be temporary, there is considerable uncertainty around the duration. Therefore, while the Company expects this matter to negatively impact its operating results, the related financial impact and duration cannot be reasonably estimated at this time.

Except as disclosed above and elsewhere in the notes to the accompanying consolidated financial statements, the Company has concluded that no further subsequent events have occurred that require disclosure.

Exhibit 1.1

THE COMPANIES LAW (AS AMENDED)

COMPANY LIMITED BY SHARES

FIFTH AMENDED AND RESTATED

MEMORANDUM OF ASSOCIATION

OF

STEALTH BIOTHERAPEUTICS CORP

(ADOPTED BY SPECIAL RESOLUTION DATED 25 JANUARY 2019)

WALKERS

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REF: JH/CB/S7050-154362

THE COMPANIES LAW (AS AMENDED)

COMPANY LIMITED BY SHARES

FIFTH AMENDED AND RESTATED

MEMORANDUM OF ASSOCIATION

OF

STEALTH BIOTHERAPEUTICS CORP

(ADOPTED BY SPECIAL RESOLUTION DATED 25 JANUARY 2019)

1. The name of the company is Stealth Biotherapeutics Corp (the "**Company**").

2. The registered office of the Company will be situated at the offices of Intertrust Corporate Services (Cayman) Limited, 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands or at such other location as the Directors may from time to time determine.

3. The objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by any law as provided by Section 7(4) of the Companies Law (as amended) of the Cayman Islands (the "**Companies Law**").

4. The Company shall have and be capable of exercising all the functions of a natural person of full capacity irrespective of any question of corporate benefit as provided by Section 27(2) of the Companies Law.

5. The Company will not trade in the Cayman Islands with any person, firm or corporation except in furtherance of the business of the Company carried on outside the Cayman Islands; provided that nothing in this section shall be construed as to prevent the Company effecting and concluding contracts in the Cayman Islands, and exercising in the Cayman Islands all of its powers necessary for the carrying on of its business outside the Cayman Islands.

6. The liability of the shareholders of the Company is limited to the amount, if any, unpaid on the shares respectively held by them.

7. The capital of the Company is **US$225,000** divided into **750,000,000** ordinary shares with a nominal or par value of **US$0.0003** provided always that subject to the Companies Law and the Articles of Association the Company shall have power to redeem or purchase any of its shares and to sub-divide or consolidate the said shares or any of them and to issue all or any part of its capital whether original, redeemed, increased or reduced with or without any preference, priority, special privilege or other rights or subject to any postponement of rights or to any conditions or restrictions whatsoever and so that unless the conditions of issue shall otherwise expressly provide every issue of shares whether stated to be ordinary, preference or otherwise shall be subject to the powers on the part of the Company hereinbefore provided.

8. The Company may exercise the power contained in Section 206 of the Companies Law to deregister in the Cayman Islands and be registered by way of continuation in some other jurisdiction.

THE COMPANIES LAW (AS AMENDED)

COMPANY LIMITED BY SHARES

FIFTH AMENDED AND RESTATED

ARTICLES OF ASSOCIATION

OF

STEALTH BIOTHERAPEUTICS CORP

(ADOPTED BY SPECIAL RESOLUTION DATED 25 JANUARY 2019)

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OF

STEALTH BIOTHERAPEUTICS CORP

(ADOPTED BY SPECIAL RESOLUTION DATED 25 JANUARY 2019)

TABLE A

The Regulations contained or incorporated in Table 'A' in the First Schedule of the Companies Law shall not apply to Stealth Biotherapeutics Corp (the "**Company**") and the following Articles shall comprise the Articles of Association of the Company.

INTERPRETATION

1. In these Articles the following defined terms will have the meanings ascribed to them, if not inconsistent with the subject or context:

"**ADS**" means an American Depositary Share representing a Share.

"**Articles**" means these articles of association of the Company, as amended or substituted from time to time.

"**Auditor**" means the person for the time being performing the duties of auditor of the Company (if any).

"**Branch Register**" means any branch Register of such category or categories of Members as the Company may from time to time determine.

"**Class**" or "**Classes**" means any class or classes of Shares as may from time to time be issued by the Company.

"**Commission**" means the United States Securities and Exchange Commission or any other federal agency for the time being administering the Securities Act or Exchange Act.

"**Companies Law**" means the Companies Law (as amended) of the Cayman Islands.

"**Designated Stock Exchange**" means any national securities exchange or automated quotation system on which the Company's Shares, ADSs or securities are then traded, including but not limited to the Nasdaq Stock Market.

"**Directors**" means the directors of the Company for the time being, or as the case may be, the directors assembled as a board or as a committee thereof.

"**Exchange Act**" means the United States Securities Exchange Act of 1934, as it may be amended, supplemented or restated from time to time and any successor to such statute, and the rules and regulations promulgated thereunder.

"**Memorandum of Association**" means the memorandum of association of the Company, as amended or substituted from time to time.

"**Office**" means the registered office of the Company as required by the Companies Law.

"**Officers**" means the officers for the time being and from time to time of the Company.

"**Ordinary Resolution**" means a resolution:

(a) passed by a simple majority of such Shareholders as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of the Company and where a poll is taken regard shall be had in computing a majority to the number of votes to which each Shareholder is entitled; or

(b) approved in writing by all of the Shareholders entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Shareholders and the effective date of the resolution so adopted shall be the date on which the instrument, or the last of such instruments, if more than one, is executed.

"**paid up**" means paid up as to the par value in respect of the issue of any Shares and includes credited as paid up.

"**Person**" means any natural person, firm, company, joint venture, partnership, corporation, association or other entity (whether or not having a separate legal personality) or any of them as the context so requires, other than in respect of a Director or Officer in which circumstances Person shall mean any person or entity permitted to act as such in accordance with the laws of the Cayman Islands.

"**Principal Register**", where the Company has established one or more Branch Registers pursuant to the Companies Law and these Articles, means the Register maintained by the Company pursuant to the Companies Law and these Articles that is not designated by the Directors as a Branch Register.

"**Register**" means the register of Members of the Company required to be kept pursuant to the Companies Law and includes any Branch Register(s) established by the Company in accordance with the Companies Law.

"**Seal**" means the common seal of the Company (if adopted) including any facsimile thereof.

"**Secretary**" means any Person appointed by the Directors to perform any of the duties of the secretary of the Company.

"**Securities Act**" means the United States Securities Act of 1933, as it may be amended, supplemented or restated from time to time or any similar federal statute and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.

"**Share**" means a share in the capital of the Company. All references to "Shares" herein shall be deemed to be Shares of any or all Classes as the context may require. For the avoidance of doubt in these Articles the expression "Share" shall include a fraction of a Share.

"**Shareholder**" or "**Member**" means a Person who is registered as the holder of Shares in the Register and includes each subscriber to the Memorandum of Association pending entry in the Register of such subscriber.

"**Share Premium Account**" means the share premium account established in accordance with these Articles and the Companies Law.

"**signed**" means bearing a signature or representation of a signature affixed by mechanical means.

"**Special Resolution**" means a special resolution of the Company passed in accordance with the Companies Law, being a resolution:

(a) passed by a majority of not less than two-thirds of such Shareholders as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of the Company of which notice specifying the intention to propose the resolution as a special resolution has been duly given and where a poll is taken regard shall be had in computing a majority to the number of votes to which each Shareholder is entitled; or

(b) approved in writing by all of the Shareholders entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the Shareholders and the effective date of the special resolution so adopted shall be the date on which the instrument or the last of such instruments, if more than one, is executed.

"**Treasury Shares**" means Shares that were previously issued but were purchased, redeemed, surrendered or otherwise acquired by the Company and not cancelled.

2. In these Articles, save where the context requires otherwise:

   (a) words importing the singular number shall include the plural number and vice versa;

   (b) words importing the masculine gender only shall include the feminine gender and any Person as the context may require;

   (c) the word "may" shall be construed as permissive and the word "shall" shall be construed as imperative;

   (d) reference to a dollar or dollars or USD (or $) and to a cent or cents is reference to dollars and cents of the United States of America;

   (e) reference to a statutory enactment shall include reference to any amendment or re-enactment thereof for the time being in force;

   (f) reference to any determination by the Directors shall be construed as a determination by the Directors in their sole and absolute discretion and shall be applicable either generally or in any particular case; and

   (g) reference to "in writing" shall be construed as written or represented by any means reproducible in writing, including any form of print, lithograph, email, facsimile, photograph or telex or represented by any other substitute or format for storage or transmission for writing or partly one and partly another.

3. Subject to the preceding Articles, any words defined in the Companies Law shall, if not inconsistent with the subject or context, bear the same meaning in these Articles.

PRELIMINARY

4. The business of the Company may be commenced at any time after incorporation.

5. The Office shall be at such address in the Cayman Islands as the Directors may from time to time determine. The Company may in addition establish and maintain such other offices and places of business and agencies in such places as the Directors may from time to time determine.

6. The expenses incurred in the formation of the Company and in connection with the offer for subscription and issue of Shares shall be paid by the Company. Such expenses may be amortised over such period as the Directors may determine and the amount so paid shall be charged against income and/or capital in the accounts of the Company as the Directors shall determine.

7. The Directors shall keep, or cause to be kept, the Register at such place or (subject to compliance with the Companies Law and these Articles) places as the Directors may from time to time determine. In the absence of any such determination, the Register shall be kept at the Office. The Directors may keep, or cause to be kept, one or more Branch Registers as well as the Principal

Register in accordance with the Companies Law, provided always that a duplicate of such Branch Register(s) shall be maintained with the Principal Register in accordance with the Companies Law and the rules or requirements of any Designated Stock Exchange.

SHARES

8. Subject to these Articles and, where applicable, the rules of the Designated Stock Exchange, all Shares for the time being unissued shall be under the control of the Directors who may:

   (a) issue, allot and dispose of the same to such Persons, in such manner, on such terms (including the issuance of Shares by way of subscription in cash or in specie) and having such rights and being subject to such restrictions as they may from time to time determine; and

   (b) grant options with respect to such Shares and issue warrants or similar instruments with respect thereto;

   and, for such purposes, the Directors may reserve an appropriate number of Shares for the time being unissued.

9. The Directors may authorise the division of Shares into any number of Classes and sub-classes and the different Classes and sub-classes shall be authorised, established and designated (or re-designated as the case may be) and the variations in the relative rights (including, without limitation, voting, dividend and redemption rights), restrictions, preferences, privileges and payment obligations as between the different Classes (if any) may be fixed and determined by the Directors.

10. The Company may insofar as may be permitted by law, pay a commission to any Person in consideration of his subscribing or agreeing to subscribe whether absolutely or conditionally for any Shares. Such commissions may be satisfied by the payment of cash or the lodgement of fully paid-up Shares. The Company may also pay such brokerage as may be lawful on any issue of Shares.

11. The Directors may refuse to accept any application for Shares, and may accept any application in whole or in part, for any reason or for no reason.

MODIFICATION OF RIGHTS

12. Whenever the capital of the Company is divided into different Classes (and as otherwise determined by the Directors) the rights attached to any such Class may, subject to any rights or restrictions for the time being attached to any Class only be materially adversely varied or abrogated with the consent in writing of the holders of not less than two-thirds of the issued Shares of the relevant Class, or with the sanction of a resolution passed at a separate meeting of the holders of the Shares of such Class by a majority of two-thirds of the votes cast at such a meeting. To every such separate meeting all the provisions of these Articles relating to general meetings of the Company or to the proceedings thereat shall, *mutatis mutandis*, apply, except that the necessary quorum shall be one or more Persons at least holding or representing by proxy one-

third in nominal or par value amount of the issued Shares of the relevant Class (but so that if at any adjourned meeting of such holders a quorum as above defined is not present, those Shareholders who are present shall form a quorum) and that, subject to any rights or restrictions for the time being attached to the Shares of that Class, every Shareholder of the Class shall on a poll have one vote for each Share of the Class held by him. For the purposes of this Article the Directors may treat all the Classes or any two or more Classes as forming one Class if they consider that all such Classes would be affected in the same way by the proposals under consideration, but in any other case shall treat them as separate Classes. The Directors may vary the rights attaching to any Class without the consent or approval of Shareholders provided that the rights will not, in the determination of the Directors, be materially adversely varied or abrogated by such action.

13. The rights conferred upon the holders of the Shares of any Class issued with preferred or other rights (including, without limitation and for the avoidance of doubt, ordinary shares) shall not, subject to any rights or restrictions for the time being attached to the Shares of that Class, be deemed to be materially adversely varied or abrogated by, *inter alia*, the creation, allotment or issue of further Shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any Shares of any Class by the Company.

CERTIFICATES

14. No Person shall be entitled to a certificate for any or all of his Shares, unless the Directors shall determine otherwise.

15. Every share certificate of the Company shall bear any legends required under applicable laws, including the Securities Act. If any share certificate is lost, destroyed or stolen, the Directors may require the holder or holders of the relevant share to provide an indemnity in a form acceptable to the Directors. Upon such indemnity being provided, a new share certificate may be issued to the holder or holders entitled to such lost, destroyed, or stolen share certificate, unless the Directors determine otherwise.

FRACTIONAL SHARES

16. The Directors may issue fractions of a Share and, if so issued, a fraction of a Share shall be subject to and carry the corresponding fraction of liabilities (whether with respect to nominal or par value, premium, contributions or otherwise), limitations, preferences, privileges, qualifications, restrictions, rights (including, without prejudice to the generality of the foregoing, voting and participation rights) and other attributes of a whole Share. If more than one fraction of a Share of the same Class is issued to or acquired by the same Shareholder such fractions shall be accumulated.

TRANSFER OF SHARES

17. Subject to these Articles and the rules or regulations of the Designated Stock Exchange or any relevant securities laws, any Member may transfer all or any Shares by an instrument of transfer in the usual or common form or in a form prescribed by the Designated Stock Exchange or in any

other form approved by the Directors and may be under hand or, if the transferor or transferee is a clearing house or its nominee(s), by hand or by machine imprinted signature or by such other manner of execution as the Directors may approve from time to time.

18. The instrument of transfer of any Share shall be executed by or on behalf of the transferor, or if so required by the Directors, shall also be executed on behalf of the transferee and shall be accompanied by the certificate (if any) of the Shares to which it relates and such other evidence as the Directors may reasonably require to show the right of the transferor to make the transfer. Notwithstanding the foregoing, uncertificated Shares shall be transferred upon presentment of proper evidence of succession, assignation or authority to transfer in accordance with customary procedures for transferring Shares in uncertificated form. The transferor shall be deemed to remain a Shareholder until the name of the transferee is entered in the Register in respect of the relevant Shares.

19. Subject to the rules of any Designated Stock Exchange on which the Shares or ADSs in question may be listed and to any rights and restrictions for the time being attached to any Share, the Directors may in their absolute discretion decline to register any transfer of Shares without assigning any reason therefor.

20. Subject to the provisions of these Articles and rules of any Designated Stock Exchange on which the Shares or ADSs in question may be listed and to any rights and restrictions for the time being attached to any Share, the registration of transfers may be suspended and the Register closed at such times and for such periods as the Directors may from time to time determine.

21. All instruments of transfer that are registered shall be retained by the Company, but any instrument of transfer that the Directors decline to register shall (except in any case of fraud) be returned to the Person depositing the same.

TRANSMISSION OF SHARES

22. The legal personal representative of a deceased sole holder of a Share shall be the only Person recognised by the Company as having any title to the Share. In the case of a Share registered in the name of two or more holders, the survivors or survivor, or the legal personal representatives of the deceased holder of the Share, shall be the only Person recognised by the Company as having any title to the Share.

23. Any Person becoming entitled to a Share in consequence of the death or bankruptcy of a Shareholder shall upon such evidence being produced as may from time to time be required by the Directors, have the right either to be registered as a Shareholder in respect of the Share or, instead of being registered himself, to make such transfer of the Share as the deceased or bankrupt Person could have made; but the Directors shall, in either case, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by the deceased or bankrupt Person before the death or bankruptcy.

24. A Person becoming entitled to a Share by reason of the death or bankruptcy of a Shareholder shall be entitled to the same dividends and other advantages to which he would be entitled if he were the registered Shareholder, except that he shall not, before being registered as a Shareholder in respect of the Share, be entitled in respect of it to exercise any right conferred by membership in relation to meetings of the Company.

ALTERATION OF SHARE CAPITAL

25. Subject to the provisions of these Articles, the Company may by Ordinary Resolution:

(a) increase the share capital by such sum, to be divided into Shares of such Classes and amount, as the resolution shall prescribe;

(b) consolidate and divide all or any of its share capital into Shares of a larger amount than its existing Shares;

(c) convert all or any of its paid up Shares into stock and reconvert that stock into paid up Shares of any denomination;

(d) subdivide its existing Shares, or any of them into Shares of a smaller amount provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in case of the Share from which the reduced Share is derived; and

(e) cancel any Shares that, at the date of the passing of the resolution, have not been taken or agreed to be taken by any Person and diminish the amount of its share capital by the amount of the Shares so cancelled.

26. All new Shares created in accordance with the provisions of the preceding Article shall be subject to the same provisions of these Articles with reference to transfer, transmission and otherwise as the Shares in the original share capital.

27. The Company may by Special Resolution reduce its share capital and any capital redemption reserve in any manner authorised by law.

REDEMPTION, PURCHASE AND SURRENDER OF SHARES

28. Subject to the Companies Law, the Company may:

(a) issue Shares on terms that they are to be redeemed or are liable to be redeemed at the option of the Company or the Shareholder on such terms and in such manner as the Directors may determine;

(b) purchase its own Shares (including any redeemable Shares) on such terms and in such manner as the Directors may determine and agree with the Shareholder;

(c) make a payment in respect of the redemption or purchase of its own Shares in any manner authorised by the Companies Law, including out of its capital; and

(d) accept the surrender for no consideration of any paid up Share (including any redeemable Share) on such terms and in such manner as the Directors may determine.

29. Any Share in respect of which notice of redemption has been given shall not be entitled to participate in the profits of the Company in respect of the period after the date specified as the date of redemption in the notice of redemption.

30. The redemption, purchase or surrender of any Share shall not be deemed to give rise to the redemption, purchase or surrender of any other Share.

31. The Directors may when making payments in respect of redemption or purchase of Shares, if authorised by the terms of issue of the Shares being redeemed or purchased or with the agreement of the holder of such Shares, make such payment either in cash or in specie including, without limitation, interests in a special purpose vehicle holding assets of the Company or holding entitlement to the proceeds of assets held by the Company or in a liquidating structure.

TREASURY SHARES

32. Shares that the Company purchases, redeems or acquires (by way of surrender or otherwise) may, at the option of the Company, be cancelled immediately or held as Treasury Shares in accordance with the Companies Law. In the event that the Directors do not specify that the relevant Shares are to be held as Treasury Shares, such Shares shall be cancelled.

33. No dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the Company's assets (including any distribution of assets to members on a winding up) may be declared or paid in respect of a Treasury Share.

34. The Company shall be entered in the Register as the holder of the Treasury Shares provided that:

(a) the Company shall not be treated as a member for any purpose and shall not exercise any right in respect of the Treasury Shares, and any purported exercise of such a right shall be void;

(b) a Treasury Share shall not be voted, directly or indirectly, at any meeting of the Company and shall not be counted in determining the total number of issued shares at any given time, whether for the purposes of these Articles or the Companies Law, save that an allotment of Shares as fully paid bonus shares in respect of a Treasury Share is permitted and Shares allotted as fully paid bonus shares in respect of a treasury share shall be treated as Treasury Shares.

35. Treasury Shares may be disposed of by the Company on such terms and conditions as determined by the Directors.

GENERAL MEETINGS

36. The Directors may, whenever they think fit, convene a general meeting of the Company.

37. For so long as the Company's Shares or ADSs are traded on a Designated Stock Exchange, the Company shall in each year hold a general meeting as its annual general meeting at such time and place as may be determined by the Directors.

38. The Directors may cancel or postpone any duly convened general meeting at any time prior to such meeting, except for general meetings requisitioned by the Shareholders in accordance with these Articles, for any reason or for no reason at any time prior to the time for holding such meeting or, if the meeting is adjourned, the time for holding such adjourned meeting. The Directors shall give Shareholders notice in writing of any cancellation or postponement. A postponement may be for a stated period of any length or indefinitely as the Directors may determine.

39. General meetings shall also be convened on the requisition in writing of any Shareholder or Shareholders entitled to attend and vote at general meetings of the Company and to exercise at least a majority of the votes permitted to be exercised at any such meeting deposited at the Office specifying the objects of the meeting by notice given no later than 21 days from the date of deposit of the requisition signed by the requisitionists, and if the Directors do not convene such meeting for a date not later than 45 days after the date of such deposit, the requisitionists themselves may convene the general meeting in the same manner, as nearly as possible, as that in which general meetings may be convened by the Directors, and all reasonable expenses incurred by the requisitionists as a result of the failure of the Directors to convene the general meeting shall be reimbursed to them by the Company.

40. If at any time there are no Directors, any two Shareholders (or if there is only one Shareholder then that Shareholder) entitled to vote at general meetings of the Company may convene a general meeting in the same manner as nearly as possible as that in which general meetings may be convened by the Directors.

NOTICE OF GENERAL MEETINGS

41. At least ten (10) but not more than sixty (60) clear days' notice of a general meeting in writing counting from the date service is deemed to take place as provided in these Articles specifying the place, the day and the hour of the meeting and the general nature of the business, shall be given in the manner hereinafter provided or in such other manner (if any) as may be prescribed by the Company by Ordinary Resolution to such Persons as are, under these Articles, entitled to receive such notices from the Company, but with the consent of all the Shareholders entitled to receive notice of some particular meeting and attend and vote thereat, that meeting may be convened by such shorter notice or without notice and in such manner as those Shareholders may think fit.

42. The accidental omission to give notice of a meeting to or the non-receipt of a notice of a meeting by any Shareholder shall not invalidate the proceedings at any meeting.

PROCEEDINGS AT GENERAL MEETINGS

43. All business carried out at a general meeting shall be deemed special with the exception of sanctioning a dividend, the consideration of the accounts, balance sheets, any report of the Directors or of the Company's auditors, and the fixing of the remuneration of the Company's auditors. No special business shall be transacted at any general meeting without the consent of all Shareholders entitled to receive notice of that meeting unless notice of such special business has been given in the notice convening that meeting. In addition, no business may be transacted at any general meeting, other than business that is either specified in the notice of the meeting given by or at the direction of the Directors (or any duly authorised committee thereof) (including on the requisition of Shareholders in accordance with these Articles) or otherwise properly brought before an annual general meeting by or at the direction of the Directors (or any duly authorised committee thereof).

44. No business shall be transacted at any general meeting unless a quorum of Shareholders is present at the time when the meeting proceeds to business. Save as otherwise provided by these Articles, one or more Shareholders holding at least a majority of the paid up voting share capital of the Company present in person or by proxy and entitled to vote at that meeting shall form a quorum.

45. The Directors may, in their absolute discretion (i) postpone an annual general meeting convened in accordance with these Articles to such time and place as may be determined by the Directors; provided that such annual general meeting may not be postponed by more than one year from the first anniversary of the prior year's annual general meeting, or (ii) cancel any other general meeting conveyed in accordance with these Articles. The Directors shall provide notice to Shareholders of such postponement or cancellation (as applicable).

46. If within half an hour from the time appointed for the meeting a quorum is not present, the meeting, if convened upon the requisition of Shareholders, shall be dissolved. In any other case it shall stand adjourned to the same day in the next week, at the same time and place, and if at the adjourned meeting a quorum is not present within half an hour from the time appointed for the meeting the Shareholder or Shareholders present and entitled to vote shall form a quorum.

47. If the Directors wish to make this facility available for a specific general meeting or all general meetings of the Company, participation in any general meeting of the Company may be by means of a telephone, webcast or similar electronic communication equipment by way of which all Persons participating in such meeting can communicate with each other and such participation shall be deemed to constitute presence in person at the meeting.

48. The chairman, if any, of the board of Directors shall preside as chairman at every general meeting of the Company.

49. If there is no such chairman, or if at any general meeting he is not present within fifteen minutes after the time appointed for holding the meeting or is unwilling to act as chairman, any Director or Person nominated by the Directors shall preside as chairman, failing which the Shareholders present in person or by proxy shall choose any Person present to be chairman of that meeting.

50. The chairman may adjourn a meeting from time to time and from place to place either:

(a) with the consent of any general meeting at which a quorum is present (and shall if so directed by the meeting); or

(b) without the consent of such meeting if, in his sole opinion, he considers it necessary to do so to:

(i) secure the orderly conduct or proceedings of the meeting; or

(ii) give all persons present in person or by proxy and having the right to speak and / or vote at such meeting, the ability to do so,

but no business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place. When a meeting, or adjourned meeting, is adjourned for fourteen days or more, notice of the adjourned meeting shall be given in the manner provided for the original meeting. Save as aforesaid, it shall not be necessary to give any notice of an adjournment or of the business to be transacted at an adjourned meeting.

51. At any general meeting a resolution put to the vote of the meeting shall be decided on a poll.

52. At any annual general meeting where a resolution for the election of directors is proposed in accordance with these Articles, a plurality of the votes cast shall be sufficient to elect a Director.

53. In the case of an equality of votes, the chairman of the meeting at which the poll takes place, shall not be entitled to a second or casting vote.

54. A poll demanded on the election of a chairman of the meeting or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such time as the chairman of the meeting directs.

VOTES OF SHAREHOLDERS

55. Subject to any rights and restrictions for the time being attached to any Share, at a general meeting of the Company on a poll every Shareholder and every Person representing a Shareholder by proxy shall have one vote for each Share of which he or the Person represented by proxy is the holder.

56. In the case of joint holders the vote of the senior who tenders a vote whether in person or by proxy shall be accepted to the exclusion of the votes of the other joint holders and for this purpose seniority shall be determined by the order in which the names stand in the Register.

57. A Shareholder of unsound mind, or in respect of whom an order has been made by any court having jurisdiction in lunacy, may vote in respect of Shares carrying the right to vote held by him, by his committee, or other Person in the nature of a committee appointed by that court, and any such committee or other Person, may vote in respect of such Shares by proxy.

58. No Shareholder shall be entitled to vote at any general meeting of the Company in person or by proxy (or in the case of a corporation or other non-natural Person by its duly authorised representative or proxy) unless all sums presently payable by him in respect of Shares carrying the right to vote held by him have been paid.

59. On a poll, votes may be given either personally or by proxy.

60. The instrument appointing a proxy shall be in writing under the hand of the appointor or of his attorney duly authorised in writing or, if the appointor is a corporation, either under Seal or under the hand of an Officer or attorney duly authorised. A proxy need not be a Shareholder.

61. An instrument appointing a proxy may be in any usual or common form or such other form as the Directors may approve.

62. The instrument appointing a proxy shall be deposited at the Office or at such other place as is specified for that purpose in the notice convening the meeting no later than the time for holding the meeting or, if the meeting is adjourned, the time for holding such adjourned meeting.

63. The instrument appointing a proxy shall be deemed to confer authority to demand or join in demanding a poll.

64. A resolution in writing signed by all the Shareholders for the time being entitled to receive notice of and to attend and vote at general meetings of the Company (or being corporations by their duly authorised representatives) shall be as valid and effective as if the same had been passed at a general meeting of the Company duly convened and held.

CORPORATIONS ACTING BY REPRESENTATIVES AT MEETINGS

65. Any corporation which is a Shareholder or a Director may by resolution of its directors or other governing body authorise such Person as it thinks fit to act as its representative at any meeting of the Company or of any meeting of holders of a Class or of the Directors or of a committee of Directors, and the Person so authorised shall be entitled to exercise the same powers on behalf of the corporation which he represents as that corporation could exercise if it were an individual Shareholder or Director.

CLEARING HOUSES

66. If a clearing house (or its nominee) is a Member of the Company it may, by resolution of its directors or other governing body or by power of attorney, authorise such person or persons as it thinks fit to act as its representative or representatives at any general meeting of the Company or at any general meeting of any class of Members of the Company provided that, if more than one person is so authorised, the authorisation shall specify the number and class of Shares in respect of which each such person is so authorised. A person so authorised pursuant to this Article shall be entitled to exercise the same powers on behalf of the clearing house (or its nominee) which he represents

as that clearing house (or its nominee) could exercise if it were an individual Member holding the number and Class of Shares specified in such authorisation.

DEPOSITARY INTERESTS

67. The Directors shall, subject always to the Companies Law, any other applicable laws and regulations, the facilities and requirements of any relevant system concerned and the provisions of these Articles, have power to implement and/or approve any arrangements they may, in their absolute discretion, think fit in relation to (without limitation) the evidencing of title to and transfer of depositary or similar interests in shares in the capital of the Company in the form of depositary interests or similar interests, instruments or securities. The Directors may from time to time take such actions and do such things as they may, in their absolute discretion, think fit in relation to the operation of any such arrangements including, without limitation, treating holders of any depositary or similar interests relating to shares in the capital of the Company as if they were the holders directly thereof for the purposes of compliance with any obligations imposed under the Articles on Members.

DIRECTORS

68. The Directors shall be divided into three (3) classes designated as Class I, Class II and Class III, respectively. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the board of Directors. At the first annual general meeting of Members, the term of office of the Class I Directors shall expire and Class I Directors appointed at such meeting shall be elected for a full term of three (3) years. At the second annual general meeting of Members, the term of office of the Class II Directors shall expire and Class II Directors appointed at such meeting shall be elected for a full term of three (3) years. At the third annual general meeting of Members, the term of office of the Class III Directors shall expire and Class III Directors at such meeting appointed shall be elected for a full term of three (3) years. At each succeeding annual general meeting of Members, Directors shall be elected for a full term of three (3) years to succeed the Directors of the class whose terms expire at such annual general meeting. Notwithstanding the foregoing provisions of this Article, each Director shall hold office until the expiration of his term, until his successor shall have been duly elected and qualified or until his earlier death, resignation or removal. No decrease in the number of Directors constituting the board of Directors shall shorten the term of any incumbent Director.

69. The board of Directors shall in each case prior to an annual general meeting determine the maximum number of Directors to be appointed at each annual general meeting. At any annual general meeting where a resolution for the election of directors is proposed in accordance with these Articles, a plurality of the votes cast shall be sufficient to elect a Director.

70. Subject to these Articles, a Director shall hold office until such time as he is removed from office by Ordinary Resolution.

71. The board of Directors may from time to time fix the maximum and minimum number of Directors to be appointed but unless such numbers are fixed as aforesaid the minimum number of Directors shall be one and the maximum number of Directors shall be unlimited.

72. The remuneration of the Directors may be determined by the Directors.

73. There shall be no shareholding qualification for Directors.

74. The Directors shall have power at any time and from time to time to appoint any Person to be a Director, either as a result of a casual vacancy or as an additional Director, subject to the maximum number (if any) imposed and assign such Director to such class as they may determine.

ALTERNATE DIRECTOR

75. Any Director may in writing appoint another Person to be his alternate and, save to the extent provided otherwise in the form of appointment, such alternate shall have authority to sign written resolutions on behalf of the appointing Director, but shall not be authorised to sign such written resolutions where they have been signed by the appointing Director, and to act in such Director's place at any meeting of the Directors. Every such alternate shall be entitled to attend and vote at meetings of the Directors as the alternate of the Director appointing him and where he is a Director to have a separate vote in addition to his own vote. A Director may at any time in writing revoke the appointment of an alternate appointed by him. Such alternate shall not be an Officer solely as a result of his appointment as an alternate other than in respect of such times as the alternate acts as a Director. The remuneration of such alternate shall be payable out of the remuneration of the Director appointing him and the proportion thereof shall be agreed between them.

POWERS AND DUTIES OF DIRECTORS

76. Subject to the Companies Law, these Articles and to any resolutions passed in a general meeting, the business of the Company shall be managed by the Directors, who may pay all expenses incurred in setting up and registering the Company and may exercise all powers of the Company. No resolution passed by the Company in general meeting shall invalidate any prior act of the Directors that would have been valid if that resolution had not been passed.

77. The Directors may from time to time appoint any Person, whether or not a Director to hold such office in the Company as the Directors may think necessary for the administration of the Company, including but not limited to, the office of chief executive officer, chief financial officer, chief legal counsel, chief scientific officer, chief business officer, chief clinical development officer, general counsel, president, one or more vice-presidents, treasurer, assistant treasurer, manager or controller, and for such term and at such remuneration (whether by way of salary or commission or participation in profits or partly in one way and partly in another), and with such powers and duties as the Directors may think fit. Any Person so appointed by the Directors may be removed by the Directors or by the Company by Ordinary Resolution. The Directors may also appoint one or more of their number to the office of managing director upon like terms, but any such appointment shall ipso facto terminate if any managing director ceases from any cause to be a Director, or if the Company by Ordinary Resolution resolves that his tenure of office be terminated.

78. The Directors may appoint any Person to be a Secretary (and if need be an assistant Secretary or assistant Secretaries) who shall hold office for such term, at such remuneration and upon such

conditions and with such powers as they think fit. Any Secretary or assistant Secretary so appointed by the Directors may be removed by the Directors or by the Company by Ordinary Resolution.

79. The Directors may delegate any of their powers to committees consisting of such member or members of their body as they think fit; any committee so formed shall in the exercise of the powers so delegated conform to any regulations that may be imposed on it by the Directors.

80. The Directors may from time to time and at any time by power of attorney (whether under Seal or under hand) or otherwise appoint any company, firm or Person or body of Persons, whether nominated directly or indirectly by the Directors, to be the attorney or attorneys or authorised signatory (any such person being an "**Attorney**" or "**Authorised Signatory**", respectively) of the Company for such purposes and with such powers, authorities and discretion (not exceeding those vested in or exercisable by the Directors under these Articles) and for such period and subject to such conditions as they may think fit, and any such power of attorney or other appointment may contain such provisions for the protection and convenience of Persons dealing with any such Attorney or Authorised Signatory as the Directors may think fit, and may also authorise any such Attorney or Authorised Signatory to delegate all or any of the powers, authorities and discretion vested in him.

81. The Directors may from time to time provide for the management of the affairs of the Company in such manner as they shall think fit and the provisions contained in the three next following Articles shall not limit the general powers conferred by this Article.

82. The Directors from time to time and at any time may establish any committees, local boards or agencies for managing any of the affairs of the Company and may appoint any Person to be a member of such committees or local boards and may appoint any managers or agents of the Company and may fix the remuneration of any such Person.

83. The Directors from time to time and at any time may delegate to any such committee, local board, manager or agent any of the powers, authorities and discretions for the time being vested in the Directors and may authorise the members for the time being of any such local board, or any of them to fill any vacancies therein and to act notwithstanding vacancies and any such appointment or delegation may be made on such terms and subject to such conditions as the Directors may think fit and the Directors may at any time remove any Person so appointed and may annul or vary any such delegation, but no Person dealing in good faith and without notice of any such annulment or variation shall be affected thereby.

84. Any such delegates as aforesaid may be authorised by the Directors to sub-delegate all or any of the powers, authorities, and discretion for the time being vested in them.

BORROWING POWERS OF DIRECTORS

85. The Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property and uncalled capital or any part thereof, or to otherwise provide

for a security interest to be taken in such undertaking, property or uncalled capital, and to issue debentures, debenture stock and other securities whenever money is borrowed or as security for any debt, liability or obligation of the Company or of any third party.

THE SEAL

86. The Seal shall not be affixed to any instrument except by the authority of a resolution of the Directors provided always that such authority may be given prior to or after the affixing of the Seal and if given after may be in general form confirming a number of affixings of the Seal. The Seal shall be affixed in the presence of a Director or a Secretary (or an assistant Secretary) or in the presence of any one or more Persons as the Directors may appoint for the purpose and every Person as aforesaid shall sign every instrument to which the Seal is so affixed in their presence.

87. The Company may maintain a facsimile of the Seal in such countries or places as the Directors may appoint and such facsimile Seal shall not be affixed to any instrument except by the authority of a resolution of the Directors provided always that such authority may be given prior to or after the affixing of such facsimile Seal and if given after may be in general form confirming a number of affixings of such facsimile Seal. The facsimile Seal shall be affixed in the presence of such Person or Persons as the Directors shall for this purpose appoint and such Person or Persons as aforesaid shall sign every instrument to which the facsimile Seal is so affixed in their presence and such affixing of the facsimile Seal and signing as aforesaid shall have the same meaning and effect as if the Seal had been affixed in the presence of and the instrument signed by a Director or a Secretary (or an assistant Secretary) or in the presence of any one or more Persons as the Directors may appoint for the purpose.

88. Notwithstanding the foregoing, a Secretary or any assistant Secretary shall have the authority to affix the Seal, or the facsimile Seal, to any instrument for the purposes of attesting authenticity of the matter contained therein but which does not create any obligation binding on the Company.

DISQUALIFICATION OF DIRECTORS

89. The office of Director shall be vacated, if the Director:

(a) becomes bankrupt or makes any arrangement or composition with his creditors;

(b) dies or is found to be or becomes of unsound mind;

(c) resigns his office by notice in writing to the Company;

(d) is removed from office by Special Resolution; or

(e) is removed from office pursuant to any other provision of these Articles.

PROCEEDINGS OF DIRECTORS

90. The Directors may meet together (either within or outside the Cayman Islands) for the despatch of business, adjourn, and otherwise regulate their meetings and proceedings as they think fit. Questions arising at any meeting shall be decided by a majority of votes. In case of an equality of votes the chairman shall not have a second or casting vote. A Director may, and a Secretary or assistant Secretary on the requisition of a Director shall, at any time summon a meeting of the Directors.

91. A Director may participate in any meeting of the Directors, or of any committee appointed by the Directors of which such Director is a member, by means of telephone, webcast or similar electronic communication equipment by way of which all Persons participating in such meeting can communicate with each other and such participation shall be deemed to constitute presence in person at the meeting.

92. The quorum necessary for the transaction of the business of the Directors shall be a majority of the Directors then appointed. A Director represented by an alternate Director at any meeting shall be deemed to be present for the purposes of determining whether or not a quorum is present.

93. A Director who is in any way, whether directly or indirectly, interested in a contract or proposed contract with the Company shall declare the nature of his interest at a meeting of the Directors. A general notice given to the Directors by any Director to the effect that he is to be regarded as interested in any contract or other arrangement which may thereafter be made with that company or firm shall be deemed a sufficient declaration of interest in regard to any contract so made. A Director may vote in respect of any contract or proposed contract or arrangement notwithstanding that he may be interested therein and if he does so his vote shall be counted and he may be counted in the quorum at any meeting of the Directors at which any such contract or proposed contract or arrangement shall come before the meeting for consideration.

94. A Director may hold any other office or place of profit under the Company (other than the office of Auditor) in conjunction with his office of Director for such period and on such terms (as to remuneration and otherwise) as the Directors may determine and no Director or intending Director shall be disqualified by his office from contracting with the Company either with regard to his tenure of any such other office or place of profit or as vendor, purchaser or otherwise, nor shall any such contract or arrangement entered into by or on behalf of the Company in which any Director is in any way interested, be liable to be avoided, nor shall any Director so contracting or being so interested be liable to account to the Company for any profit realised by any such contract or arrangement by reason of such Director holding that office or of the fiduciary relation thereby established. A Director, notwithstanding his interest, may be counted in the quorum present at any meeting of the Directors whereat he or any other Director is appointed to hold any such office or place of profit under the Company or whereat the terms of any such appointment are arranged and he may vote on any such appointment or arrangement.

95. Any Director may act by himself or his firm in a professional capacity for the Company, and he or his firm shall be entitled to remuneration for professional services as if he were not a Director;

provided that nothing herein contained shall authorise a Director or his firm to act as Auditor to the Company.

96. The Directors shall cause minutes to be made in books or loose-leaf folders provided for the purpose of recording:

(a) all appointments of Officers made by the Directors;

(b) the names of the Directors present at each meeting of the Directors and of any committee of the Directors; and

(c) all resolutions and proceedings at all meetings of the Company, and of the Directors and of committees of Directors.

97. When the chairman of a meeting of the Directors signs the minutes of such meeting the same shall be deemed to have been duly held notwithstanding that all the Directors have not actually come together or that there may have been a technical defect in the proceedings.

98. A resolution in writing signed by all the Directors or all the members of a committee of Directors entitled to receive notice of a meeting of Directors or committee of Directors, as the case may be (an alternate Director, subject as provided otherwise in the terms of appointment of the alternate Director, being entitled to sign such a resolution on behalf of his appointer), shall be as valid and effectual as if it had been passed at a duly called and constituted meeting of Directors or committee of Directors, as the case may be. When signed a resolution may consist of several documents each signed by one or more of the Directors or his duly appointed alternate.

99. The continuing Directors may act notwithstanding any vacancy in their body but if and for so long as their number is reduced below the number fixed by or pursuant to these Articles as the necessary quorum of Directors, the continuing Directors may act for the purpose of increasing the number, or of summoning a general meeting of the Company, but for no other purpose.

100. The Directors may elect a chairman of their meetings and determine the period for which he is to hold office but if no such chairman is elected, or if at any meeting the chairman is not present within fifteen minutes after the time appointed for holding the meeting, the Directors present may choose one of their number to be chairman of the meeting.

101. Subject to any regulations imposed on it by the Directors, a committee appointed by the Directors may elect a chairman of its meetings. If no such chairman is elected, or if at any meeting the chairman is not present within fifteen minutes after the time appointed for holding the meeting, the committee members present may choose one of their number to be chairman of the meeting.

102. A committee appointed by the Directors may meet and adjourn as it thinks proper. Subject to any regulations imposed on it by the Directors, questions arising at any meeting shall be determined by a majority of votes of the committee members present and in case of an equality of votes the chairman shall not have a second or casting vote.

103. All acts done by any meeting of the Directors or of a committee of Directors, or by any Person acting as a Director, shall notwithstanding that it be afterwards discovered that there was some defect in the appointment of any such Director or Person acting as aforesaid, or that they or any of them were disqualified, be as valid as if every such Person had been duly appointed and was qualified to be a Director.

DIVIDENDS

104. Subject to any rights and restrictions for the time being attached to any Shares, or as otherwise provided for in the Companies Law and these Articles, the Directors may from time to time declare dividends (including interim dividends) and other distributions on Shares in issue and authorise payment of the same out of the funds of the Company lawfully available therefor.

105. Subject to any rights and restrictions for the time being attached to any Shares, the Company by Ordinary Resolution may declare dividends, but no dividend shall exceed the amount recommended by the Directors.

106. The Directors may determine, before recommending or declaring any dividend, to set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall be applicable for meeting contingencies, or for equalising dividends or for any other purpose to which those funds may be properly applied and pending such application may, at the determination of the Directors, either be employed in the business of the Company or be invested in such investments as the Directors may from time to time think fit.

107. Any dividend may be paid in any manner as the Directors may determine. If paid by cheque it will be sent through the post to the registered address of the Shareholder or Person entitled thereto, or in the case of joint holders, to any one of such joint holders at his registered address or to such Person and such address as the Shareholder or Person entitled, or such joint holders as the case may be, may direct. Every such cheque shall be made payable to the order of the Person to whom it is sent or to the order of such other Person as the Shareholder or Person entitled, or such joint holders as the case may be, may direct.

108. The Directors when paying dividends to the Shareholders in accordance with the foregoing provisions of these Articles may make such payment either in cash or in specie and may determine the extent to which amounts may be withheld therefrom (including, without limitation, any taxes, fees, expenses or other liabilities for which a Shareholder (or the Company, as a result of any action or inaction of the Shareholder) is liable).

109. Subject to any rights and restrictions for the time being attached to any Shares, all dividends shall be declared and paid according to the amounts paid up on the Shares, but if and for so long as nothing is paid up on any of the Shares dividends may be declared and paid according to the par value of the Shares.

110. If several Persons are registered as joint holders of any Share, any of them may give effectual receipts for any dividend or other moneys payable on or in respect of the Share.

111. No dividend shall bear interest against the Company.

BOOKS OF ACCOUNT

112. The books of account relating to the Company's affairs shall be kept in such manner as may be determined from time to time by the Directors.

113. The books of account shall be kept at the Office, or at such other place or places as the Directors think fit, and shall always be open to the inspection of the Directors.

114. The Directors may from time to time determine whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of Shareholders not being Directors, and no Shareholder (not being a Director) shall have any right of inspecting any account or book or document of the Company except as conferred by law or authorised by the Directors.

115. The accounts relating to the Company's affairs shall be audited in such manner and with such financial year end and the accounting principles as may be determined from time to time by the Directors or failing any determination as aforesaid shall not be audited.

116. The Directors in each year shall prepare, or cause to be prepared, an annual return and declaration setting forth the particulars required by the Companies Law and deliver a copy thereof to the Registrar of Companies in the Cayman Islands.

AUDIT

117. The Directors or, if authorised to do so, the audit committee of the Directors, may appoint an Auditor of the Company who shall hold office on such terms as the Directors determine.

118. Every Auditor of the Company shall have a right of access at all times to the books and accounts and vouchers of the Company and shall be entitled to require from the Directors and officers of the Company such information and explanation as may be necessary for the performance of the duties of the Auditor.

119. Auditors shall, if so required by the Directors, make a report on the accounts of the Company during their tenure of office at the next annual general meeting following their appointment in the case of a company which is registered with the Registrar of Companies as an ordinary company, and at the next extraordinary general meeting following their appointment in the case of a company which is registered with the Registrar of Companies as an exempted company, and at any other time during their term of office, upon request of the Directors or any general meeting of the Shareholders.

CAPITALISATION OF RESERVES

120. Subject to the Companies Law and these Articles, the Directors may:

(a) resolve to capitalise an amount standing to the credit of reserves (including a Share Premium Account, capital redemption reserve and profit and loss account), whether or not available for distribution, including, but not limited to, applying such sum in paying up in full unissued Shares to be allotted and issued to any depositary of the Company for the purposes of the issue, allotment and delivery by the depository of ADSs to employees (including Directors) or service providers of the Company upon exercise or vesting of any options or awards granted under any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the Directors and the Members;

(b) appropriate the sum resolved to be capitalised to the Shareholders in proportion to the nominal amount of Shares (whether or not fully paid) held by them respectively and apply that sum on their behalf in or towards:

(i) paying up the amounts (if any) for the time being unpaid on Shares held by them respectively, or

(ii) paying up in full unissued Shares or debentures of a nominal amount equal to that sum,

and allot the Shares or debentures, credited as fully paid, to the Shareholders (or as they may direct) in those proportions, or partly in one way and partly in the other, but the Share Premium Account, the capital redemption reserve and profits which are not available for distribution may, for the purposes of this Article, only be applied in paying up unissued Shares to be allotted to Shareholders credited as fully paid;

(c) make any arrangements they think fit to resolve a difficulty arising in the distribution of a capitalised reserve and in particular, without limitation, where Shares or debentures become distributable in fractions the Directors may deal with the fractions as they think fit;

(d) authorise a Person to enter (on behalf of all the Shareholders concerned) into an agreement with the Company providing for either:

(i) the allotment to the Shareholders respectively, credited as fully paid, of Shares or debentures to which they may be entitled on the capitalisation, or

(ii) the payment by the Company on behalf of the Shareholders (by the application of their respective proportions of the reserves resolved to be capitalised) of the amounts or part of the amounts remaining unpaid on their existing Shares,

and any such agreement made under this authority being effective and binding on all those Shareholders; and

(e) generally do all acts and things required to give effect to any of the actions contemplated by this Article.

SHARE PREMIUM ACCOUNT

121. The Directors shall in accordance with the Companies Law establish a Share Premium Account and shall carry to the credit of such account from time to time a sum equal to the amount or value of the premium paid on the issue of any Share.

122. There shall be debited to any Share Premium Account on the redemption or purchase of a Share the difference between the nominal value of such Share and the redemption or purchase price provided always that at the determination of the Directors such sum may be paid out of the profits of the Company or, if permitted by the Companies Law, out of capital.

NOTICES

123. Any notice or document may be served by the Company or by the Person entitled to give notice to any Shareholder either personally, or by posting it airmail or air courier service in a prepaid letter addressed to such Shareholder at his address as appearing in the Register, or by electronic mail to any electronic mail address such Shareholder may have specified in writing for the purpose of such service of notices, or by facsimile should the Directors deem it appropriate. In the case of joint holders of a Share, all notices shall be given to that one of the joint holders whose name stands first in the Register in respect of the joint holding, and notice so given shall be sufficient notice to all the joint holders.

124. Any Shareholder present, either personally or by proxy, at any meeting of the Company shall for all purposes be deemed to have received due notice of such meeting and, where requisite, of the purposes for which such meeting was convened.

125. Any notice or other document, if served by:

(a) post, shall be deemed to have been served five clear days after the time when the letter containing the same is posted;

(b) facsimile, shall be deemed to have been served upon production by the transmitting facsimile machine of a report confirming transmission of the facsimile in full to the facsimile number of the recipient;

(c) recognised courier service, shall be deemed to have been served 48 hours after the time when the letter containing the same is delivered to the courier service; or

(d) electronic mail, shall be deemed to have been served immediately upon the time of the transmission by electronic mail.

In proving service by post or courier service it shall be sufficient to prove that the letter containing the notice or documents was properly addressed and duly posted or delivered to the courier service.

126. Any notice or document delivered or sent in accordance with the terms of these Articles shall notwithstanding that such Shareholder be then dead or bankrupt, and whether or not the Company has notice of his death or bankruptcy, be deemed to have been duly served in respect of any Share registered in the name of such Shareholder as sole or joint holder, unless his name shall at the time of the service of the notice or document, have been removed from the Register as the holder of the Share, and such service shall for all purposes be deemed a sufficient service of such notice or document on all Persons interested (whether jointly with or as claiming through or under him) in the Share.

127. Notice of every general meeting of the Company shall be given to:

(a) all Shareholders holding Shares with the right to receive notice and who have supplied to the Company an address for the giving of notices to them; and

(b) every Person entitled to a Share in consequence of the death or bankruptcy of a Shareholder, who but for his death or bankruptcy would be entitled to receive notice of the meeting.

No other Person shall be entitled to receive notices of general meetings.

INDEMNITY

128. Every Director (including for the purposes of this Article any alternate Director appointed pursuant to the provisions of these Articles), Secretary, assistant Secretary, or other Officer (but not including the Company's Auditors) and the personal representatives of the same (each an "**Indemnified Person**") shall be indemnified and secured harmless out of the assets and funds of the Company against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such Indemnified Person, other than by reason of such Indemnified Person's own dishonesty, wilful default or fraud as determined by a court of competent jurisdiction, in or about the conduct of the Company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such Indemnified Person in defending (whether successfully or otherwise) any civil proceedings concerning the Company or its affairs in any court whether in the Cayman Islands or elsewhere.

129. No Indemnified Person shall be liable:

(a) for the acts, receipts, neglects, defaults or omissions of any other Director or Officer or agent of the Company; or

(b) for any loss on account of defect of title to any property of the Company; or

(c) on account of the insufficiency of any security in or upon which any money of the Company shall be invested; or

(d) for any loss incurred through any bank, broker or other similar Person; or

(e) for any loss occasioned by any negligence, default, breach of duty, breach of trust, error of judgement or oversight on such Indemnified Person's part; or

(f) for any loss, damage or misfortune whatsoever which may happen in or arise from the execution or discharge of the duties, powers, authorities, or discretions of such Indemnified Person's office or in relation thereto;

unless the same shall happen through such Indemnified Person's own dishonesty, wilful default or fraud as determined by a court of competent jurisdiction.

NON-RECOGNITION OF TRUSTS

130. Subject to the proviso hereto, no Person shall be recognised by the Company as holding any Share upon any trust and the Company shall not, unless required by law, be bound by or be compelled in any way to recognise (even when having notice thereof) any equitable, contingent, future or partial interest in any Share or (except only as otherwise provided by these Articles or as the Companies Law requires) any other right in respect of any Share except an absolute right to the entirety thereof in each Shareholder registered in the Register, provided that, notwithstanding the foregoing, the Company shall be entitled to recognise any such interests as shall be determined by the Directors.

WINDING UP

131. If the Company shall be wound up the liquidator shall apply the assets of the Company in such manner and order as he thinks fit in satisfaction of creditors' claims.

132. If the Company shall be wound up, the liquidator may, with the sanction of an Ordinary Resolution divide amongst the Shareholders in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose set such value as he deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as between the Shareholders or different Classes. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the Shareholders as the liquidator, with the like sanction shall think fit, but so that no Shareholder shall be compelled to accept any assets whereon there is any liability.

AMENDMENT OF ARTICLES OF ASSOCIATION

133. Subject to the Companies Law and the rights attaching to the various Classes, the Company may at any time and from time to time by Special Resolution alter or amend these Articles in whole or in part.

CLOSING OF REGISTER OR FIXING RECORD DATE

134. For the purpose of determining those Shareholders that are entitled to receive notice of, attend or vote at any meeting of Shareholders or any adjournment thereof, or those Shareholders that are entitled to receive payment of any dividend, or in order to make a determination as to who is a Shareholder for any other purpose, the Directors may provide that the Register shall be closed for transfers for a stated period which shall not exceed in any case 40 days. If the Register shall be so closed for the purpose of determining those Shareholders that are entitled to receive notice of, attend or vote at a meeting of Shareholders the Register shall be so closed for at least ten days immediately preceding such meeting and the record date for such determination shall be the date of the closure of the Register.

135. In lieu of or apart from closing the Register, the Directors may fix in advance a date as the record date for any such determination of those Shareholders that are entitled to receive notice of, attend or vote at a meeting of the Shareholders and for the purpose of determining those Shareholders that are entitled to receive payment of any dividend the Directors may, at or within 90 days prior to the date of declaration of such dividend, fix a subsequent date as the record date for such determination.

136. If the Register is not so closed and no record date is fixed for the determination of those Shareholders entitled to receive notice of, attend or vote at a meeting of Shareholders or those Shareholders that are entitled to receive payment of a dividend, the date on which notice of the meeting is posted or the date on which the resolution of the Directors declaring such dividend is adopted, as the case may be, shall be the record date for such determination of Shareholders. When a determination of those Shareholders that are entitled to receive notice of, attend or vote at a meeting of Shareholders has been made as provided in this Article, such determination shall apply to any adjournment thereof.

REGISTRATION BY WAY OF CONTINUATION

137. The Company may by Special Resolution resolve to be registered by way of continuation in a jurisdiction outside the Cayman Islands or such other jurisdiction in which it is for the time being incorporated, registered or existing. In furtherance of a resolution adopted pursuant to this Article, the Directors may cause an application to be made to the Registrar of Companies to deregister the Company in the Cayman Islands or such other jurisdiction in which it is for the time being incorporated, registered or existing and may cause all such further steps as they consider appropriate to be taken to effect the transfer by way of continuation of the Company.

MERGERS AND CONSOLIDATION

138. The Company may merge or consolidate in accordance with the Companies Law.

139. To the extent required by the Companies Law, the Company may by Special Resolution resolve to merge or consolidate the Company.

DISCLOSURE

140. The Directors, or any authorised service providers (including the Officers, the Secretary and the registered office agent of the Company), shall be entitled to disclose to any regulatory or judicial authority, or to any stock exchange on which the Shares or ADSs may from time to time be listed, any information regarding the affairs of the Company including, without limitation, information contained in the Register and books of the Company.

Registrar of Companies
Government Administration Building
133 Elgin Avenue
George Town
Grand Cayman

Stealth BioTherapeutics Corp (with registered number 165223) (the "Company")

TAKE NOTICE that by ordinary resolution of the members passed on 25 March 2020 the authorised share capital of the Company was increased from US$225,000 divided into 750,000,000 ordinary shares with a par value of US$0.0003 each to US$360,000 divided into 1,200,000,000 ordinary shares of a nominal or par value of US$0.0003 each.

Exhibit 2.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES PURSUANT TO SECTION 12 OF THE EXCHANGE ACT

The following description of the American Depositary Shares ("ADSs"), each representing 12 ordinary shares, $0.0003 nominal value per share, of Stealth BioTherapeutics Corp ("us," "our," "we," or "the Company"), which are the only securities of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), summarizes certain information regarding the ADSs in our articles of association (the "Articles of Association"), the deposit agreement among us, Citibank, N.A. ("Citibank"), the ADS holders and all other persons indirectly or beneficially holding ADSs (the "deposit agreement") and applicable provisions of the Companies Law (2020 Revision) of the Cayman Islands (the "Companies Law") and the common law of the Cayman Islands, and is qualified by reference to our Articles of Association and the form of deposit agreement, which are incorporated by reference as Exhibits 1.1 and 2.1, respectively, to the Report on Form 20-F, of which this Exhibit 2.3 is a part. Our ADSs are listed and trade on the Nasdaq Global Market. The ordinary shares underlying the ADSs are held by Citibank, as depositary.

DESCRIPTION OF SHARE CAPITAL

Issued Share Capital

Our authorized share capital is US$360,000 divided into 1,200,000,000 ordinary shares. Our ordinary shares may be held in either certificated or uncertificated form.

Registrar

Our register of members, or share register, reflects only record owners of our ordinary shares. Holders of our ADSs are not treated as one of our shareholders and their names are therefore not entered in our share register. The depositary, the custodian or their nominees are the holders of the shares underlying our ADSs.

Articles of Association

Subject to other provisions in our Articles of Association, our shareholders may by ordinary resolution increase our authorized share capital or by special resolution reduce the share capital and amend our Articles of Association.

General

All of our outstanding ordinary shares are fully paid and non-assessable.

Our issued and outstanding ordinary shares are not entitled to any preemptive conversion or redemption rights at the sole option of the holder of ordinary shares. Our shareholders may freely hold and vote their shares (subject to certain restrictions contained in our Articles of Association, such as the process for validly appointing a proxy).

Our board of directors may provide for other classes of shares, including classes of preferred shares, out of our authorized but unissued share capital, which could be utilized for a variety of corporate purposes, including future offerings to raise capital for corporate purposes or for use in employee benefit plans. Such additional classes of shares shall have such rights, restrictions, preferences, privileges and payment obligations as determined by our board of directors. If we issue any preferred shares, the rights, preferences and privileges of holders of our ordinary shares will be subject to, and may be adversely affected by, the rights of the holders of such preferred shares. See "—Variation of Rights of Shares."

Repurchase Rights

Any repurchase of our own shares by us as may be agreed with the relevant shareholders shall be approved by our board of directors in compliance with the Companies Law and our Articles of Association, and we may make a payment in respect of such repurchase in any manner authorized by the Companies Law and our Articles of Association, including out of our capital. A payment out of capital by a Cayman Islands company is not lawful unless immediately following the date on which the payment out of capital is proposed to be made the company shall be able to pay its debts as they fall due in the ordinary course of business. Only shares that are fully paid may be repurchased, and there must be at least one share remaining in issue following the repurchase.

Voting Rights

Voting at any meeting of shareholders is by a poll. Each ordinary share is entitled to one vote.

A quorum required for a meeting of shareholders consists of at least one or more of shareholders present in person or by proxy and entitled to vote representing the holders of at least a majority of all of our issued voting share capital. Shareholders' meetings are held annually and may otherwise be convened by our board of directors on its own initiative, with at least 10 days advance notice to the shareholders. Shareholders' meetings shall also be convened on the requisition in writing of any shareholder or shareholders holding at least a majority of the issued voting share capital, subject to certain procedural requirements. Advance notice of at least 21 days is required for convening extraordinary general meetings.

Any ordinary resolution to be made by our shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast in person or by proxy at a meeting of our shareholders. A special resolution requires the affirmative vote of not

less than two-thirds of the votes cast in person or by proxy at a meeting of our shareholders. A special resolution is required for certain matters specified in the Companies Law as requiring approval by special resolution, including, without limitation, amending our Articles of Association, reducing our authorized share capital, changing our name, and appointing a voluntary liquidator.

An ordinary resolution or a special resolution may also be adopted by way of unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

Dividends

With the exception of section 34 of the Companies Law, there are no statutory provisions relating to the payment of dividends in the Cayman Islands. Based upon English case law, which is regarded as persuasive in the Cayman Islands, dividends may be paid only out of profits. Section 34 of the Companies Law permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account.

Liquidation

On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), assets available for distribution among the holders of ordinary shares shall be distributed among the holders of the ordinary shares on a pro rata basis.

Transfer of Shares

Subject to the restrictions of our Articles of Association and the Nasdaq Listing Rules or any relevant securities law, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form prescribed by Nasdaq or any other form approved by our board of directors.

Subject to the Nasdaq Listing Rules and any rights or restrictions for time being attached to any share, our board of directors may in their absolute discretion decline to register any transfer of shares.

Subject to our Articles of Association and the Nasdaq Listing Rules and any rights or restrictions for time being attached to any share, the registration of transfers of shares may be suspended and our register of members closed at such times and for such periods as our board of directors may from time to time determine.

Variation of Rights of Shares

The rights attached to any class of shares may, subject to any rights or restrictions attached to any class, be materially adversely varied or abrogated only with written consent of the holders of not less than two-thirds of the issued shares of the relevant class or with the sanction of a resolution passed at a separate meeting of the holders of the shares of such class by a majority of two-thirds of the votes cast at such a meeting.

The rights conferred upon the shareholders of any class (including, without limitation and for the avoidance of doubt, the ordinary shares) shall not, subject to any rights or restrictions attached to the shares of that class, be deemed to be materially adversely varied or abrogated by, among other things, the creation, allotment or issuance of further shares ranking pari passu with or subsequent to such class or the redemption or purchase of any shares of any class by us.

Inspection of Books and Records

Holders of our ordinary shares have no general right under the Companies Law to inspect or obtain copies of our register of members or our corporate records other than our Articles of Association or our register of mortgages and charges.

Borrowing Power

Our board of directors may exercise all powers to borrow money and to mortgage or charge our undertaking, property and uncalled capital, to provide for a security interest to be taken in such undertaking, property or uncalled capital, to issue debentures, debenture stock and other securities whenever money is borrowed or as security for any debt, liability or obligation of us or of any third party.

Limitations on the Rights to Own Ordinary Shares

There are no specific limitations under our Articles of Association or under the Companies Law that limit the right of non-resident or foreign owners to hold or vote ordinary shares.

Change of Control

There is no specific provision in our Articles of Association or under the Companies Law that would have the effect of delaying, deferring or preventing a change of control and that would operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of our subsidiaries).

Ownership Threshold

There is no specific provision in our Articles of Association or under the Companies Law that govern the ownership threshold above which shareholder ownership in the Company must be disclosed.

Differences in Corporate Law

	DELAWARE	CAYMAN ISLANDS
Title of Organizational Documents	Certificate of Incorporation and Bylaws	Memorandum and Articles of Association
Duties of Directors	Under Delaware law, the business and affairs of a corporation are managed by or under the direction of its board of directors. In exercising their powers, directors are charged with a fiduciary duty of care to protect the interests of the corporation and a fiduciary duty of loyalty to act in the best interests of its shareholders. The duty of care requires that directors act in an informed and deliberative manner and inform themselves, prior to making a business decision, of all material information reasonably available to them. The duty of care also requires that directors exercise care in overseeing and investigating the conduct of the corporation's employees. The duty of loyalty may be summarized as the duty to act in good faith, not out of self-interest, and in a manner which the director reasonably believes to be in the best interests of the shareholders.	As a matter of Cayman Islands law, directors of Cayman Islands companies owe fiduciary duties to the company which include, amongst other things, a duty to act in good faith in their dealings with or on behalf of the company and exercise their powers and fulfill the duties of their office honestly. Five core duties are: ■ a duty to act in good faith in what the directors *bona fide* consider to be the best interests of the company (and in this regard, it should be noted that the duty is owed to the company and not to associate companies, subsidiaries or holding companies); ■ a duty not to personally profit from opportunities that arise from the office of director (unless the company permits him to do so); ■ a duty of trusteeship of the company's assets; ■ a duty to avoid conflicts of interest; and ■ a duty to exercise powers for the purpose for which such powers were conferred. A director of a Cayman Islands company also owes the company a duty to act with skill, care and diligence. A director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be expected from a person of his or her knowledge and experience.
Limitations on Personal Liability of Directors	Subject to the limitations described below, a certificate of incorporation may provide for the elimination or limitation of the personal liability of a director to the corporation or its shareholders for monetary damages for a breach of fiduciary duty as a director. Such provision cannot limit liability for breach of loyalty, acts or omissions not in good faith, intentional misconduct, unlawful payment of dividends or unlawful share purchase or redemption. In addition, the certificate of incorporation cannot limit liability for any act or omission occurring prior to the date when such provision becomes effective.	The Companies Law has no equivalent provision to Delaware law regarding the limitation of director's liability. However, as a matter of public policy, Cayman Islands law will not allow the limitation of a director's liability to the extent that the liability is a consequence of the director committing a crime or of the director's own fraud, dishonesty or willful default.

	DELAWARE	CAYMAN ISLANDS
Indemnification of Directors, Officers, Agents, and Others	A corporation has the power to indemnify any director, officer, employee, or agent of the corporation who was, is, or is threatened to be made a party who acted in good faith and in a manner they believed to be in the best interests of the corporation, and if with respect to a criminal proceeding, had no reasonable cause to believe his conduct would be unlawful, against amounts actually and reasonably incurred.	Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of directors and officers, except to the extent any such provision may be held by the Cayman Islands Court to be contrary to public policy, such as to provide indemnification against the consequences of committing a crime, or against the indemnified person's own fraud, dishonesty or willful default.

	DELAWARE	CAYMAN ISLANDS
Interested Directors Voting Requirements	Under Delaware law, a transaction in which a director who has an interest is not void or voidable solely because such interested director is present at or participates in the meeting that authorizes the transaction if: (i) the material facts as to such interested director's relationship or interests are disclosed or are known to the board of directors and the board in good faith authorizes the transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors are less than a quorum, (ii) such material facts are disclosed or are known to the shareholders entitled to vote on such transaction and the transaction is specifically approved in good faith by vote of the shareholders, or (iii) the transaction is fair as to the corporation as of the time it is authorized, approved or ratified. Under Delaware law, a director could be held liable for any transaction in which such director derived an improper personal benefit. The certificate of incorporation may include a provision requiring supermajority approval by the directors or shareholders for any corporate action. In addition, under Delaware law, certain business combinations involving interested shareholders require approval by a supermajority of the non-interested shareholders.	Under our Articles of Association, directors who are in any way, whether directly or indirectly, interested in a contract or proposed contract with our company must declare the nature of their interest at a meeting of the board of directors. Following such declaration, a director may vote in respect of any contract or proposed contract notwithstanding his interest; provided that, in exercising any such vote, such director's duties remain as described above. As a matter of Cayman Islands law, certain matters must be approved by special resolution of the shareholders, including amending or adopting memorandum or articles of association of a Cayman Islands company, appointment of inspectors to examine company affairs, reduction of share capital (subject, in relevant circumstances, to court approval), change of name, authorization of a plan of merger or transfer by way of continuation to another jurisdiction or consolidation, voluntary winding up of the company or the recalling of the liquidation of the company. The Companies Law requires that a special resolution be passed by a majority of at least two-thirds or such higher percentage as set forth in the articles of association, of shareholders being entitled to vote and do vote in person or by proxy at a general meeting, or by unanimous written consent of shareholders entitled to vote at a general meeting. Our Articles of Association does not provide for a higher threshold. The Companies Law defines "special resolutions" only. A company's articles of association can therefore tailor the definition of "ordinary resolutions" as a whole, or with respect to specific provisions. Our Articles of Association provide that an ordinary resolution is a resolution (i) passed by a simple majority of such shareholders as, being entitled to do so, vote in person (or, where proxies are allowed, by proxy) at a general meeting and regard shall be had in computing a majority to the number of votes to which each shareholder is entitled or (ii) approved in writing by all of the shareholders entitled to vote at a general meeting in one or more instruments each signed by one or more of the shareholders and the effective date of the resolution so adopted shall be the date on which the instrument (or the last of such instruments, if more than one) is executed.
Voting for Directors	Under Delaware law, unless otherwise specified in the certificate of incorporation or bylaws of the corporation, directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors.	Our Articles of Association provide that at an annual general meeting where a resolution for the election of directors is proposed in accordance with our Articles of Association, a plurality of the votes cast shall be sufficient to elect a director.
Cumulative Voting	No cumulative voting for the election of directors unless so provided in the certificate of incorporation.	No cumulative voting for the election of directors unless so provided in the articles of association. Our Articles of Association do not provide for cumulative voting on the election of the directors as described above.
Directors' Powers Regarding Bylaws	The certificate of incorporation may grant the directors the power to adopt, amend or repeal bylaws.	Our Articles of Association may only be amended by a special resolution of the shareholders.
Nomination and Removal of Directors and Filling Vacancies on Board	Shareholders may generally nominate directors if they comply with advance notice provisions and other procedural requirements in company bylaws. Holders of a majority of the shares may remove a director with or without cause, except in certain cases involving a classified board or if the company uses cumulative voting. Unless otherwise provided for in the certificate of incorporation or bylaws, directorship vacancies are filled by a majority of the directors elected or then in office.	Nomination and removal of directors and filling of board vacancies are governed by the terms of the articles of association. Our Articles of Association provide that a director shall hold office until such time they resign upon the expiry of a full term of three years, if they are removed from office by ordinary resolution of the shareholders or otherwise in accordance with our Articles of Association.

DELAWARE	CAYMAN ISLANDS

	DELAWARE	CAYMAN ISLANDS
Mergers and Similar Arrangements	Under Delaware law, with certain exceptions, a merger, consolidation, exchange or sale of all or substantially all the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. Under Delaware law, a shareholder of a corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such shareholder would otherwise receive in the transaction. Delaware law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary, of which it owns at least 90% of each class of capital stock without a vote by shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights.	The Companies Law provides for the merger or consolidation of two or more companies into a single entity. The legislation makes a distinction between a "consolidation" and a "merger." In a consolidation, a new entity is formed from the combination of each participating company, and the separate consolidating parties, as a consequence, cease to exist and are each stricken by the Registrar of Companies in the Cayman Islands, referred to as the Registrar of Companies. In a merger, one company remains as the surviving entity, having in effect absorbed the other merging parties that then cease to exist. Two or more Cayman Islands-registered companies may merge or consolidate. Cayman Islands-registered companies may also merge or consolidate with overseas companies provided that the laws of the foreign jurisdiction permit such merger or consolidation. A plan of merger or consolidation shall be authorized by each constituent company by way of (i) a special resolution of the members of each such constituent company; and (ii) such other authorization, if any, as may be specified in such constituent company's articles of association. If one of the constituent companies is an overseas company, a declaration from a director of the overseas company is required to confirm that the merger or consolidation is permitted or not prohibited by the constituent overseas company and by the laws of the jurisdiction in which the overseas company is existing, and that those constitutional documents have been or will be complied with. Shareholder approval is not required where a parent company registered in the Cayman Islands seeks to merge with one or more of its subsidiaries registered in the Cayman Islands and a copy of the plan of merger is given to every member of each subsidiary company to be merged unless that member agrees otherwise. Secured creditors must consent to the merger although application can be made to the Cayman Islands Court for such requirement to be waived if such secured creditor does not grant its consent to the merger. Where an overseas company wishes to merge with a Cayman Islands company, consent or approval to the transfer of any security interest granted by the overseas company to the resulting Cayman Islands entity in the transaction is required, unless otherwise released or waived by the secured party. If the merger plan is approved, it is then filed with the Cayman Islands General Registry along with a declaration by a director of each company. The Registrar of Companies will then issue a certificate of merger which shall be prima facie evidence of compliance with all requirements of the Companies Law in respect of the merger or consolidation. The surviving or consolidated entity remains or becomes active while the other company or companies are automatically dissolved. Unless the shares of such shareholder are publicly listed or quoted, dissenting shareholders in a merger or consolidation of this type are entitled to payment of the fair value of their shares if such shareholder provides a written objection before the vote on such merger or consolidation. With respect to shares that are listed or quoted, a shareholder shall have similar rights only if it is required by the terms of the merger or consolidation to accept for such shares property other than (i) shares (or depositary receipts in respect thereof) in the surviving or consolidated company; (ii) listed or quoted shares (or depositary receipts in respect thereof) of another company; (iii) cash in lieu of any fractions of shares or depositary receipts described at (i) and (ii); or (iv) any combination of shares, depositary receipts or cash described in (i)—(iii). Cayman Islands companies may also be restructured or amalgamated under supervision of the Cayman Islands Court by way of a court-sanctioned "scheme of arrangement." A scheme of arrangement is one of several transactional mechanisms available in the Cayman Islands for achieving a restructuring. Others include share capital exchange, merger (as described above), asset acquisition or control, through contractual arrangements, of an operating business. A Cayman Islands Court scheme of arrangement requires the approval of a majority in number, of each class of shareholders and creditors with whom the arrangement is to be made and who must in addition represent three-fourths in value of each

		such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at the meeting summoned for that purpose. The convening of the meetings and subsequently the terms of the arrangement must be sanctioned by the Cayman Islands Court. While a dissenting shareholder would have the right to express to the Cayman Islands Court its view that the transaction ought not be approved, the Cayman Islands Court can be expected to approve the scheme of arrangement if it is satisfied that: ■ the classes which are required to approve the scheme of arrangement have been properly constituted, so that the members of such classes are properly represented; ■ the meetings held by the company in relation to the approval of the scheme of arrangement by such classes have been convened and held in accordance with any directions given by the Cayman Islands Court; ■ the scheme of arrangement has been properly explained to the shareholders or creditors so that they have been able to exercise an informed vote in respect of the scheme; the scheme of arrangement is one which an intelligent and honest man, who is a member of the relevant class and properly acting might approve. When a takeover offer is made and accepted by holders of 90% of the shares within four months, the offeror may, within a two-month period following the expiration of the said four month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection may be made to the Cayman Islands Court but is unlikely to succeed unless there is evidence of fraud, bad faith or collusion. If the arrangement and reconstruction are thus approved, any dissenting shareholders would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of U.S. corporations, providing rights to receive payment in cash for the judicially determined value of the shares. Our Articles of Association provide that we may by special resolution resolve to merge or consolidate in accordance with the Companies Law.
Shareholder Suits	Class actions and derivative actions generally are available to shareholders under Delaware law for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court generally has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.	The rights of shareholders under Cayman Islands law are not as extensive as those under Delaware law. Class actions are generally not available to shareholders under Cayman Islands laws; historically, there have not been any reported instances of such class actions having been successfully brought before the Cayman Islands Court. In principle, we will normally be the proper plaintiff and a derivative action may be brought by a minority shareholder in only limited circumstances. In this regard, the Cayman Islands Court would ordinarily be expected to follow English case law precedent, which would permit a shareholder to commence an action in the company's name to remedy a wrong done to the company where the act complained of cannot be ratified by the shareholders and where control of the company by the wrongdoer results in the company not pursuing a remedy itself. The case law shows that derivative actions have been permitted in respect of acts that are beyond the company's corporate power, illegal, where the individual rights of the plaintiff shareholder have been infringed or are about to be infringed and acts that are alleged to constitute a "fraud on the minority." The winning party in such an action generally would be able to recover a portion of attorney's fees incurred in connection with such action.

	DELAWARE	CAYMAN ISLANDS
Inspection of Corporate Records	Under Delaware law, shareholders of a Delaware corporation have the right during normal business hours to inspect for any proper purpose, and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation.	Shareholders of a Cayman Islands exempted company have no general right under Cayman Islands law to inspect or obtain copies of the register of members or other corporate records (other than the register of mortgages or charges) of the company. However, these rights may be provided in the company's articles of association. Our Articles of Association provide that the holders of our ordinary shares will have no general right to inspect or obtain copies of our register of members or our corporate records other than our Articles of Association. The Registrar of Companies shall make available the list of the names of the current directors of a Cayman Islands company and, where applicable, the current alternate directors of a Cayman Islands company for inspection by any person, on payment of the fee required under the Companies Law for each inspection and subject to such conditions as the Registrar of Companies may impose.
Shareholder Proposals	Unless provided in the corporation's certificate of incorporation or bylaws, Delaware law does not include a provision restricting the manner in which shareholders may bring business before a meeting.	The Companies Law does not provide shareholders any right to bring business before a meeting or requisition a general meeting. However, these rights may be provided in the company's articles of association. Our Articles of Association provide for extraordinary general meeting to be convened on the requisition in writing of any shareholder(s) entitled to attend and vote at our extraordinary general meetings and to exercise at least a majority of the votes permitted to be exercised at any such meeting subject to certain procedural requirements.
Approval of Corporate Matters by Written Consent	Delaware law permits shareholders to take action by written consent signed by the holders of outstanding shares having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting of shareholders.	The Companies Law allows a special resolution to be passed in writing only if signed by all the voting shareholders (if authorized by the articles of association).
Calling of Special Shareholders Meetings	Delaware law permits the board of directors or any person who is authorized under a corporation's certificate of incorporation or bylaws to call a special meeting of shareholders.	The Companies Law does not have provisions governing the proceedings of shareholders meetings which are usually provided in the articles of association. Our Articles of Association provide for an extraordinary general meeting to be convened on the requisition in writing of any shareholder(s) entitled to attend and vote at our extraordinary general meetings and to exercise at least a majority of the votes permitted to be exercised at any such meeting subject to certain procedural requirements.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

General

Citibank is acting as the depositary for the ADSs. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts (the "ADRs"). The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A.—Hong Kong, located at 9/F, Citi Tower, One Bay East, 83 Hoi Bun Road, Kwun Tong, Kowloon, Hong Kong. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, 12 ordinary shares that are on deposit with the depositary and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-ordinary

shares ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If a person becomes an owner of ADSs, that person will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents the holder's ADSs. The deposit agreement and the ADR specify our rights and obligations as well as the ADS holder's rights and obligations as owner of ADSs and those of the depositary. The ADS holders appoint the depositary to act on their behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws of the United States.

In addition, applicable laws and regulations may require the ADS holder to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. The ADS holder is solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on the ADS holder's behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

Holders of ADSs are not treated as one of our shareholders and will not have direct shareholder rights. The depositary will hold on the ADS holders' behalf the shareholder rights attached to the ordinary shares underlying the ADSs.

Holders of ADSs will be able to exercise the shareholders rights for the ordinary shares represented by the ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement, the holders of ADSs need to arrange for the cancellation of the ADSs and become a direct shareholder.

The manner in which the ADS holder owns the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertified ADSs) may affect the ADS holder's rights and obligations, and the manner in which, and extent to which, the depositary's services are made available to the ADS holder. As an owner of ADSs, the ADS holder may hold his or her ADSs either by means of an ADR registered in the holder's name, through a brokerage or safekeeping account, or through an account established by the depositary in the holder's name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system or DRS). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If the ADS holder decides to hold his or her ADSs through the holder's brokerage or safekeeping account, the holder must rely on the procedures of the holder's broker or bank to assert the holder's rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit the ADS holder's ability to exercise the ADS holder's rights as an owner of ADSs. The ADS holder should consult with his or her broker or bank if the ADS holder has any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes the ADS holder has opted to own the ADSs directly by means of an ADS registered in the ADS holder's name and, as such, we will refer to the ADS holder as the "holder."

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Distributions

Holders of ADSs generally have the right to receive the distributions we make on the securities deposited with the custodian. Their receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of the Cayman Islands.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS the holder holds will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). The holder of ADSs may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of the holder's rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depositary will not distribute the rights to the holder of ADSs if:

- we do not timely request that the rights be distributed to the holder or we request that the rights not be distributed to the holder; or
- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to the holder of ADSs. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to the ADS holder only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable the ADS holder to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to the ADS holder, the ADS holder will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to the holder of ADSs. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to the holder of ADSs and if we provide to the depositary all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to the holder of ADSs and will sell the property if:

- we do not request that the property be distributed to the holder or if we ask that the property not be distributed to the holder; or
- we do not deliver satisfactory documents to the depositary; or
- the depositary determines that all or a portion of the distribution to the holder is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. The holder of ADSs may have to pay fees, expenses, taxes and other governmental charges upon the redemption of the ADS holder's ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for the holder's ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, the holder's ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to the holder, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of the holder's existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary may not lawfully distribute such property to the holder, the depositary may sell such property and distribute the net proceeds to the holder as in the case of a cash distribution.

Issuance of ADSs upon Deposit of Ordinary Shares

The depositary may create ADSs on the holder's behalf if the holder or the holder's broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person the holder indicates only after the holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. The holder's ability to deposit ordinary shares and receive ADSs may be limited by the legal considerations in the United States and Cayman Islands applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary will only issue ADSs in whole numbers.

When the holder makes a deposit of ordinary shares, the holder will be responsible for transferring good and valid title to the depositary. As such, the holder will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised;
- the holder is duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement);
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements; and
- the deposit of the ordinary shares does not violate any applicable provisions of the Cayman Islands.

If any of the representations or warranties are incorrect in any way, we and the depositary may, at the holder's cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, Combination and Split Up of ADRs

ADR holders will be entitled to transfer, combine or split up their ADRs and the ADSs evidenced thereby. For transfers of ADRs, the ADR holder will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have ADRs either combined or split up, the ADR holder must surrender the ADRs in question to the depositary with the ADR holder's request to have them combined or split up, and the ADR holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Ordinary Shares Upon Cancellation of ADSs

Holders of ADSs will be entitled to present their ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. The ADS holders' ability to withdraw the ordinary shares held in respect of the ADSs may be limited by the legal considerations in the United States and Cayman Islands applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by the ADSs, the holder will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. The holder assumes the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If ADSs are registered in the holder's name, the depositary may ask the holder to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel the holder's ADSs. The withdrawal of the ordinary shares represented by the holder's ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

The holders of ADSs will have the right to withdraw the securities represented by their ADSs at any time except for:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges;
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit; and/or
- other circumstances specifically contemplated by Section I.A.(l) of the General Instructions to Form F-6 (as such General Instructions may be amended from time to time).

The deposit agreement may not be modified to impair the holder's right to withdraw the securities represented by the ADSs except to comply with mandatory provisions of law.

Voting Rights

Holders of ADSs generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by their ADSs.

At our request, the depositary will distribute to the holders of ADSs any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary may distribute to holders of ADSs instructions on how to receive such materials upon request.

If the depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs as follows:

- The depositary will vote (or cause the custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

- Holders of ADSs in respect of which no timely voting instructions have been received shall be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us to vote the ordinary shares represented by such holders' ADSs; provided, however, that no such discretionary proxy shall be given with respect to any matter to be voted upon as to which we inform the depositary that (i) we do not wish such proxy to be given, (ii) substantial opposition exists, or (iii) the rights of holders of ordinary shares may be adversely affected.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure the holder that the holder will receive voting materials in time to enable the holder to return voting instructions to the depositary in a timely manner.

Amendments and Termination

We may agree with the depositary to modify the deposit agreement at any time without the ADS holder's consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to the ADS holder's substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act of 1933, as amended (the "Securities Act"), or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges the holders are required to pay. In addition, we may not be able to provide the holder with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders of ADSs will be bound by the modifications to the deposit agreement if the holders continue to hold their ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent the holders from withdrawing the ordinary shares represented by their ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, the ADS holder's rights under the deposit agreement will be unaffected.

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until the holder requests the cancellation of its ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. Holders of ADSs may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary's obligations to holders of ADSs. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and without negligence and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to the holder on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles of Association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Association or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to the holder.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act or Exchange Act liability is intended by any provision of the deposit agreement, in each case to the extent established under applicable U.S. laws.

Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and the ADS holder. Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

STEALTH BIOTHERAPEUTICS CORP

2019 SHARE INCENTIVE PLAN

1. Purpose

The purpose of this 2019 Share Incentive Plan (the "***Plan***") of Stealth BioTherapeutics Corp, an exempted company incorporated under the laws of the Cayman Islands with registered number 165223 (the "***Company***"), is to advance the interests of the Company's shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's shareholders. Except where the context otherwise requires, the term "***Company***" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the United States Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "***Code***") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "***Board***").

2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "***Securities Act***"), or any successor form) are eligible to be granted Awards under the Plan. Each person who is granted an Award under the Plan is deemed a "***Participant***." "***Award***" means Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Shares (as defined in Section 7), Restricted Share Units (as defined in Section 7) and Other Share-Based Awards (as defined in Section 8).

3. Administration and Delegation

(a) Administration by Board. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "***Committee***"). All references in the Plan to the "***Board***" shall mean the Board or a Committee of the Board to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

4. Shares Available for Awards

(a) Number of Shares; Share Counting.

(1) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan (any or all of which Awards may be in the form of Incentive Share Options, as defined in Section 5(b)) for up to such number of shares of ordinary shares, $0.0003 nominal par value per share, of the Company (the "***Ordinary Shares***") as is equal to the sum of:

(A) 22,692,938 Ordinary Shares; plus

(B) such additional number of Ordinary Shares (up to 25,502,748 shares) as is equal to the number of Ordinary Shares subject to awards granted under the Company's 2006 Share Incentive Plan, as amended (the "***Existing Plan***") that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of Incentive Share Options to any limitations of the Code); plus

(C) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2020 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2029, equal to the least of (i) 31,780,518 Ordinary Shares, (ii) 4% of the outstanding shares on such date and (iii) an amount determined by the Board.

Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(2) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan:

(A) all Ordinary Shares covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of Ordinary Shares and provides that only one such Award may be exercised (a "***Tandem SAR***"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(B) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of Ordinary Shares subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Ordinary Shares not being issued (including as a result of an SAR that was settleable either in cash or in shares actually being settled in cash), the unused Ordinary Shares covered by such Award shall again be available for the grant of Awards; *provided, however*, that (1) in the case of Incentive Share Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the

exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR; and

(C) Ordinary Shares delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase Ordinary Shares upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall be added back to the number of shares available for the future grant of Awards.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or shares of an entity, the Board may grant Awards in substitution for any options or other shares or share-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1), except as may be required by reason of Section 422 and related provisions of the Code.

(c) Limit on Awards to Non-Employee Directors. In any calendar year, the value of Awards under the Plan and the 2020 ADS Incentive Plan made to any non-employee director for service as a director (calculated based on the grant date fair value of such Awards for financial reporting purposes) shall not exceed $1,000,000. The Board may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Board may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

5. Share Options

(a) General. The Board may grant options to purchase Ordinary Shares (each, an "***Option***") and determine the number of Ordinary Shares to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to the applicable statutes and federal or state securities laws, as it considers necessary or advisable.

(b) Incentive Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "***Incentive Option***") shall only be granted to employees of the Company, any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Option shall be designated a "***Nonstatutory Option***." The Company shall have no liability to a Participant, or any other party, if an Option

(or any part thereof) that is intended to be an Incentive Option is not an Incentive Option or if the Company converts an Incentive Option to a Nonstatutory Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Ordinary Shares on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "***Grant Date Fair Market Value***" of Ordinary Shares for purposes of the Plan will be determined as follows:

(1) if the Ordinary Shares trade on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Ordinary Shares do not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Ordinary Shares are not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of Ordinary Shares for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participants' agreement that the Administrator's determination is conclusive and binding even though others might make a different determination.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Ordinary Shares subject to the Option will be issued by the Company to the Participant fully paid as soon as practicable following exercise.

(f) Payment Upon Exercise. Ordinary Shares purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of Ordinary Shares owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board) for repurchase by the Company, provided (i) such method of payment is then permitted under applicable law, (ii) such Ordinary Shares, if acquired directly from the Company, were owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Ordinary Shares are not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Option agreement or approved by the Board in its sole discretion, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Ordinary Shares (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

(g) Limitation on Repricing. Unless such action is approved by the Company's shareholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of Ordinary Shares and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Ordinary Shares (valued in the manner determined by (or in the manner

approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Global Market or any other exchange or marketplace on which the Company stock is listed or traded (the "***Exchange***").

6. Share Appreciation Rights

(a) General. The Board may grant Awards consisting of share appreciation rights ("***SARs***") entitling the holder, upon exercise, to receive an amount of Ordinary Shares or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of an Ordinary Share (valued in the manner determined by (or in the manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Ordinary Shares on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided, however*, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's shareholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(b)) covering the same or a different number of Ordinary Shares and having an exercise or measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Ordinary Shares (valued in the manner determined by (or in a manner approved by) the Board) or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Exchange.

7. Restricted Shares; Restricted Share Units

(a) General. The Board may grant Awards entitling recipients to acquire Ordinary Shares ("***Restricted Shares***"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such

shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive Ordinary Shares or cash to be delivered at the time such Award vests or is settled ("***Restricted Share Units***") (Restricted Shares and Restricted Share Units are each referred to herein as a "***Restricted Share Award***").

(b) Terms and Conditions for All Restricted Share Awards. The Board shall determine the terms and conditions of a Restricted Share Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Shares.

(1) Dividends. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, shares or property) declared and paid by the Company with respect to Restricted Shares ("***Accrued Dividends***") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to shareholders of that class of shares or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Shares.

(2) Share Certificates. The Company may require that any share certificates issued in respect of shares of Restricted Shares, as well as dividends or distributions paid on such Restricted Shares, shall be deposited in escrow by the Participant, together with a share power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "***Designated Beneficiary***" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to Restricted Share Units.

(1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Share Unit, the Participant shall be entitled to receive from the Company such number of Ordinary Shares or (if so provided in the applicable Award agreement) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of Ordinary Shares as are set forth in the applicable Restricted Share Unit agreement. The Board may provide that settlement of Restricted Share Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.

(2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Share Units.

(3) Dividend Equivalents. The Award agreement for Restricted Share Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding Ordinary Shares ("***Dividend Equivalents***"). Dividend Equivalents may be settled in cash and/or Ordinary Shares and may be subject to the same restrictions on transfer and forfeitability as the Restricted Share Units with respect to which paid, in each case to the extent provided in the Award agreement.

8. Other Share-Based Awards

(a) General. The Board may grant other Awards of Ordinary Shares, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, Ordinary Shares or other property ("***Other Share-Based Awards***"). Such Other Share-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Share-Based Awards may be paid in Ordinary Shares or cash, as the Board shall determine.

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Share-Based Award, including any purchase price applicable thereto.

9. Adjustments for Changes in Ordinary Shares and Certain Other Events

(a) Changes in Capitalization. In the event of any share split, reverse share split, share consolidation, share dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Ordinary Shares other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a) and 4(c), (iii) the number and class of shares and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding Restricted Share Award and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Restricted Stock Unit Award and Other Share-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Ordinary Shares by means of a share dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such share dividend shall be entitled to receive, on the distribution date, the share dividend with respect to the Ordinary Shares acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such share dividend.

(b) Reorganization Events.

(1) Definition. A "***Reorganization Event***" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Ordinary Shares of the Company are converted into or exchanged for the right to receive cash, shares, securities or other property or are cancelled, (b) any transfer or disposition of all of the Ordinary Shares of the Company for cash, shares, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Shares.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Shares on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/or unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Ordinary Shares will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "***Acquisition Price***"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of Ordinary Shares subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 9(b)(2)(A), in the case of outstanding Restricted Share Units that are subject to Section 409A of the Code: (i) if the applicable Restricted Share Unit agreement provides that the Restricted Share Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(A)(i) and the

Restricted Share Units shall instead be settled in accordance with the terms of the applicable Restricted Share Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted Share Units pursuant to clause (i) of Section 9(b)(2)(A), then the unvested Restricted Share Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 9(b)(2)(A)(i), an Award (other than Restricted Shares) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each Ordinary Share subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, shares, securities or other property) received as a result of the Reorganization Event by holders of Ordinary Shares for each Ordinary Share held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Ordinary Shares); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely ordinary shares of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of ordinary shares of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding Ordinary Shares as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Shares. Upon the occurrence of a Reorganization Event other than a liquidation, winding up or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Shares shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, shares, securities or other property which the Ordinary Shares were converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Shares; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Shares or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation, winding up or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Shares or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Shares then outstanding shall automatically be deemed terminated or satisfied.

10. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A of the Code, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Ordinary Shares subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver share certificates or otherwise recognize ownership of Ordinary Shares under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Committee, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of Ordinary Shares, including shares retained from the Award

creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided*, *however*, except as otherwise provided by the Committee, that the total tax withholding where shares are being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal, state and local tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain Ordinary Shares having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of Ordinary Shares (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e) with respect to repricings and Section 11(d) with respect to actions requiring shareholder approval, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Option to a Nonstatutory Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.

(g) Conditions on Delivery of Shares. The Company will not be obligated to issue any Ordinary Shares pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

11. Miscellaneous

(a) No Right to Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or

otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights as Shareholder; Clawback Policy. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a shareholder with respect to any Ordinary Shares to be issued with respect to an Award until becoming the record shareholder of such shares. In accepting an Award under the Plan, a Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future.

(c) Effective Date and Term of Plan. The Plan shall become effective immediately prior to the effectiveness of the Company's registration statement for its initial public offering (the "***Effective Date***"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that no amendment that would require shareholder approval under the rules of the Exchange may be made effective unless and until the Company's shareholders approve such amendment. In addition, if at any time the approval of the Company's shareholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon shareholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if shareholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (ii) it may not be exercised or settled (or otherwise result in the issuance of Ordinary Shares) prior to such shareholder approval.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred

compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "***New Payment Date***"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the Cayman Islands, excluding choice-of-law principles of the law of any jurisdiction that would require the application of the laws of a jurisdiction other than the Cayman Islands.

Exhibit 4.20

STEALTH BIOTHERAPEUTICS CORP

2020 ADS INCENTIVE PLAN

1. Purpose

The purpose of this 2020 ADS Incentive Plan (the "***Plan***") of Stealth BioTherapeutics Corp, an exempted company incorporated under the laws of the Cayman Islands with registered number 165223 (the "***Company***"), is to advance the interests of the Company's shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's shareholders. Except where the context otherwise requires, the term "***Company***" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the United States Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "***Code***") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "***Board***").

2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as such terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "***Securities Act***"), or any successor form) are eligible to be granted Awards under the Plan. Each person who is granted an Award under the Plan is deemed a "***Participant***." "***Award***" means Restricted ADSs (as defined in Section 5), Restricted ADS Units (as defined in Section 5) and Other ADS-Based Awards (as defined in Section 6).

3. Administration and Delegation

(a) Administration by Board. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "***Committee***"). All references in the Plan to the "***Board***" shall mean the Board or a Committee of the Board to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

4. ADSs Available for Awards

(a) Number of ADSs; ADS Counting.

(1) Authorized Number of ADSs. Subject to adjustment under Section 7, Awards may be made under the Plan for up to such number of shares of American Depositary Shares (the "***ADSs***"), each representing 12 ordinary shares, $0.0003 nominal par value per share, of the Company (the "***Ordinary Shares***") as is equal to the sum of:

(A) 2,083,333 ADSs; plus

(B) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2030, equal to the least of (i) ADSs representing 4% of the outstanding Ordinary Shares on such date and (ii) an amount determined by the Board.

ADSs issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares. References to ADSs, to the extent relevant in the context, shall be interpreted to mean Ordinary Shares underlying ADSs.

(2) ADS Counting. For purposes of counting the number of ADSs available for the grant of Awards under the Plan:

(A) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of ADSs subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any ADSs not being issued, the unused ADSs covered by such Award shall again be available for the grant of Awards; and

(B) ADSs delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to satisfy tax withholding obligations with respect to Awards (including ADSs retained from the Award creating the tax obligation) shall be added back to the number of ADSs available for the future grant of Awards.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or shares of an entity, the Board may grant Awards in substitution for any shares or share-based awards granted by such entity or an affiliate thereof (the "***Substitute Awards***"). Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1), except as may be required by the Code.

(c) Limit on Awards to Non-Employee Directors. In any calendar year, the value of Awards under the Plan and the 2019 Share Incentive Plan (the "***2019 Plan***") made to any non-employee director for service as a director (calculated based on the grant date fair value of such Awards for financial reporting purposes) shall not exceed $1,000,000. The Board may make

exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Board may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

5. Restricted ADSs; Restricted ADS Units

(a) General. The Board may grant Awards entitling recipients to acquire ADSs ("***Restricted ADSs***"), subject to the right of the Company to repurchase all or part of such ADSs at their issue price or other stated or formula price (or to require forfeiture of such ADSs if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive ADSs or cash to be delivered at the time such Award vests or is settled ("***Restricted ADS Units***") (Restricted ADSs and Restricted ADS Units are each referred to herein as a "***Restricted ADS Award***").

(b) Terms and Conditions for All Restricted ADS Awards. The Board shall determine the terms and conditions of a Restricted ADS Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted ADSs.

(1) Dividends. Unless otherwise provided in the applicable Award agreement, any dividends (whether paid in cash, shares or property) declared and paid by the Company with respect to Restricted ADSs ("***Accrued Dividends***") shall be paid to the Participant only if and when such ADSs become free from the restrictions on transferability and forfeitability that apply to such ADSs. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to shareholders of that class of shares or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying Restricted ADSs.

(2) ADS Certificates. The Company may require that any ADS certificates issued in respect of Restricted ADSs, as well as dividends or distributions paid on such Restricted ADSs, shall be deposited in escrow by the Participant, together with an ADS power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "***Designated Beneficiary***" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to Restricted ADS Units.

(1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted ADS Unit, the Participant shall be entitled to receive from the Company such number of (A) ADSs, (B) (if so provided in the applicable

Award agreement) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of ADSs as are set forth in the applicable Restricted ADS Unit agreement or (C) (if so provided in the applicable Award agreement) a grant of an Award (as defined in the 2019 Plan) under the 2019 Plan. The Board may provide that settlement of Restricted ADS Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code.

(2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted ADS Units.

(3) Dividend Equivalents. The Award agreement for Restricted ADS Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding ADSs ("***Dividend Equivalents***"). Dividend Equivalents may be settled in cash and/or ADSs and may be subject to the same restrictions on transfer and forfeitability as the Restricted ADS Units with respect to which paid, in each case to the extent provided in the Award agreement.

6. Other ADS-Based Awards.

(a) General. The Board may grant other Awards of ADSs, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, ADSs or other property ("***Other ADS-Based Awards***"). Such Other ADS-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other ADS-Based Awards may be paid in ADSs, cash or Awards under the 2019 Plan, as the Board shall determine.

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other ADS-Based Award, including any purchase price applicable thereto.

7. Adjustments for Changes in ADSs and Certain Other Events.

(a) Changes in Capitalization. In the event of any share split, reverse share split, share consolidation, share dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event in each case resulting in an adjustment or consequence to the ADSs, or any dividend or distribution to holders of ADSs other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the ADS counting rules set forth in Section 4(a) and 4(c), (iii) the number of ADSs subject to and the repurchase price per ADS subject to each outstanding Restricted ADS Award and (iv) the ADS and per-ADS-related provisions and the purchase price, if any, of each outstanding Restricted ADS Unit Award and Other ADS-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board.

(b) Reorganization Events.

(1) Definition. A "***Reorganization Event***" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Ordinary Shares of the Company are converted into or exchanged for the right to receive cash, shares, securities or other property or are cancelled, (b) any transfer, disposition, exchange or conversion of all of the Ordinary Shares of the Company for cash, shares, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted ADSs.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted ADSs on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/or unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of ADSs will receive upon consummation thereof a cash payment for each ADS surrendered in the Reorganization Event (the "***Acquisition Price***"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of ADSs subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 7(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 7(b)(2)(A), in the case of outstanding Restricted ADS Units that are subject to Section 409A of the Code: (i) if the applicable Restricted ADS Unit agreement provides that the Restricted ADS Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 7(b)(2)(A)(i) and the Restricted ADS Units shall instead be settled in accordance with the terms of the applicable Restricted ADS Unit agreement; and (ii) the Board may only undertake the actions set forth in

clauses (iii), (iv) or (v) of Section 7(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A of the Code; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A of the Code, and the acquiring or succeeding corporation does not assume or substitute the Restricted ADS Units pursuant to clause (i) of Section 7(b)(2)(A), then the unvested Restricted ADS Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 7(b)(2)(A)(i), an Award (other than Restricted ADSs) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each ADS subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, shares, securities or other property) received as a result of the Reorganization Event by holders of ADSs for each ADS held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding ADSs); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely shares of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determines to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per ADS consideration received by holders of outstanding ADSs as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted ADSs. Upon the occurrence of a Reorganization Event other than a liquidation, winding up or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted ADSs shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, shares, securities or other property which the ADSs were converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted ADSs; *provided, however*, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted ADSs or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation, winding up or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted ADSs or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted ADSs then outstanding shall automatically be deemed terminated or satisfied.

8. General Provisions Applicable to Awards.

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law,

except by will or the laws of descent and distribution or pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A of the Code, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the ADSs subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 8(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver ADS certificates or otherwise recognize ownership of ADSs under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any ADSs on purchase, vesting or release from forfeiture of an Award or at the same time as payment of the purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Committee, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of ADSs, including ADSs retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided*, *however*, except as otherwise provided by the Committee, that the total tax withholding where ADSs are being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on

minimum statutory withholding rates for federal, state and local tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain ADSs having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of ADSs (up to the number of ADSs having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. ADSs used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award. Except as otherwise provided in Section 9(d) with respect to actions requiring shareholder approval, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type and changing the date of exercise or realization. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 7.

(g) Conditions on Delivery of ADSs. The Company will not be obligated to issue any ADSs pursuant to the Plan or to remove restrictions from ADSs previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such ADSs have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

9. Miscellaneous

(a) No Right to Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights as Shareholder; Clawback Policy. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a shareholder with respect to any ADSs to be issued with respect to an Award until becoming the

record holder of such ADSs. In accepting an Award under the Plan, a Participant agrees to be bound by any clawback policy the Company has in effect or may adopt in the future.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board ("***Effective Date***"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that no amendment that would require shareholder approval under the rules of the Nasdaq Global Market, or any other exchange or marketplace on which the Company shares are listed or traded, may be made effective unless and until the Company's shareholders approve such amendment. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 9(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon shareholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if shareholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (ii) it may not be exercised or settled (or otherwise result in the issuance of ADSs) prior to such shareholder approval.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A of the Code and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A of the Code) (the "***New Payment Date***"), except as Section 409A of the Code may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to

the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A of the Code but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the Cayman Islands, excluding choice-of-law principles of the law of any jurisdiction that would require the application of the laws of a jurisdiction other than the Cayman Islands.

RESTRICTED ADS UNIT AWARD AGREEMENT
UNDER THE STEALTH BIOTHERAPEUTICS CORP
2020 ADS INCENTIVE PLAN

Name of Grantee:

No. of Restricted ADS Units:

Grant Date:

Pursuant to the Stealth BioTherapeutics Corp 2020 ADS Incentive Plan, as it may have been amended from time to time through the date hereof (the "**Plan**"), Stealth BioTherapeutics Corp (the "**Company**") hereby grants an award of the number of Restricted ADS Units listed above (an "**Award**") to the Grantee named above. Each Restricted ADS Unit represents the right to receive one fully paid American Depositary Share (an "**ADS**"), each representing 12 ordinary shares, of nominal or par value of $0.0003 of the Company, upon the vesting of the Restricted ADS Unit, subject to the terms and conditions set forth herein.

1. Vesting of Restricted ADS Units. The Restricted ADS Units shall vest on the Vesting Dates specified in the following schedule so long as the Grantee remains an Eligible Participant (as defined below) of the Company or a subsidiary of the Company on such Vesting Dates. Upon vesting of the Restricted ADS Units, the Company will issue for each Restricted ADS Unit that becomes vested, one ADS, in accordance with Paragraph 3 of this Agreement.

Vesting Date	Incremental Number of ADSs Vested

The Board may at any time accelerate the vesting schedule specified in this Paragraph 1.

2. Forfeiture of Unvested Restricted ADS Units Upon Cessation of Services. In the event that the Grantee ceases to be an Eligible Participant for any reason or no reason, with or without cause, prior to the satisfaction of the vesting conditions set forth in Paragraph 1 above, any Restricted ADS Units that have not vested as of such date shall automatically and without notice terminate and be forfeited without the payment of any consideration to the Grantee, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted ADS Units. The Grantee

shall be an "Eligible Participant" if he or she is an employee, director or officer of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants or advisors of which are eligible to receive awards of Restricted ADS Units under the Plan.

3. Issuance of ADSs. As soon as practicable following each Vesting Date (but in no event later than 60 days following such date), the Company shall issue to the Grantee the number of fully paid ADSs equal to the aggregate number of Restricted ADS Units that have vested pursuant to Paragraph 1 of this Agreement on such date, subject to the payment of any withholding taxes pursuant to Paragraph 5 of this Agreement, and the Grantee shall thereafter have all the rights of a shareholder of the Company with respect to such shares.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Board set forth in Section 3(a) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Tax Withholding.

(a) The Grantee acknowledges that he or she is responsible for obtaining the advice of the Grantee's own tax advisors with respect to the award of Restricted ADS Units and the Grantee is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the Restricted ADS Units. The Grantee understands that the Grantee (and not the Company) shall be responsible for the Grantee's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the Restricted ADS Units. The Grantee acknowledges that no election under Section 83(b) of the Code, is available with respect to Restricted ADS Units.

(b) The Grantee acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Grantee any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the Restricted ADS Units. At such time as the Grantee is not aware of any material nonpublic information about the Company or the ADSs, the Grantee shall execute the instructions set forth in in Exhibit A attached hereto (the "**Durable Automatic Sale Instructions**") as the means of satisfying such tax obligation. If the Grantee does not execute the Durable Automatic Sale Instructions prior to an applicable vesting date, then the Grantee agrees that if under applicable law the Grantee will owe taxes at such vesting date on the portion of the Award then vested, the Company shall be entitled to immediate payment from the Grantee of the amount of any tax required to be withheld by the Company. The Company shall not issue any ADSs to the Grantee until it is satisfied that all required withholdings have been made.

6. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

7. No Right to Continued Service. The Grantee acknowledges and agrees that, notwithstanding the fact that the vesting of the Restricted ADS Units is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of a continued service relationship or confer upon the Grantee any rights with respect to a continued service relationship by the Company.

8. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any ADSs issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until both (i) the Restricted ADS Units have vested as provided in Paragraph 1 of this Agreement and (ii) the ADSs have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

9. Integration. The grant of this Award satisfies in full all commitments that the Company has to the Grantee with respect to the issuance of shares, share options or other equity securities.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "**Relevant Companies**") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "**Relevant Information**"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

12. Grantee's Acknowledgements. The Grantee acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Grantee's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is fully aware of the legal and binding effect of this Agreement; and (v) agrees that in accepting this award, he or she will be bound by any clawback policy that the Company may adopt in the future.

STEALTH BIOTHERAPEUTICS CORP

By:_____
Name: Irene P. McCarthy
Title: Director and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Grantee's name and address:

_____
_____
_____
_____
_____

Exhibit A

Durable Automatic Sale Instruction

This Durable Automatic Sale Instruction is being delivered to Stealth BioTherapeutics Corp (the "**Company**") by the undersigned on the date set forth below.

I hereby acknowledge that the Company has granted, or may in the future from time to time grant, to me Restricted ADS Units under the Company's long-term equity incentive plans as in effect from time to time.

I acknowledge that upon the vesting dates applicable to any such Restricted ADS Units, I will have compensation income equal to the fair market value of the Company's American Depositary Shares ("**ADSs**"), each representing 12 ordinary shares, of nominal or par value of $0.0003 of the Company (the "**Ordinary Shares**"), subject to the Restricted ADS Units that vest on such date and that the Company is required to withhold all applicable income and employment taxes based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes (the "**Tax Withholding Obligations**") in respect of that compensation income on the applicable vesting date.

I desire to establish a process to satisfy such Tax Withholding Obligations in respect of all Restricted ADS Units that have been, or may in the future be, granted by the Company to me through an automatic sale of a portion of the ADSs that would otherwise be issued to me on each applicable vesting date, such portion to be in an amount sufficient to satisfy the Tax Withholding Obligations, with the proceeds of such sale to be delivered to the Company in satisfaction of such Tax Withholding Obligations.

I understand that the Company has arranged for the administration and execution of its long-term equity incentive plans and the sale of securities by plan participants thereunder pursuant to an Internet-based platform administered by a third party (the "**Agent**") and the Agent's designated brokerage partner.

Upon any vesting of my Restricted ADS Units from and after the date of this Durable Automatic Sale Instruction, I hereby instruct and authorize the Company to arrange for the Agent (or its designated brokerage partner) to automatically sell on my behalf that number of ADSs representing the whole number of ADSs issuable with respect to my Restricted ADS Units that vest to generate cash proceeds sufficient to satisfy the Tax Withholding Obligations and the Company shall receive such net proceeds in satisfaction of such Tax Withholding Obligations. Such ADSs will be sold on the day the Tax Withholding Obligations arises (e.g., a Vesting Date)

or as soon thereafter as practicable. I agree and acknowledge that I shall be responsible for all brokerage fees and other costs of sale, and I agree to indemnify and hold the Company harmless from any losses, costs, damages or expenses relating to any such sale.

I acknowledge that the Company or its designee is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the Grantee's Tax Withholding Obligation. Accordingly, I agree to pay to the Company as soon as practicable, including through additional payroll withholding, any amount of the Tax Withholding Obligation that is not satisfied by the sale of any ADSs representing Ordinary Shares described above.

I acknowledge that these Durable Automatic Sale Instruction is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Securities Exchange Act of 1934, as amended, and to be interpreted to comply with the requirements of Rule 10b5-1(c), and that I am not aware of any material, nonpublic information with respect to the Company as of the date listed below.

Print Name: _____

Date: _____

Exhibit 8.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
Stealth BioTherapeutics, Inc.	Delaware
Stealth BioTherapeutics (HK) Limited	Hong Kong
Stealth BioTherapeutics (Shanghai) Limited	People’s Republic of China

Exhibit 12.1

CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. §1350)

I, Irene P. McCarthy, certify that:

1. I have reviewed this annual report on Form 20-F of Stealth BioTherapeutics Corp;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 1, 2020

By: /s/ Irene P. McCarthy
Name: Irene P. McCarthy
Title: Chief Executive Officer (principal executive officer and principal financial officer)

Exhibit 13.1

Officer Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Stealth BioTherapeutics Corp (the "Company"), hereby certifies, to such officer's knowledge, that:

The annual report on Form 20-F for the year ended December 31, 2019 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2020

By: /s/ Irene P. McCarthy
Name: Irene P. McCarthy
Title: Chief Executive Officer (principal executive officer and principal financial officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-230452 on Form S-8 of our report dated April 1, 2020, relating to the consolidated financial statements of Stealth BioTherapeutics Corp appearing in this Annual Report on Form 20-F for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

April 1, 2020